have a generator category for their hazardous waste pharmaceuticals; all healthcare facilities are regulated the same under part 266 subpart P. Second, if EPA limited this consolidation provision to LQGs, then there would be a very small subset of receiving healthcare facilities that would be able to take advantage of this provision. Since subpart P allows healthcare facilities operating under this subpart to not count their hazardous waste pharmaceuticals towards their generator category, some healthcare facilities may no longer be LQGs for their other hazardous waste. It is highly unlikely that a long-term care pharmacy would remain an LQG under this rule since the majority of the hazardous waste that would be handled at these pharmacies would be pharmaceuticals. If we were to limit this provision to only LQG receiving facilities, then we would be preventing LTCFs from consolidating at long-term care pharmacies. Therefore, we determined that requiring the receiving facilities to be LQGs or to comply with LQG standards as a condition of the consolidation provision would severely limit the value of this provision.

In addition, the Agency is not finalizing a requirement for healthcare facilities that receive hazardous waste pharmaceuticals from VSQG healthcare facilities to manage the received pharmaceutical waste under the part 262 LQG standards. The Agency does not see the necessity in having more stringent management standards for healthcare facilities that receive pharmaceutical waste, because subpart P management standards are the same for all non-VSQG healthcare facilities, regardless of the amount of hazardous waste pharmaceuticals they generate. The Agency has determined that the subpart P standards are sufficiently protective of human health and the environment since all pharmaceuticals at a receiving healthcare facility must be managed under the same subpart P standards, regardless of whether they were generated on site or received from off site. If a state determines that the standards being finalized for healthcare facilities that receive hazardous waste pharmaceuticals from off-site are not adequate, that state may implement its own standards, provided they are more stringent.

The waste management industry, as well as some states, recommended that EPA require a notification when a facility was receiving hazardous waste pharmaceuticals and at least some minimal requirements for labeling, recordkeeping, and documentation of shipments. One state also recommended that we issue licenses to facilities that were receiving hazardous waste pharmaceuticals in order to track who was taking advantage of this provision. Consistent with our rationale for the limited shipping requirements for "potentially creditable hazardous waste pharmaceuticals" in this rule, the Agency believes that the shipping of hazardous waste pharmaceuticals poses a relatively low risk of release to the environment but a high risk for diversion of the pharmaceuticals when labeled "pharmaceuticals." The hazardous waste that are being shipped often are in pill form or blister packs and not fifty-gallon drums of liquids that can be easily spilled. They are not likely to pose the same risks that typical hazardous waste could cause during shipping and transport, but there is a real risk to them being stolen if attention is brought to the contents of the containers. If the four conditions are met, the Agency believes this ensures the proper management of hazardous waste pharmaceuticals and adding new labeling and shipping requirements is unnecessary to accomplish that goal. Furthermore, the part 262 VSQG regulations do not require labeling or recordkeeping, and VSQGs might not take advantage of this consolidation provision if the requirements are too onerous, thus continuing to put their hazardous waste pharmaceuticals in municipal solid waste landfills.

The waste management industry asked for clarification on hazardous waste pharmaceuticals consolidation across state lines that have different requirements for VSQGs. There is nothing in this section that prevents a healthcare facility from sending their hazardous waste pharmaceuticals to a healthcare facility in another state provided both states have adopted this provision. Each state has their own requirements, so it would be prudent for VSQG healthcare facilities to make sure that the state in which they are consolidating has adopted this provision and does not impose any additional requirements on the receiving healthcare facility that accepts this waste.

EPA also received comments on what types of facilities could take advantage of this provision, specifically whether this provision will include wholesale drug distribution centers. In the final rule, EPA has defined wholesale distributors as a type of healthcare facility under § 266.500. Wholesale distributors were not an example that was given to us at proposal for this consolidation provision, but if all four conditions were met and there was a contractual or business relationship between the VSQG healthcare facility and the wholesale distributor, they would not be precluded from using this provision. However, we would note that when a wholesale distributor receives hazardous waste pharmaceutical return from a healthcare facility, the pharmaceuticals are usually restocked, which means they are pharmaceutical products and not hazardous waste pharmaceuticals.

Lastly, a non-profit organization asked us to clarify if these consolidated hazardous waste pharmaceuticals would be eligible for redistribution or evaluation for donation once consolidated to the receiving facility. In regard to redistribution or evaluation for donation, if the receiving healthcare facility can lawfully donate or redistribute the consolidated hazardous waste pharmaceuticals, there is nothing in this provision that prevents that from occurring, but those shipments would not fall under the consolidation provision in subpart P. If a VSQG is sending products to another facility, then the receiving facility should evaluate the received pharmaceuticals as they would any other products they receive for continued use, redistribution to secondary markets, donation and/or any other lawful possibilities. At this point, they are not a solid or hazardous waste and not subject to the requirements in § 266.502(l) or § 266.503(b).

EPA would also note that this provision is optional and it is not meant to impose undue burden on healthcare facilities. This section does not require a VSQG healthcare facility to ship their hazardous waste pharmaceuticals to a receiving healthcare facility. VSQG healthcare facilities continue to have the option, unless the state regulations are more stringent, of sending their hazardous waste pharmaceuticals to any of the types of facilities specified in § 262.14, including a municipal solid waste landfill.

XI. Standards for Healthcare Facilities That Accumulate Potentially Creditable Hazardous Waste Pharmaceuticals Prior to Shipment to Reverse Distributors (§ 266.503)

A. Healthcare Facilities Making a Hazardous Waste Determination for Potentially Creditable Pharmaceuticals (§ 266.503(a))

1. Summary of Proposal

EPA proposed standards for healthcare facilities managing potentially creditable hazardous waste pharmaceuticals in § 266.503 of subpart P. As with non-creditable hazardous waste pharmaceuticals, a healthcare

facility must determine which potentially creditable pharmaceuticals are listed or characteristic hazardous wastes, in order to determine which potentially creditable pharmaceuticals are subject to regulation under this subpart.

Accordingly, we proposed that a healthcare facility that generates a solid waste that is a potentially creditable pharmaceutical must determine whether the potentially creditable solid waste pharmaceutical is a potentially creditable hazardous waste pharmaceutical (*i.e.*, is listed in 40 CFR part 261 subpart D or exhibits a characteristic identified in 40 CFR part 261 subpart C).

We also proposed that a healthcare facility may choose to manage all of its potentially creditable waste pharmaceuticals (both hazardous and non-hazardous) together as potentially creditable hazardous waste pharmaceuticals while accumulating on site and when shipping off site under § 266.509. If a healthcare facility chooses this approach of commingling its hazardous and non-hazardous potentially creditable waste pharmaceuticals, it would not need to make individual hazardous waste determinations, but would have made a generic decision that all of its potentially creditable waste pharmaceuticals are hazardous and would manage them as potentially creditable hazardous waste pharmaceuticals in accordance with the requirements in 40 CFR part 266 subpart P.

We proposed that healthcare facilities may choose to manage potentially creditable non-hazardous waste pharmaceuticals as potentially creditable hazardous waste pharmaceuticals under the shipping standards of § 266.509. Additionally, EPA proposed that healthcare facilities would be prohibited from sending hazardous waste other than potentially creditable hazardous waste pharmaceuticals to a reverse distributor. This was in keeping with our position that a reverse distributor's function in managing hazardous waste should be limited to managing hazardous waste pharmaceuticals that have a reasonable expectation of receiving manufacturer credit and not non-creditable hazardous waste pharmaceuticals or other non-pharmaceutical hazardous waste.

2. Summary of Comments

Pharmacists, some wholesalers, and manufacturers expressed concern that making hazardous waste determinations at their facilities would require additional staff, additional training on making hazardous waste determination, as well as more storage space in which to hold the hazardous waste as the determinations are being made.

We received mixed comments on commingling potentially creditable non-hazardous and hazardous waste pharmaceuticals. Healthcare facilities and pharmacists were in favor of EPA allowing commingling potentially creditable non-hazardous and hazardous waste pharmaceuticals, and the benefit it offers in handling their pharmaceutical waste or continuing the common practice of commingling potentially creditable non-hazardous and hazardous waste pharmaceuticals when sent to reverse distributors. On the other hand, waste management and states raised concerns that commingling potentially creditable non-hazardous and hazardous waste pharmaceuticals may prevent healthcare facilities from sending their waste across state lines or to certain reverse distributors, due to state regulations and/or reverse distributors' policies.

3. Final Rule Provisions

EPA is finalizing the standards as proposed, with some minor changes. Under this section, a healthcare facility has two choices: (1) Make a hazardous waste determination on each potentially creditable waste pharmaceutical and determine individually which are hazardous waste and thus subject to regulation under this subpart or, (2) commingle all potentially creditable pharmaceutical waste whether or not it is hazardous waste and manage the commingled pharmaceuticals under this subpart and thereby not have to make individual hazardous waste determinations.

EPA removed "even if the solid waste pharmaceuticals do not exhibit a characteristic identified in 40 CFR part 261 subpart C and are not listed in 40 CFR part 261 subpart D" from the non-hazardous waste provision of this section since it was redundant with determinations of solid waste pharmaceuticals and whether they are potentially creditable or not.

EPA has also modified the regulatory language in the final rule to make clear that when a healthcare facility commingles potentially creditable non-hazardous and hazardous waste pharmaceuticals, the healthcare facility is choosing to subject the potentially creditable non-hazardous waste pharmaceuticals to all of subpart P while being managed at a healthcare facility and in preparation for shipping off-site. Once potentially creditable non-hazardous and hazardous waste pharmaceuticals are commingled they are subject to all applicable subpart P management standards while they remain commingled. As a practical matter, however, we expect that the primary impact to healthcare facilities will be that potentially creditable non-hazardous waste pharmaceuticals are subject to the shipping standards of § 266.509. Once potentially creditable non-hazardous waste pharmaceuticals are shipped off site to a reverse distributor, a reverse distributor may choose to segregate the non-hazardous waste pharmaceuticals from the hazardous waste pharmaceuticals. This process of segregation by the reverse distributor would require the reverse distributor to make new hazardous waste determinations on the commingled pharmaceuticals.

4. Comments and Responses

We received many comments on making hazardous waste determinations and commingling potentially creditable non-hazardous and hazardous waste pharmaceuticals. While the commenters raised valid concerns on why making hazardous waste determinations can be burdensome on a healthcare facility, or why commingling potentially creditable non-hazardous and hazardous waste pharmaceuticals may not work for all facilities, EPA made only minor editorial changes to this section of the final rule. The Agency determined that more substantive changes were unnecessary because this provision contains sufficient flexibility by providing healthcare facilities with two options.

a. *Making hazardous waste determinations.* Pharmacists, some wholesalers, and manufacturers expressed concern that being required to make hazardous waste determinations at their facilities would impose undue burden because they would have to hire additional staff and train them to make accurate waste determination. They argue that they would also need to allocate more space in which to store waste as the determinations are being made. Some commenters stated that making hazardous waste determinations may prevent healthcare facilities from sending their hazardous waste pharmaceuticals to reverse distributors at all. In support of the comments above, manufacturers and wholesalers argued that reverse distributors have the appropriate RCRA expertise to make accurate waste determinations, that they have served as a consolidation point for unused and hazardous waste pharmaceuticals for many years, and that the process has been effective and successful. The Agency notes, however, that allowing potentially creditable

pharmaceuticals to be sent to a reverse distributor without a hazardous waste determination being made at the point of generation violates a basic tenet of RCRA, because the decision to send them to a reverse distributor is effectively a decision to discard. In addition, the burden mentioned by commenters associated with making individual waste determinations would likely be significantly mitigated by exercising the option to manage all potentially creditable waste pharmaceuticals as potentially creditable hazardous waste pharmaceuticals.

b. *Commingled waste stream.* As previously noted, we received mixed comments on commingling potentially creditable non-hazardous hazardous waste pharmaceuticals.

EPA proposed the option of commingling potentially creditable non-hazardous and hazardous waste pharmaceuticals to mitigate the burden of complying with the management standards, particularly for healthcare personnel making hazardous waste determinations. Given that many healthcare facilities currently commingle their potentially creditable non-hazardous and hazardous waste pharmaceuticals, we expect the practice to continue. However, if commingling causes undue burden on a facility due to state regulations, reverse distributor policies, or other reasons, then the healthcare facility does not have to utilize this option and can make individual hazardous waste determinations in accordance with § 266.503(a). This is an individual decision for each healthcare facility and each healthcare facility may choose what works best for managing its potentially creditable pharmaceutical waste.

Retailers and reverse distributors recommended that healthcare facilities should be allowed to make a determination about whether the item will be managed as hazardous when it becomes a waste at the time of arrival at the retail store or healthcare facility. They believe this practice would be impeded if all pharmaceuticals must be managed as potentially creditable hazardous waste pharmaceuticals when they become waste. If this is common practice among healthcare facilities, then the need to commingle their waste may not be something that is important. Allowing the commingling of all solid waste pharmaceuticals is meant to ease the burden on healthcare facilities that are not currently making hazardous waste determinations, or do not wish to make them, by allowing them to manage and ship all of their potentially creditable waste pharmaceuticals together.

B. Accepting Potentially Creditable Hazardous Waste Pharmaceuticals From an Off-Site Healthcare Facility That Is a Very Small Quantity Generator (§ 266.503(b))

1. Summary of Proposal

EPA proposed to allow healthcare facilities operating under subpart P to accept potentially creditable and non-creditable hazardous waste pharmaceuticals from an off-site VSQG healthcare facility without a hazardous waste manifest, provided four conditions are met. We proposed this provision in § 266.502(m) under the standards for managing non-creditable hazardous waste pharmaceuticals.[235] We proposed that healthcare facilities operating under subpart P could accept both potentially creditable and non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a VSQG. Previously, the part 262 VSQG regulations did not allow a healthcare facility to send its hazardous waste off-site to another healthcare facility, unless the receiving healthcare facility is one of the eight types of facilities listed in § 262.14(a)(5)(i–viii). For more detailed information on our proposal, please refer to section X.N.

2. Summary of Comments

EPA only received one comment in this section concerning changes to the generator category of the receiving facility. A trade association of pharmacists was concerned that allowing VSQG consolidation would affect the generator category of the receiving healthcare facility, and that it would need to report as an LQG.

3. Final Rule Provision

In the proposed rulemaking, EPA intended to allow healthcare facilities to accept both potentially creditable and non-creditable (including commingled) hazardous waste pharmaceuticals from an off-site VSQG healthcare facility, provided the receiving healthcare facility complies with the four conditions of § 266.502(m) (now in § 266.502(l)). In the final rule, we clarified our intention to allow healthcare facilities to accept both potentially creditable and non-creditable (including commingled) hazardous waste pharmaceuticals from an off-site VSQG healthcare facility by placing similar standards in § 266.503(b) under the standards for managing potentially creditable hazardous waste pharmaceuticals. This does not reflect a change from what was proposed, only that the consolidation standards apply to healthcare facilities receiving both non-creditable and potentially creditable hazardous waste pharmaceuticals.

Under the final rule, a healthcare facility that is a VSQG can send both its potentially creditable hazardous waste pharmaceuticals and non-creditable (including commingled) hazardous waste pharmaceuticals to an off-site healthcare facility operating under subpart P, provided the receiving healthcare facility complies with the four requirements of the respective sections. Regulations for the receiving healthcare facilities now appear in § 266.502(l) for non-creditable hazardous waste pharmaceuticals and in § 266.503(b) for potentially creditable hazardous waste pharmaceuticals. VSQG healthcare facilities that send their hazardous waste pharmaceuticals to an off-site healthcare facility are subject to the regulations in § 266.504(b), with further discussion in section XII.B of the preamble.

Under § 266.503(b) of the final rule, a healthcare facility may accept potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a VSQG under § 262.14, without a permit or without having interim status, provided the receiving healthcare facility:

(1) Is under the control of the same person, as defined in § 260.10, as the VSQG healthcare facility that is sending potentially creditable hazardous waste pharmaceuticals off site, or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the VSQG healthcare facility;

(2) Is operating under subpart P for the management of its potentially creditable hazardous waste pharmaceuticals;

(3) Manages the potentially creditable hazardous waste pharmaceuticals that it receives from off site in compliance with subpart P; and

(4) Keeps records of the potentially creditable hazardous waste pharmaceuticals shipments it receives from off site for three years from the date that the shipment is received.

It is important to note that a VSQG healthcare facility that chooses to consolidate its hazardous waste pharmaceuticals at an off-site healthcare facility is not considered to be operating under subpart P, and does not need to notify as a VSQG operating under subpart P.

[235] This provision is now found at § 266.502(l).

4. Comments and Responses

A pharmacists' association was concerned that allowing for VSQG consolidation would change the generator category of the receiving healthcare facilities and that the consolidating facility would need to report as an LQG. All healthcare facilities operating under part 266 subpart P are regulated the same, regardless of the amount of hazardous waste pharmaceuticals they generate. Further, healthcare facilities managing their hazardous waste pharmaceuticals under this subpart do not count their hazardous waste pharmaceuticals toward their generator category so consolidation of this additional hazardous waste pharmaceuticals at their facilities would not change the generator category of the receiving healthcare facility.

C. Accumulation Time, Container Management and Labeling for Healthcare Facilities Managing Potentially Creditable Hazardous Waste Pharmaceuticals

Under the hazardous waste generator regulations in part 262, EPA requires specific management standards for containers that hold hazardous waste. However, potentially creditable hazardous waste pharmaceuticals pose a lower risk of release into the environment than traditional industrial hazardous waste. The risk of release is lower for several reasons.

First, potentially creditable hazardous waste pharmaceuticals must be in original manufacturers' packaging by definition and are often in their outer packaging as well, providing two layers of protection from leaks or spills.[236] Second, potentially creditable hazardous waste pharmaceuticals are typically generated in the pharmacy area of a healthcare facility where there is restricted access, creating a layer of security for these pharmaceuticals. Third, EPA has been informed that it is common practice at healthcare facilities for potentially creditable waste pharmaceuticals that are destined for a reverse distributor to be taken from the shelves of the pharmacy periodically and promptly boxed for off-site shipment.

For the reasons listed above, EPA did not propose specific standards for managing and labeling containers of potentially creditable hazardous waste pharmaceuticals at healthcare facilities. For the same reasons, we also did not propose a limit on how long healthcare facilities may accumulate containers of potentially creditable hazardous waste pharmaceuticals.

This is not to say that all potentially creditable hazardous waste pharmaceuticals waste pharmaceuticals are safe and pose no risk of spill or release into the environment. It is important to note that the accumulation of some potentially creditable hazardous waste pharmaceuticals, such as liquids and aerosols, may pose more of a risk due to possible spills or leaks than solid pills. However, EPA believes that the small quantities in which liquid and aerosol potentially creditable hazardous waste pharmaceuticals are generated, along with the DOT packaging requirements (49 CFR parts 173, 178, and 180), significantly reduces the risks of spills or releases to the environment.

In addition, to further mitigate the potential for spills or leaks, as a best management practice, EPA encourages healthcare facilities to place the original containers, and packaging containing liquids and aerosols pharmaceuticals, in separate individual containers (*e.g.*, sealed storage bag) before placing them in the accumulation container.

1. Accumulation Time and Container Management of Potentially Creditable Hazardous Waste Pharmaceuticals

a. Summary of proposal. EPA did not propose a limit on how long healthcare facilities may accumulate containers of potentially creditable hazardous waste pharmaceuticals or specific standards for how the containers must be managed during accumulation.

b. Summary of comments. Most commenters were in favor of adding some guidelines for accumulation time and container management. Some states commented that the proposed standards for non-creditable hazardous waste pharmaceuticals should be applied to both non-creditable and potentially creditable hazardous waste pharmaceuticals to prevent confusion from having multiple accumulation standards, and to provide extra protection of human health and the environment.

c. Final rule provisions. EPA is not finalizing a time limit for accumulating containers of potentially creditable hazardous waste pharmaceuticals. EPA is also not finalizing specific container management standards for healthcare facilities that accumulate containers of potentially creditable hazardous waste pharmaceuticals

d. Comments and responses. Several states expressed concern about the security of potentially creditable hazardous waste pharmaceuticals during accumulation. These commenters agreed that potentially creditable hazardous waste pharmaceuticals should be accumulated in a designated area that is labeled and kept locked or sealed according to best management practices for that facility as an additional deterrent to illicit diversion. Commenters also expressed concerned that not having designated accumulation areas could lead to situations where healthcare facility personnel may misplace or forget the locations of accumulation containers. States were concerned that the potential for healthcare facilities to receive manufacturer credit does not sufficiently encourage proper management.

As previously discussed, potentially creditable hazardous waste pharmaceuticals do not pose the same risks as other hazardous wastes. We received many comments, especially from the retail industry, about the condition of packages being important for being eligible and receiving manufacturer credit. For example, broken and/or leaking containers cannot be sent to a reverse distributor per the definition of "potentially creditable hazardous waste pharmaceuticals," so there is an incentive to manage these items carefully. There is also an incentive to not overaccumulate wastes in healthcare facilities since manufacturer credit is only issued by reverse distributors and in many cases, cannot be collected by a healthcare facility until the reverse distributor receives them.

It is also important to note that many of these potentially creditable hazardous waste pharmaceuticals are already being generated and stored in secure areas, such as pharmacies, and being handled by personnel that have pharmaceutical expertise. EPA is also recommending that liquids and aerosols be put in sealed plastic bags, containers, or other management practices during accumulation to reduce the risk of spills and releases.

As for labeling the accumulation area with the words pharmaceutical waste, the concern still remains for increasing the potential for illicit diversion of these potentially creditable hazardous waste pharmaceuticals by bringing attention to the fact that it contains pharmaceuticals. Therefore, the Agency is not finalizing a requirement for healthcare facilities to label accumulation areas for potentially creditable hazardous waste pharmaceuticals.

Finally, if a state is uncomfortable with our approach to the accumulation of potentially creditable hazardous waste pharmaceuticals, it may choose to be more stringent in this regard when it adopts the rule.

[236] See 73 FR 73529; December 2, 2008.

2. Labeling Requirements for Containers of Potentially Creditable Hazardous Waste Pharmaceuticals

a. Summary of proposal. EPA did not propose specific labeling standards for containers holding potentially creditable hazardous waste pharmaceuticals while they are accumulated on-site at a healthcare facility because they are in original manufacturer packaging, they are already labeled, and any additional labeling would be duplicative or apply to secondary containers, such as boxes used to ship to reverse distributors.

In addition, due to concerns regarding illicit diversion of pharmaceuticals, EPA believes that it is safer not to call attention to the fact that these containers hold pharmaceuticals. Unlike floor or patient care pharmaceutical waste, the potentially creditable hazardous waste pharmaceuticals returned to a reverse distributor often have high black-market value that makes them susceptible to diversion. Thus, EPA did not propose to require a label for containers used to accumulate potentially creditable hazardous waste pharmaceuticals.

b. Summary of comments. Many states believe that labeling should be required for all containers of hazardous waste to ensure proper management and disposal. Proper management, according to comments, includes accumulation in designated locations with individual containers labeled for inspection.

Other commenters expressed concerns that containers that are not labeled are subject to inaccurate waste determinations and will be mishandled and treated as non-creditable hazardous waste pharmaceuticals and sent to a TSDF rather than as potentially creditable which could ultimately be destined for a reverse distributor.

c. Final rule provision. EPA is not finalizing labeling standards for containers of potentially creditable hazardous waste pharmaceuticals accumulated by healthcare facilities.

d. Comments and responses. While the commenter's concerns apply to hazardous waste in general and for hazardous waste going to a TSDF, we do not believe they are equally applicable to containers of potentially creditable hazardous waste pharmaceuticals. First, containers of potentially creditable hazardous waste pharmaceuticals are in original manufacturer's packaging (or have been repackaged for use in a LTCF) and thus the contents are easily identifiable. Second, if a healthcare facility does not label an accumulation container on site and then forgets about it or misidentifies where it needs to go, then no manufacturer credit will be issued for those potentially creditable hazardous waste pharmaceuticals. Likewise, if a healthcare facility does label the containers on site and the contents are illicitly diverted, then the healthcare facility will not receive the manufacturer credit for those items. Healthcare facilities have a monetary incentive to keep track of what is in these containers, regardless of whether they are labeled, and to make sure they arrive unmolested at the reverse distributor.

Additionally, by imposing labeling requirements, EPA does not want to deter the practice of commingling potentially creditable hazardous waste pharmaceuticals with potentially creditable non-hazardous waste pharmaceuticals since both are typically transported together to a reverse distributor.

Therefore, EPA concludes that it is not necessary to require any labeling standards for potentially creditable hazardous waste pharmaceuticals.

D. No Biennial Reporting for Potentially Creditable Hazardous Waste Pharmaceuticals Generated at Healthcare Facilities (§ 266.503(d))

1. Summary of Proposal

The Agency proposed that healthcare facilities are not subject to biennial reporting requirements under § 262.41 with respect to potentially creditable hazardous waste pharmaceuticals managed under this subpart.

2. Summary of Comments

One state commented that it would prefer to be notified about who is handling this waste to ensure that healthcare facilities are adhering to the prohibition on sewering, since they will not know who is handling this waste.

3. Final Rule Provision

The Agency is finalizing as proposed that healthcare facilities are not subject to biennial reporting requirements under § 262.41 with respect to potentially creditable hazardous waste pharmaceuticals managed under this subpart. Potentially creditable hazardous waste pharmaceutical quantities will be captured by the reverse distributors' required biennial reports,[237] therefore, a requirement for healthcare facilities to report quantities of potentially creditable hazardous waste pharmaceuticals generated would be duplicative.

4. Comments and Responses

One state was concerned that they would not know which healthcare facilities are generating potentially creditable hazardous waste pharmaceuticals. All healthcare facilities operating under this subpart will be required to submit a one-time notification that they are subject to subpart P (§ 266.502(a)(1)). States will, therefore, be informed of what healthcare facilities are operating under subpart P and can inspect accordingly.

E. Recordkeeping Requirements for Healthcare Facilities Managing Potentially Creditable Hazardous Waste Pharmaceuticals (§ 266.503(e))

1. Summary of Proposal

EPA proposed to require healthcare facilities to keep records of the shipments of potentially creditable hazardous waste pharmaceuticals to reverse distributors.

Specifically, we proposed that healthcare facilities that initiate a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor keep (1) records of advance notification, (2) shipping papers or bills of lading, and (3) records of delivery confirmation. We proposed that a healthcare facility must retain these records for three years after the shipment was initiated. These records document that shipments of potentially creditable hazardous waste pharmaceuticals have been taken into the control and custody of the receiving reverse distributor and have not been diverted. In most cases, retaining records for three years should be sufficient for inspection purposes; however, we proposed that the periods of retention are automatically extended during unresolved enforcement activity, or at the request of the EPA Regional Administrator.

2. Summary of Comments

One state agreed that three years was a sufficient retention period to enable inspectors to identify issues upon inspection. State and local governments requested clarification about what types of documentation (*e.g.,* shipping papers/bills of lading) satisfies the requirement. One commenter argued that the receiving facility should document efforts made to locate shipments that did not arrive.

3. Final Rule Provision

EPA is finalizing the proposed recordkeeping provision for potentially creditable hazardous waste pharmaceuticals for healthcare facilities and reverse distributors that initiate a

[237] This provision is found at § 266.510(c)(9)(i)

shipment to another reverse distributor with two changes. First, as we discuss later in the shipping standards, we have eliminated the requirement for healthcare facilities to provide advance notification of shipments of potentially creditable hazardous waste pharmaceuticals to reverse distributors. Thus, we have removed the requirement to keep a record of the advance notification. Second, EPA removed the reference to bills of lading from the recordkeeping requirement while keeping shipping papers since bills of lading are a type of shipping papers under DOT regulations. This is also responsive to comments asking for clarification. Healthcare facilities initiating shipments of potentially creditable hazardous waste pharmaceuticals must keep, (1) delivery confirmation for each shipment and (2) shipping papers prepared in accordance with 49 CFR part 172 subpart C, if applicable. EPA is finalizing that these records must be retained for three years unless there is an unresolved enforcement activity or a request by the EPA Regional Administrator to keep them longer. In that case, the period of retention is automatically extended. EPA is finalizing this requirement as proposed despite input from commenters, as this is standard practice with enforcement activity. At the request of commenters, we have added a requirement that all records must be readily available upon request by an inspector.

F. Response to Spills for Healthcare Facilities Managing Potentially Creditable Hazardous Waste Pharmaceuticals (§ 266.503(f))

1. Summary of Proposal

EPA proposed response requirements for spills of non-creditable hazardous waste pharmaceuticals but did not propose similar response requirements for releases of potentially creditable hazardous waste pharmaceuticals.

2. Summary of Comments

A commenter suggested that spills of potentially creditable hazardous waste pharmaceuticals should also be subject to the same containment and cleanup requirements as non-creditable hazardous waste pharmaceuticals. The commenter also asked whether EPA intended that all spills of potentially creditable hazardous waste pharmaceuticals render them non-creditable.

3. Final Rule Provision

EPA agrees with comments that all spills of hazardous waste pharmaceuticals, both potentially creditable and non-creditable, must be contained, and that all spills of potentially creditable hazardous waste pharmaceuticals renders them non-creditable. Therefore, in response to this comment, we have added a similar provision to the healthcare facility standards of § 266.503(f) for responding to releases of potentially creditable hazardous waste pharmaceuticals.

The standards in this section are based upon what is being finalized in the standards for response to spills of non-creditable hazardous waste pharmaceuticals at healthcare facilities in § 266.502(k). The final rule requires that a healthcare facility must immediately contain all spills of potentially creditable hazardous waste pharmaceuticals and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals in accordance with subpart P.

It is EPA's understanding that unused/undispensed pharmaceuticals that remain in original manufacturer's packaging often receive manufacturer credit even if the packaging has been opened. In the event of a spill, a healthcare facility should reevaluate whether any pharmaceuticals that remain in their containers (not spilled) are still eligible to receive manufacturer credit per the definition of potentially creditable hazardous waste pharmaceutical in § 266.500. The healthcare facility must determine whether the pharmaceuticals that remain in the containers are potentially creditable and manage them according to subpart P. Even if a healthcare facility determines that the remaining pharmaceuticals are potentially creditable, it must also ensure that the decision is consistent with the manufacturer's policies. It is important to note that this only applies to whatever might be left in the container and was not spilled.

XII. How does this rule apply to healthcare facilities that are very small quantity generators for both their hazardous waste pharmaceuticals and their non-pharmaceutical hazardous waste? (§ 266.504)

A. Very Small Quantity Generators Using Reverse Distributors (§ 266.504(a))

1. Summary of Proposal

VSQGs are subject to a limited set of federal RCRA Subtitle C hazardous waste regulations, provided that they comply with the conditions set forth in § 262.14.[238] Under § 262.14, VSQGs are limited in where they may send their hazardous waste for treatment and disposal.[239] In § 266.504(a), we proposed to allow VSQG healthcare facilities to send their potentially creditable hazardous waste pharmaceuticals to a reverse distributor. Without this change, VSQGs would have been required to send all their hazardous waste pharmaceuticals, including those that are potentially creditable, to one of the types of facilities in § 262.14, which does not include a reverse distributor. Although we proposed to make this change within part 266 subpart P, we requested comment on whether stakeholders would prefer this change to be made within the VSQG regulations in § 262.14 (formerly the CESQG regulations in § 261.5) instead. VSQGs are still required to send their non-pharmaceutical hazardous waste and their non-creditable hazardous waste pharmaceuticals to one of the types of facilities listed in § 262.14.[240]

2. Summary of Comments

States, waste management and reverse distributors supported allowing VSQG healthcare facilities to send their potentially creditable hazardous waste to reverse distributors. These same commenters were also in favor of including their change in both this rule and § 262.14 to ensure that all healthcare facilities that might have potentially creditable hazardous waste pharmaceuticals would be aware of this provision and be able to take advantage of it.

3. Final Rule Provision

We are finalizing this provision as proposed, with minor edits. In general, this final rulemaking will preserve the current regulatory scheme for VSQGs: healthcare facilities that qualify as VSQGs for their total count of hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste will maintain their conditional exemption under § 262.14 and will not be subject

[238] Since the hazardous waste pharmaceutical rule was proposed, § 261.5 has been renumbered to § 262.14 as part of the reorganization of the generator regulations in the Generator Improvements final rule and this will be referenced later in this section.

[239] Since the Pharmaceutical rule was proposed§ 261.5(f)(3)(i)–(vii) for acute hazardous waste and § 261.5(g)(3)(i)–(vii) for non-acute hazardous waste has been combined and renumbered to § 262.14(a)(5)(i)–(vii) for acute and non-acute hazardous waste in the Hazardous Waste Generator Improvements final rule.

[240] A VSQG healthcare facility may be able to send its hazardous waste pharmaceuticals for consolidation at another healthcare facility operating under subpart P as allowed by § 266.504(b), or a large quantity generator and 262.14(a)(5)(viii), see section X of the preamble for further discussion.

to most aspects of this proposal. Healthcare facilities that are VSQGs are subject to three provisions of part 266 subpart P: The sewer ban in § 266.505, the empty container standards in § 266.507, and the optional provisions in § 266.504.

In response to commenter's request for clarity, the final rule makes it clear that § 266.504 applies to VSQG healthcare facilities that are VSQGs when counting both its hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste. Section 266.504 does not apply to healthcare facilities that become VSQGs under this rule as a result of not having to count their hazardous waste pharmaceuticals. Such healthcare facilities are VSQGs with respect to their non-pharmaceutical hazardous waste only and must operate under subpart P for their hazardous waste pharmaceuticals.

Under the final rule, a healthcare facility that is a VSQG when counting both its hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may choose to send its potentially creditable hazardous waste pharmaceuticals to a reverse distributor. In response to comments, EPA has added a conforming change to the VQSG generator provision in § 262.14(a)(5)(ix) for added clarity on this point. It is a restatement of § 266.504(a) which allows VSQG healthcare facilities to send their potentially creditable hazardous waste pharmaceuticals to a reverse distributor.

A healthcare facility that is a VSQG for both their hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste is given a choice. The healthcare facility may

- Operate as a standard VSQG under part 262 rules, and can use the optional provisions in § 266.504, or
- Operate under as a healthcare facility under part 266 subpart P.

4. Comments and Responses

The waste management industry requested that EPA regulate all healthcare facilities under the proposed subpart P requirements regardless of generator category. While this rule's requirements are meant to create uniformity for healthcare facilities managing hazardous waste pharmaceuticals, we want to avoid creating undue burden on VSQGs and have declined to make them subject to part 266 subpart P except for the sewer prohibition in § 266.505, the empty container provisions in § 266.507 and the optional provisions in § 266.504..

B. Off-Site Collection of Hazardous Waste Pharmaceuticals Generated by Healthcare Facilities (§ 266.504(b))

1. Summary of Proposal

EPA proposed that a healthcare facility that is a VSQG may send its hazardous waste pharmaceuticals to another healthcare facility provided the receiving healthcare facility meets certain conditions. These conditions were proposed in § 266.502(m) of this subpart.

2. Summary of Comments

One state was concerned about how consolidation might affect the generator category of the receiving facility. The commenter also raised concerns about the receiving facility performing some functions of a reverse distributor.

3. Final Rule Provision

EPA is finalizing the proposed provision with conforming changes that correspond with other sections within this rule and one additional change. The first conforming change added the words "hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste" to clarify that only healthcare facilities that are VSQGs for both their hazardous waste pharmaceuticals and their non-pharmaceutical hazardous waste may take advantage of this provision. The second conforming change converted the term CESQG to VSQG according to the 2016 Hazardous Waste Generator Improvements final rule. EPA notes that the consolidation provisions for healthcare facilities that receive both non-creditable hazardous waste pharmaceuticals and potentially creditable hazardous waste pharmaceuticals from off-site were added to the regulations in §§ 266.502(l) and 266.503(b) (sections X.N and XI.B of the preamble), respectively. The final change added flexibility for VSQGs to meet the consolidation provisions that were added as part of the 2016 Hazardous Waste Generator Improvements final rule in lieu of the subpart P off-site consolidation provisions. In this case, the receiving LQG would have to meet the conditions in § 262.17(f) while the VSQG healthcare facility would have to meet the conditions in § 262.14(a)(5)(viii).

The final rule provision allows a healthcare facility that is a VSQG for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste to send its hazardous waste pharmaceuticals off-site provided either of the following is met: (1) The receiving healthcare facility meets the conditions in § 266.502(1) and § 266.503(b) of this subpart, as applicable, or (2) the VSQG healthcare facility meets the conditions in § 262.14(a)(5)(viii), and the receiving large quantity generator meets the conditions in § 262.17(f).

4. Comments and Responses

One commenter asked for clarification about whether EPA will allow consolidation of a healthcare facility's potentially creditable or non-creditable hazardous waste pharmaceuticals at a reverse distributor. In response, the Agency is clarifying that subpart P does not allow healthcare facilities to consolidate any pharmaceutical waste at a reverse distributor. Healthcare facilities may only consolidate their waste at another facility that meets the definition of a healthcare facility as defined in § 266.500. See sections X.N and XI.B, respectively, for further discussion about healthcare facilities that receive non-creditable and potentially creditable hazardous waste pharmaceuticals from off-site healthcare facilities.

C. Long-Term Care Facilities That Are Very Small Quantity Generators Can Dispose Hazardous Waste Pharmaceuticals in Drug Enforcement Administration Collection Receptacles (§ 266.504(c))

1. Summary of Proposal

We proposed that a LTCF that is a VSQG that has an on-site DEA collection receptacle could use the collection receptacle for its hazardous waste pharmaceuticals, even if they are not controlled substances. We reasoned that since DEA already allows controlled substances to be commingled with non-controlled substances, it was consistent to allow VSQG hazardous waste pharmaceuticals that are not controlled substances to be placed in DEA authorized collection receptacles along with controlled substances. Further, we reasoned that the management of VSQG hazardous waste pharmaceuticals as DEA controlled substances is preferable to management as municipal solid waste because it provides greater protection to patients, visitors, and workers at LTCFs to have the hazardous waste pharmaceuticals in DEA authorized collection receptacles than down the sewer or in the facility's regular trash.

2. Summary of Comments

The few comments we received on this specific provision of the proposed rulemaking were mostly supportive.

3. Final Rule Provisions

We are finalizing the provision that allows an LTCF that is a VSQG to use

a DEA authorized collection receptacle to dispose of its hazardous waste pharmaceuticals with three minor changes. The first change is to clarify again that this provision only applies to LTCFs that are VSQGs for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste and are therefore not subject to subpart P (except the sewer prohibition of § 266.505, the empty container standards of § 266.507, and the optional provisions of § 266.504). The second change is to clarify that the DEA authorized collection receptacle that the VSQG LTCF uses to dispose of its hazardous waste pharmaceuticals must be on-site. The third change is to exclude items such as contaminated personal protective equipment or clean-up residues from being placed into the DEA authorized collection receptacle. Although these items meet our new definition of pharmaceutical, a DEA authorized collection receptacle is designed for the collection of the pharmaceuticals themselves and not larger items that might be contaminated by the pharmaceuticals, such as contaminated PPE or clean-up residues. For instance, they are required to have small openings and limited volumes, making their use for contaminated PPE and clean-up residues impractical.

4. Comments and Responses

One commenter thought that this proposed provision was "not feasible" because "take-back kiosks for controlled substances are intended to be used by end users and not the DEA registrant." [241] In many, if not most, cases at an LTCF, the hazardous waste pharmaceuticals will be from an ultimate user and the DEA regulations permit the collection receptacles to be used for collecting both controlled and non-controlled substances from ultimate users. There are more limited cases where an LTCF may have its own inventory of non-controlled hazardous waste pharmaceuticals.

Although EPA concurs with the commenters that the DEA authorized collection receptacles are only for controlled substances from ultimate users, EPA does not believe that the same limitation needs to be placed on the pharmaceuticals from VSQGs that are hazardous waste but not controlled substances. In fact, it could be argued that long-term care facilities that are VSQGs would be allowed to use DEA authorized collection receptacles for their hazardous waste pharmaceuticals even without this new provision, provided the waste from the DEA authorized collection receptacles is treated or disposed at one of the types of facilities identified in § 262.14(a)(5) (*e.g.*, facilities that are permitted or have interim status to manage hazardous waste and facilities that are permitted, licensed or registered by a state to manage hazardous waste, municipal waste or non-municipal waste). Nevertheless, we did propose, and are finalizing the provision in § 266.504(c) making it clear that an LTCF that is a VSQG can place its hazardous waste pharmaceuticals in an on-site DEA collection receptacle.

However, as the commenter pointed out, it is important to note that the DEA regulations for controlled substances are much narrower in what may be placed in a collection receptacle; DEA only allows controlled substances from ultimate users (patients) to be placed in collection receptacles that are at long-term care facilities. As a result, if a LTCF (or any other healthcare facility) is a DEA registrant, it may not place its inventory of controlled substances in a collection receptacle, even if it is a VSQG.

D. Long-Term Care Facilities With 20 Beds or Fewer Are Presumed To Be Very Small Quantity Generators (§ 266.504(d))

1. Summary of Proposal

EPA took comment on whether we should provide a rebuttable presumption that LTCFs with fewer than 10 beds are assumed to be VSQGs and thus would not be required to keep track of the amount of hazardous waste generated each month. The Agency did not propose regulatory language for this provision. EPA asked commenters to submit data to support a 10-bed cutoff to show that LTCFs with fewer than 10 beds are generally VSQGs. Alternatively, if commenters supported a different cutoff for the rebuttable assumption, EPA asked that the commenters submit information to support their suggested cutoff.

2. Summary of Comments

Comments on the rebuttable presumption for LTCFs with fewer than 10 beds varied. One state did not support providing a rebuttable presumption for LTCFs with fewer than 10 beds and argued that all generators should be required to count the hazardous waste they generate.[242] One state expressed support for providing a rebuttable presumption and requested that EPA keep the cutoff at 10 beds.[243] One state did not support providing the rebuttable presumption because most healthcare facilities in their state, including LTCFs, have more than 10 beds but generate only VSQG quantities of hazardous waste.[244]

Two healthcare industry commenters that supported the rebuttable presumption asked that EPA increase the cutoff from 10 beds to 20 beds.[245] One healthcare industry commenter supported the rebuttable presumption and asked that EPA increase the bed cutoff from 10 beds to 15 beds.[246]

3. Final Rule Provisions

Under the final rule, EPA is finalizing a rebuttable presumption in § 266.504(d) that LTCFs with 20 beds or fewer are assumed to be VSQGs and thus are not required to demonstrate the amount of hazardous waste generated each month. Under this presumption, LTCFs are only subject to the requirements for VSQG healthcare facilities as described elsewhere in this proposal, including the requirement not to sewer hazardous waste pharmaceuticals (§ 266.505), the empty container standards (§ 266.507), and the optional provisions of § 266.504. Under the final rule, the EPA Regional Administrator has the responsibility to demonstrate that a LTCF with 20 beds or fewer generates quantities of hazardous waste that are in excess of the VSQG limits as defined in § 260.10 if the EPA Regional Administrator wishes to mandate that the LTCF operate under subpart P. A LTCF with more than 20 beds that operates as a VSQG under § 262.14 must demonstrate that it generates quantities of hazardous waste that are within the VSQG limits as defined by § 260.10.

Based on available data, EPA believes it is reasonable to be responsive to the healthcare industry commenters who supported the rebuttable presumption and to increase the cutoff to 20 beds. The available information on hazardous waste generation at LTCFs suggests that LTCFs with 20 beds or fewer are generally VSQGs. Although EPA did not receive any data from the healthcare industry commenters, one state commented that most healthcare facilities in their state, including LTCFs, have many more than 10 beds but generate only VSQG quantities of

[241] See comment number EPA–HQ–RCRA–2007–0932–0280.

[242] See comment number EPA–HQ–RCRA–2007–0932–0238 in the docket for this rulemaking.

[243] See comment number EPA–HQ–RCRA–2007–0932–0242 in the docket for this rulemaking.

[244] See comment number EPA–HQ–RCRA–2007–0932–0332 in the docket for this rulemaking.

[245] See comment numbers EPA–HQ–RCRA–2007–0932–0239 and EPA–HQ–RCRA–2007–0932–0282 in the docket for this rulemaking.

[246] See comment number EPA–HQ–RCRA–2007–0932–0328 in the docket for this rulemaking.

hazardous waste.[247] Additionally, EPA estimates that there are between 2,875 and 4,770 long-term care facilities that generate hazardous waste and that 98 to 99 percent of the facilities are VSQGs.[248] Although EPA estimates that there are few LTCF hazardous waste generators that are SQGs or LQGs, EPA does not have data on the number of beds at each facility, making it difficult to estimate a facility size threshold at which a LTCF becomes an SQG or an LQG. EPA conducted additional analysis using data on the average size of LTCFs in the United States and data on the average volume of hazardous waste generated annually at LTCFs that submitted a biennial hazardous waste report between 2001 and 2015 in order to estimate the average size at which a LTCFs become SQGs or LQGs.[249] The estimates suggest that LTCFs with fewer than 20 beds will generally be VSQGs. Therefore, EPA concludes that it is reasonable to provide a rebuttable presumption that LTCFs with 20 beds or fewer are assumed to be VSQGs and thus are not required to demonstrate the amount of hazardous waste generated each month.

XIII. Sewer Disposal Prohibition (§ 266.505)

A. Regulatory Background on the Domestic Sewage Exclusion

Under RCRA and the Subtitle C hazardous wastes regulations, if a material is not a solid waste, then it cannot be considered a hazardous waste. Under § 261.4(a)(1)(ii) of the RCRA regulations, "Any mixture of domestic sewage and other wastes that passes through a sewer system to a publicly-owned treatment works for treatment" is not a solid waste for purposes of Subtitle C regulation. This exclusion was finalized by EPA on May 19, 1980, based on the reasoning that "Mixed waste streams that pass through sewer systems to publicly-owned treatment works (POTWs) will be subject to controls under the Clean Water Act (CWA). The Agency's construction grants program provides financial assistance for the proper treatment of these wastes. In addition, the Agency's pretreatment program provides a basis for EPA and the local communities to ensure that users of sewer and treatment systems do not dump wastes in the system that will present environmental problems." [250]

In 1984, Congress enacted the Hazardous and Solid Waste Amendments (HSWA) to the Solid Waste Disposal Act (SWDA), as amended by RCRA. HSWA included a new Section 3018, entitled Domestic Sewage. This section directed EPA to do two things with respect to the § 261.4(a)(1)(ii) exclusion for mixtures of domestic sewage and other wastes: (1) Submit a Report to Congress (RTC) that describes the types, size and number of generators which dispose of such wastes in this manner, the types and quantities of wastes disposed of in this manner, and identify significant generators, wastes and waste constituents not regulated under existing Federal law or regulated in a manner sufficient to protect human health and the environment; and (2) based on the report, revise the appropriate existing regulations to "ensure that substances . . . which pass through a sewer system to a publicly owned treatment works are adequately controlled to protect human health and the environment."

EPA submitted its Report to Congress on February 7, 1986 (Domestic Sewage Study). Subsequent to the Report to Congress, EPA issued an advance notice of proposed rulemaking on August 22, 1986; [251] a response to comments on the advanced notice of proposed rulemaking on June 22, 1987; [252] a notice of proposed rulemaking (NPR) on November 23, 1988; [253] and a final rule on July 24, 1990.[254] That final rule expanded an existing prohibition on the discharge of pollutants which create a fire or explosion hazard in the POTW, so that it included, but was not limited to, "waste streams with a closed cup flashpoint of less than 140 degrees Fahrenheit or 60 degrees Centigrade using the test methods specified in 40 CFR 261.21." [255] Although the RCRA characteristic of reactivity (D003) was not specifically mentioned in the CWA regulations, discharges of some D003 reactive hazardous wastes are also prohibited by this section of the CWA regulations: (1) Chemicals that react violently with water [256] and (2) chemicals that form potentially explosive mixtures with water.[257]

The 1990 CWA final rule added a new prohibition such that no discharge shall "result in the presence of toxic gases, vapors or fumes within the POTW in a quantity that may cause acute worker health and safety problems." [258] Similarly, although the RCRA characteristic of reactivity (D003) was not specifically mentioned in this section of the CWA regulations, discharges of some D003 reactive hazardous wastes are also prohibited by this section: (1) Chemicals that, when mixed with water, generate toxic gases, vapors or fumes in quantity sufficient to present a danger to human health or the environment [259] or (2) cyanide or sulfide bearing waste which, when exposed to pH conditions between 2 and 12.5, can generate toxic gases, vapors or fumes in a quantity sufficient to present a danger to human health or the environment.[260]

In addition, some D002 corrosive hazardous wastes were prohibited prior to the 1990 CWA final rule and remain prohibited. Under RCRA, a waste is considered D002 for corrosivity if it has a pH of less than or equal to 2 (strongly acidic) or greater than or equal to 12.5 (strongly basic). Section 403.5(b)(2) of the CWA regulations prohibits discharges with a pH of less than 5.0, except under limited circumstances. Therefore, acidic D002 hazardous waste is prohibited from being discharged under the CWA regulations.

Note that although the exclusion for mixtures of domestic sewage and other wastes is found under the RCRA regulations in § 261.4(a)(1)(ii), and it was HSWA, which is an amendment to RCRA, that directed the review of and amendments to that exclusion, the sewer ban of liquid ignitable D001 hazardous wastes and some D002 and D003 hazardous wastes was established under 40 CFR 403.5(b), which is under the CWA regulations. Also note that EPA left open the possibility of additional future action when it stated in the preamble to the July 24, 1990, final rule, its intent "to carefully review the effect of this rule and promulgate in the future any additional regulations that experience reveals are necessary to improve control over hazardous waste and other industrial user discharges to POTWs." [261]

[247] See comment number EPA–HQ–RCRA–2007–0932–0332 in the docket for this rulemaking.

[248] Regulatory Impact Analysis in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[249] See memorandum "Long-Term Care Facility Summary Data and Hazardous Waste Generation Data" in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[250] May 19, 1980; 45 FR 33097.

[251] See the advance notice of proposed rulemaking in August 22, 1986; 51 FR 30166.

[252] See the response to comments in June 22, 1987; 52 FR 23477.

[253] See the proposed rule November 23, 1988; 53 FR 47632.

[254] See the final rule in July 24, 1990; 55 FR 30082.

[255] See the prohibition in 40 CFR 403.5(b)(1).

[256] See 40 CFR 261.23(a)(2).

[257] See 40 CFR 261.23(a)(3).

[258] See 40 CFR 403.5(b)(7).

[259] See 40 CFR 261.23(a)(4).

[260] See 40 CFR 261.23(a)(5).

[261] July 24, 1990 **Federal Register**; 55 FR 30084.

B. Summary of Proposal

In 2015, EPA proposed to impose a sewer ban on all hazardous waste pharmaceuticals managed by healthcare facilities and reverse distributors. That is, healthcare facilities and reverse distributors subject to part 266 subpart P would not be able to use the RCRA domestic sewage exclusion in § 261.4(a)(1)(ii) any longer for their hazardous waste pharmaceuticals. They would be prohibited from disposing of pharmaceuticals that are listed hazardous waste and/or exhibit one or more of the four hazardous waste characteristics (*i.e.*, ignitability, corrosivity, reactivity, or toxicity) by putting them down a drain (*e.g.*, sink, toilet, or floor drain).

EPA proposed this sewer prohibition of hazardous waste pharmaceuticals for several reasons. First, as described in detail in the preamble to the proposed rulemaking, a number of studies had shown that flushing of leftover medications had become a prevalent practice used in lieu of proper hazardous waste management and that experience had, indeed, revealed that additional regulations were "necessary to improve control over hazardous waste and other industrial user discharges to POTWs." [262]

Second, although EPA establishes national regulations under the CWA (called effluent limitations guidelines and pretreatment standards) to reduce discharges of pollutants from industries to surface waters and POTWs, currently there are no national effluent limitations or pretreatment standards that apply to healthcare facilities discharging pharmaceuticals to POTWs. Furthermore, traditional wastewater treatment operations implemented at POTWs are designed to remove conventional pollutants, such as suspended solids and biodegradable organic compounds. They are not designed to remove pharmaceuticals that are present in discharges from medical and veterinary facilities. While some POTWs may have implemented advanced treatment technologies, these technologies are not designed to remove pharmaceuticals. EPA released a study in 2009 in which over 100 chemicals (including some pharmaceuticals) were analyzed in the influent and effluent at nine POTWs.[263] Although it was a limited study and difficult to generalize the results to all POTWs, it does indicate that the capabilities of treatment technologies currently employed by POTWs does not include treatment to remove active pharmaceutical ingredients (APIs).[264] In a more recent study, EPA measured concentrations of 56 APIs in effluent samples from 50 large POTWs across the country and discovered at least one API in each sample.[265] In addition, as stated in EPA's Health Services Industry study, "synthetic compounds, such as pharmaceuticals, are often manufactured to be resistant to metabolic transformation. As a result, some pharmaceutical compounds that are present in the influent to POTWs may pass through treatment systems at conventional POTWs and discharge to receiving waters." [266]

Third, the pharmaceuticals entering the environment, through flushing or other means, are having a negative effect on aquatic ecosystems and on fish and animal populations. A recent article highlighted the scientific literature that examines the effect of pharmaceuticals on freshwater ecosystems, particularly the effect of pharmaceuticals on key ecological processes.[267] The RIA for the proposed rulemaking more fully summarized the scientific literature with regard to ecological effects.[268] The scientific research with regard to human health effects due to pharmaceuticals in the environment is still ongoing. Nevertheless, the important features and risks of the problem can be summarized as follows: [269]

(1) Pharmaceuticals are intrinsically bioactive compounds; therefore, they can potentially impact living systems.

(2) There is a continuous and worldwide increase in their use and, thus, on their subsequent input into the environment.

(3) Many of the hundreds of frequently prescribed pharmaceuticals are known for targeted effects and adverse off-target side effects, a problem that can be exacerbated by interactive effects during therapy involving co-administration and disposal.

While healthcare facilities that are VSQGs were generally not subject to the proposed rulemaking, EPA proposed that the sewer ban of hazardous waste pharmaceuticals also apply to healthcare facilities that are VSQGs. The RIA for the rule projects that the vast majority of healthcare facilities are VSQGs (81–86 percent).[270] Some particular types of healthcare facilities have an even larger proportion of VSQGs: For example, the RIA estimates that of the LTCFs that generate hazardous waste, 98–99 percent of LTCFs are VSQGs.[271] EPA was and remains concerned that these smaller healthcare facilities are more likely to dispose of their hazardous waste pharmaceuticals via the sewer. EPA estimates that there are between 50,900 and 84,800 healthcare facilities that are VSQGs.[272] Given this large number, the combined impact of sewer disposal by healthcare facilities that are VSQGs has an even greater potential to provide a substantial impact on the environment, as well as human health. EPA solicited comment on whether it was appropriate to apply the proposed ban on the sewer disposal of hazardous waste pharmaceuticals to all healthcare facilities, including healthcare facilities that are VSQGs. Comments submitted to the Agency in response to this request are discussed in the next section.

We note that EPA's proposed ban on sewering hazardous waste pharmaceuticals is consistent with other federal state, and local actions. For example, the DEA has finalized regulations to implement the Secure and Responsible Drug Disposal Act of 2010.[273] DEA's regulations require a "non-retrievable" method of destruction of controlled substances. The preamble to DEA's proposed and final rules state that flushing does not meet the non-retrievable standard for destruction.[274] According to the preamble of the DEA final rule, DEA received 20 comments supporting their position against

[262] July 24, 1990 **Federal Register**; 55 FR 30084.

[263] EPA, Occurrence of Contaminants of Emerging Concern in Wastewater from Nine Publicly Owned Treatment Works, August 2009; EPA–821–R–09–009.

[264] Eggen RI, Hollender J, Joss A, Schärer M, Stamm C, "Reducing the Discharge of Micropollutants in the Aquatic Environment: The Benefits of Upgrading Wastewater Treatment Plant." Environmental Science and Technology 2014, 48(14) 7683–7689.

[265] Kostich MS, Batt AL, Lazorchak JM, "Concentrations of prioritized pharmaceuticals in effluents from 50 large wastewater treatment plants in the US and implications for risk estimation." Environmental Pollution 2014, 184:354–9.

[266] Health Services Industry Study: Management and Disposal of Unused Pharmaceuticals (Interim Technical Report) August 2008; EPA–821–R–08–013.

[267] Richmond EK, Grace MR, Kelly JJ, Reisinger AJ, Rosi EJ, Walters, DM. "Pharmaceuticals and personal care products (PPCPs) are ecological disrupting compounds (EcoDC)." Elem Sci Anth 2017, 5:66.

[268] See page 147 of the Regulatory Impact Analysis for the proposed rule in the docket EPA–HQ–RCRA–2007–0932–0151.

[269] A. Ginebreda et al., Environmental risk assessment of pharmaceuticals in rivers: Relationships between hazard indexes and aquatic macroinvertebrate diversity indexes in the Llobregat River (NE Sapin). Environ Int. (2009), doi:10.1016/j.envint.2009.10.003.

[270] See the Regulatory Impact Analysis for the final rule in the docket EPA–HQ–RCRA–2007–0932.

[271] Ibid.

[272] Ibid.

[273] September 9, 2014; 79 FR 53520.

[274] Proposed rule: December 21, 2012; 77 FR 75784 (see page 75803); and Final rule: September 9, 2014; 79 FR 53520 (see page 53548).

flushing controlled substances.[275] The comments supporting the prohibition against sewering came from states, regional, and local hazardous waste management programs, recycling associations, non-governmental organizations (NGOs), trade associations and environmental organizations. Many of these commenters noted that wastewater treatment systems do not eliminate many of the drugs that are flushed into the sewers and requested that DEA clearly state in the regulatory language, not just preamble, that sewering is not allowable as a means of destruction.

In addition, four states, the District of Columbia, and local California jurisdictions have taken action to limit the sewering of pharmaceuticals and another state has introduced a bill. "Colorado has prohibited the discharging of solid/hazardous waste down the drain since the adoption of RCRA in the 1980s."[276] In 2009, Illinois passed the Safe Pharmaceutical Disposal Act, which prohibits healthcare facilities from flushing any solid dosage form other than DEA schedule II drugs into public sewers or septic systems.[277] In 2012, New Jersey passed a similar law that prohibits healthcare facilities from discharging prescription medications into public sewers or septic systems.[278] In 2002, California banned the use of lindane in pharmaceuticals after it found that lindane was adversely impacting wastewater quality. The authors of the paper "Outcomes of the California Ban on Pharmaceutical Lindane: Clinical and Ecologic Impacts state that "This is the first time that a pharmaceutical has been outlawed to protect water quality."[279] After researching and documenting environmental benefits of the ban, the authors conclude, "This ban serves as a model for governing bodies considering limits on the use of lindane or other pharmaceuticals." Also in California, some county departments, such as Sacramento County and Contra Costa County, prohibit sewering of hazardous waste pharmaceuticals.[280] And the District of Columbia has promulgated municipal regulations, effective January 1, 2011, that prohibits healthcare facilities from flushing pharmaceutical products.[281] The Connecticut legislature has also considered a bill to ban the discharge of medication into public or private wastewater collection systems or septic systems, although it has not yet become law.[282] Nevertheless, the Connecticut Department of Energy and Environmental Protection's (CT DEEP) "current hazardous waste management regulations essentially ban sewer disposal of RCRA waste by requiring all generators in Connecticut, including [VSQGs], to ensure delivery by a licensed waste transporter with an EPA ID Number to a facility authorized to receive the waste."[283]

The Agency sought comment on several areas related to the prohibition on sewering hazardous waste pharmaceuticals. First, the Agency requested comment on whether the sewer ban should apply to healthcare facilities that are VSQGs. Second, we requested comment on the trade-offs inherent in prohibiting sewer disposal; that is, would the benefit of the reduction in aquatic risk be outweighed by additional opportunities for diversion and the possibility of inadvertent exposures for certain workers? Third, we sought comment on whether it would be appropriate to allow any exceptions to the sewer ban, such as for leftover portions of hazardous wastes that are also controlled substances.[284] Finally, the Agency sought comment on whether it would be helpful to incorporate in 40 CFR 261.4(a)(1)(ii), a cross-reference to the CWA regulations that prohibit the sewering of certain hazardous wastes.

C. Summary of Comments

Nearly a third of the commenters to the proposed rulemaking commented on the proposed prohibition of sewering hazardous waste pharmaceuticals. Commenters were nearly unanimous in their support for the prohibition on sewering of hazardous waste pharmaceuticals. Support was expressed by a broad and diverse set of commenters, including state and local governments, sewer districts, environmental groups, and waste management companies. Although some commenters had suggestions for minor exceptions, few commenters expressed complete opposition to the prohibition on sewering. Furthermore, there was widespread support from commenters for applying the prohibition on sewering hazardous waste pharmaceuticals to healthcare facilities that are VSQGs. As one commenter noted, "given the large number of small generators . . . If each of these small generators were allowed to discharge even a small amount of pharmaceuticals, the overall volume would be significant."[285]

D. Final Rule Provisions

Given the environmental concerns described above combined with the overwhelming support that we received from commenters, we are finalizing the prohibition of sewering hazardous waste pharmaceuticals. The prohibition on sewering hazardous waste pharmaceuticals applies to all reverse distributors and all healthcare facilities, including healthcare facilities that are VSQGs. Furthermore, EPA is not providing any exceptions to the prohibition on sewering. Therefore, the prohibition on sewering hazardous waste pharmaceuticals applies to all hazardous waste pharmaceuticals that are generated by any healthcare facilities and reverse distributors, including hazardous waste pharmaceuticals that are also controlled substances and any pharmaceutical wastage from partial administration of hazardous waste pharmaceuticals. How the sewer prohibition intersects with the disposal of pharmaceutical wastage will be discussed in greater detail in section XIV.D.2. rather than this section.

In response to commenters' suggestions, we are making some minor editorial changes, including adding two cross references to the CWA prohibitions on sewering hazardous wastes in § 403.5(b). One cross reference will be added to § 261.4(a)(1)(ii) and the other cross reference will be added to § 266.505. We also eliminated the second sentence of the proposed prohibition, which read: The exclusion in § 261.4(a)(1)(ii) for mixtures of domestic sewage and other wastes that pass through a sewer system to a publicly owned treatment works does not apply to hazardous waste pharmaceuticals.

[275] September 9, 2014; 79 FR 53520 (see page 53548).

[276] See comment number: EPA–HQ–RCRA–2007–0932–0242.

[277] Illinois Public Act 096–0221.

[278] Nicknamed Bateman's Law, after Senator Christopher "Kip" Bateman (R-Somerset) that sponsored the legislation.

[279] Humphreys, et al. Environmental Health Perspectives. 2008 March; 116(3) 297–302.

[280] See comment number: EPA–HQ–RCRA–2007–0932–0378.

[281] DCMR Title 22–B Chapter 5 Safe Disposal of Unused Pharmaceuticals in Health Care Facilities

[282] State of Connecticut General Assembly, January Session 2013, Raised Bill No. 6439. An Act Concerning the Disposal and Collection of Unused Medication.

[283] See comment number EPA–HQ–RCRA–2007–0932–0341.

[284] In a DEA letter dated October 17, 2014, DEA refers to leftover, partially administered drugs as "pharmaceutical wastage." *https://www.deadiversion.usdoj.gov/drug_disposal/dear_practitioner_pharm_waste_101714.pdf*

[285] See comment number EPA–HQ–RCRA–2007–0932–0337.

Oklahoma Department of Environmental Quality (OK DEQ) expressed concern that this "second sentence could be interpreted that EPA is exerting RCRA authority over domestic sewage if it contains [hazardous waste pharmaceuticals]—an area that has been exclusively under Clean Water Act jurisdiction since the first regulations were promulgated in 1980." [286] EPA had proposed the second sentence in an attempt to be abundantly clear that the proposed prohibition on sewering hazardous waste pharmaceuticals supersedes the exclusion in § 261.4(a)(1)(ii). We did not intend to assert RCRA jurisdiction over domestic sewage; therefore, we have concluded that it is better to remove the sentence in order to avoid the concern expressed by OK DEQ. Nevertheless, we wish to emphasize that the prohibition on sewering hazardous waste pharmaceuticals being finalized in § 266.505 does, in fact, supersede the exclusion in § 261.4(a)(1)(ii). To make that point clear, we are amending § 261.4(a)(1)(ii) to state that any mixture of domestic sewage and other wastes that passes through a sewer system to a publicly-owned treatment works for treatment, *except as prohibited by §§ 266.505 and Clean Water Act requirements at 40 CFR 403.5(b),* is not a solid waste.

E. Comments and Responses

Many comments suggested various ways in which we should broaden the applicability of the prohibition on sewering hazardous waste pharmaceuticals. In some cases, commenters urged us to apply the prohibition to all pharmaceuticals, not just hazardous waste pharmaceuticals. Subtitle D of RCRA, which governs the management of non-hazardous (solid) waste, does not provide EPA the statutory authority to apply the prohibition to non-hazardous waste pharmaceuticals. Nevertheless, EPA strongly recommends against sewering any pharmaceuticals. The American Water Works Association asked us to extend the prohibition to prevent the sewering of pharmaceuticals that are radioactive and patient waste containing radioactive pharmaceuticals. As discussed previously, hazardous waste pharmaceuticals that also contain a radioactive component subject to the Atomic Energy Act of 1954 (*i.e.,* "mixed waste") are regulated by multiple agencies. The hazardous waste component is regulated under EPA or the authorized state RCRA programs, while either the NRC or the Department of Energy regulates the radioactive component of the waste under the Atomic Energy Act.[287] Therefore, a "mixed waste" pharmaceutical that is both radioactive and RCRA hazardous waste is prohibited from being discharged to the sewer. We strongly recommend against sewering other radioactive pharmaceuticals and patient waste containing radioactive pharmaceuticals.

Other commenters suggested that the prohibition should not be limited to discharges to POTWs; rather, it should also apply to discharges to septic tanks, privately owned treatment works and federally owned treatment works. Section 261.4(a)(1)(ii) allows the discharge of what would otherwise be a hazardous waste to POTWs, without being considered a solid or hazardous waste. The prohibition on discharges of hazardous waste pharmaceuticals being finalized today is intended to reduce the scope of that exclusion in the existing regulations. Discharges of hazardous waste to other types of sewage systems, such as septic tanks, privately owned treatment works and federally owned treatment works are not allowed by exclusion in § 261.4(a)(1)(ii). Therefore, the discharge of hazardous wastes to septic tanks, privately owned treatment works and federally owned treatment works is already prohibited, even though it is not explicitly stated.

We note that although our RCRA statutory authority limits us to apply the prohibition on sewering narrowly to pharmaceuticals that are RCRA hazardous wastes, EPA strongly recommends as a best management practice to not sewer any waste pharmaceutical (*i.e.,* hazardous or non-hazardous) from any source or location. This recommendation against sewering pharmaceuticals includes households and assisted living facilities, except in the relatively rare situation when households and assisted living facilities are specifically directed by FDA guidance to flush certain potentially dangerous drugs down the toilet (as noted on pharmaceutical packaging), when a drug take-back option is not readily available, to help ensure that they are not misused or accidentally ingested or touched.[288] In lieu of sewering, we recommend that households, including residents of assisted living facilities, follow the guidelines developed by the U.S. Office of National Drug Control Policy (ONDCP), the FDA, and EPA for the disposal of unwanted household pharmaceuticals. In summary, the guidelines for households disposing of pharmaceuticals are as follows (in order of preference):

(1) Use a drug take-back event or program, when available;

(2) Dispose in household trash, after mixing the unwanted medicines with an unpalatable substance such as dirt, cat litter, or used coffee grounds and placing in a sealed container; and

(3) Only if the drug label specifically instructs you to, flush the unwanted medicine down the toilet.[289]

We also note that the CWA prohibitions on discharges of hazardous waste in § 403.5(b) are broader than just pharmaceuticals and apply beyond healthcare facilities and reverse distributors. Like all of the prohibited discharges under the CWA regulations, the prohibitions of hazardous waste discharges apply to any industrial user. Additionally, the CWA prohibitions on hazardous waste discharges apply to all D001 ignitable liquids, acidic D002 hazardous wastes, and D003 reactive hazardous wastes that (1) react violently with water,[290] (2) form potentially explosive mixtures with water,[291] or (3) result in the presence of toxic gases, vapors or fumes within the POTW in a quantity that may cause acute worker health and safety problems,[292] not just pharmaceuticals that exhibit those characteristics.

Some commenters asked us to include some exceptions to the prohibition on discharges of hazardous waste pharmaceuticals. Specifically, one commenter who supported our proposed ban on sewering of hazardous waste pharmaceuticals, and even supported extending it to non-hazardous waste pharmaceuticals, suggested that we allow exceptions "for those that do not contain active pharmaceutical ingredients, such as sterile water and 0.9% sodium chloride for injection and irrigation." [293] First, as a point of clarification, because sterile water and 0.9% sodium chloride are not hazardous waste, they would not be subject to the prohibition of discharging hazardous waste pharmaceuticals to the

[286] See commenter number EPA–HQ–RCRA–2007–0932–0231.

[287] The NRC regulates radioactive wastes generated by commercial or non-DOE facilities, whereas DOE regulates radioactive wastes generated by DOE facilities.

[288] *https://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/UCM337803.pdf.*

[289] *https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm.*

[290] See 40 CFR 261.23(a)(2).

[291] See 40 CFR 261.23(a)(3).

[292] See 40 CFR 403.5(b)(7).

[293] See comment number EPA–HQ–RCRA–2007–0932–0230.

sewer. And even though, as a general rule, we strongly recommend against sewering any pharmaceutical, regardless of whether it meets our definition of hazardous waste, we agree with the commenter that it seems unnecessary to prohibit the sewering of sterile water and 0.9% sodium chloride.

Other commenters asked us to make other exceptions to the prohibition on discharging hazardous waste pharmaceuticals. For example, the Healthcare Waste Institute suggested that we allow the discharge of hazardous waste pharmaceuticals that are specifically allowed by the local wastewater treatment agency or POTW.[294] CT DEEP made a similar suggestion, saying that we should allow discharges if they are "explicitly authorized by a National Pollutant Discharge Elimination System (NPDES) or State pretreatment permit."[295] We have concluded that such an allowance is unnecessary because no known pretreatment standards or local limits have been established that specifically allow for the discharge of any pharmaceuticals. Note that 40 CFR part 439 separately regulates discharges from pharmaceutical manufacturers to POTWs and waters of the U.S. Furthermore, in the absence of water quality standards for specific drugs, we would like to avoid a situation where local wastewater treatment agencies might feel pressured to make judgments on which discharges would be acceptable without knowing the effects on aquatic life or the synergistic effects of multiple drugs.

We received few comments related to our inquiry about trade-offs inherent in prohibiting sewer disposal. Sharps Compliance did note that as "our experience as a DEA authorized collector has shown, regulations that ban the sewering in conjunction with a proactive collection and destruction program offer the best protection against both environmental harm and the risk of diversion."[296] In addition, CT DEEP commented they do "not believe there is an unfavorable risk trade-off inherent in prohibiting sewer disposal," indicating both risks are manageable.[297]

Eli Lilly was one of the few commenters that opposed the prohibition on sewering hazardous waste pharmaceuticals, even though, as a manufacturer, they are not subject to the prohibition.[298] They expressed two reasons for their opposition: (1) They do not believe that a total prohibition is based on sound risk management decisions and should be more flexible to exclude pharmaceuticals which FDA says should be disposed of down the drain, and (2) they believe that an effluent guideline under the CWA regulations is more appropriate and that EPA's Office of Water has decided not to promulgate an effluent guideline for the healthcare industry. As discussed previously, the prohibition on sewering hazardous waste pharmaceuticals and the FDA flush list do not conflict with one another. The prohibition applies to healthcare facilities (which does not include assisted living facilities) and reverse distributors, while the FDA flush list is directed to households and assisted living facilities and includes the caveat that flushing takes place only when a drug take-back option is not readily available. As to the commenter's second point, while it is true that the Office of Water has not yet promulgated an effluent guideline for the healthcare industry, this should not be taken as a sign that a decision has been made affirmatively that an effluent guideline is not appropriate at some time in the future. Rather, the Office of Water has preferred that the Office of Resource Conservation and Recovery (ORCR) first focus on preventing intentional discharges of hazardous waste pharmaceuticals. We firmly believe that the prohibition of sewering hazardous waste pharmaceuticals would complement any future action taken by the Office of Water to issue effluent guidelines for the healthcare industry.

XIV. Conditional Exemptions for Hazardous Waste Pharmaceuticals That Are Also Drug Enforcement Administration Controlled Substances and Household Waste Pharmaceuticals Collected in Take-Back Programs (§ 266.506)

A. Summary of Proposal

Prior to this final rulemaking, the management and disposal of a pharmaceutical that was both a RCRA hazardous waste and a DEA controlled substance was regulated under both the RCRA Subtitle C hazardous waste regulations, which is under EPA's or the authorized state's purview, and the Controlled Substances Act and its implementing regulations, which is under DEA's purview. At the time of the proposal, EPA was aware of only a handful of pharmaceuticals in common usage that are both hazardous waste and controlled substances and therefore subject to regulation by both EPA and the DEA. These are identified in Table 3:

TABLE 3—PHARMACEUTICALS STILL USED IN HEALTHCARE THAT ARE DEA CONTROLLED SUBSTANCES AND RCRA HAZARDOUS WASTES

Name of drug	Other name(s)	Medical uses	RCRA HW code	DEA CS schedule	Comment
Chloral; chloral hydrate.	Acetaldehyde, trichloro-; Aquachloral, Noctec, Somnote, Supprettes.	Sedative	U034, toxic	IV	Used in hospital pediatric units; common ingredient in vet anesthetics.
Fentanyl sublingual spray.	Subsys	Analgesic	D001, ignitable	II	Ignitable due to alcohol content.
Phenobarbital	Bellergal-S, Donnatal, Luminal,	Anticonvulsant	D001, ignitable	IV	Ignitable due to alcohol content.
Testosterone gels	Androgel, Fortesta, Testim	Hormone	D001, ignitable	III	Ignitable due to gel base.
Valium injectable	Diazepam	Anti-anxiety	D001, ignitable	IV	Ignitable due to alcohol content.

[294] See comment number EPA–HQ–RCRA–2007–0932–0296.

[295] See comment number EPA–HQ–RCRA–2007–0932–0341.

[296] See comment number EPA–HQ–RCRA–2007–0932–0248.

[297] See comment number EPA–HQ–RCRA–2007–0932–0341.

[298] See comment number EPA–HQ–RCRA–2007–0932–0249.

Chloral hydrate (U034), which is listed for toxicity, is the only dually regulated hazardous waste/controlled substance that is a listed hazardous waste.[299] The other four dually regulated hazardous wastes/controlled substances in common use are considered hazardous because they exhibit the characteristic of ignitibility (D001). While the active ingredient is not ignitable, these particular forms of the pharmaceuticals are ignitable because they are prepared in ignitable solutions, such as alcohol.

EPA is aware of three additional hazardous waste pharmaceuticals that are DEA controlled substances, but it is our understanding that they are no longer in common usage, although there may be legacy supplies remaining in healthcare facilities. See Table 4.

TABLE 4—DEA CONTROLLED SUBSTANCES AND RCRA HAZARDOUS WASTES PHARMACEUTICALS THAT ARE NOT IN COMMON USE

Name of drug	Other name(s)	Medical uses	RCRA HW code	DEA CS schedule	Comment
Paraldehyde	1,3,5-Trioxane, 2,4,6-trimethyl-; Paral	Anticonvulsant	U182 toxic	IV	No longer in common use.
Paregoric	camphorated tincture of opium	Analgesic, expectorant, antidiarrheal.	D001 ignitable	III	No longer in common use.
Opium Tincture	Laudanam	Analgesic, antidiarrheal	D001 ignitable	II	No longer in common use.

Similarly, as noted in Table 5, phentermine is a controlled substance, but the medical form is a phentermine salt, and the salts are no longer considered to be within the scope of the P046 listing.[300]

TABLE 5—PHARMACEUTICALS THAT ARE DEA CONTROLLED SUBSTANCES AND RCRA HAZARDOUS WASTES SALT(S) NO LONGER CONSIDERED HAZARDOUS WASTE

Name of drug	Other name(s)	Medical uses	RCRA HW code	DEA CS schedule	Comment
Phentermine	alpha, alpha-Dimethylphenethyl amine; Benzeneethanamine, alpha,alpha-dimethyl-; Adipex-P, Atti Plex P, Fastin, Ionamin, Kraftobese, Panshape M, Obe-Nix, Pentercot, Phentride, Pro-Fast, Raphtre, Supramine, Tara-8, Termene, Termine, Zantryl.	Appetite suppressant.	P046, Acutely toxic	IV	If in salt form, it does not meet the P046 listing and medical dosage forms are salts.

EPA requested comment on whether these are, indeed, the only pharmaceuticals in common usage that are regulated both as DEA controlled substances, and when discarded, as RCRA hazardous waste.

To eliminate duplicative regulation for these handful of hazardous wastes that are also controlled substances, EPA proposed to conditionally exempt from RCRA Subtitle C regulation those hazardous wastes that are also DEA controlled substances. Specifically, EPA proposed that hazardous wastes that are also controlled substances will be exempt from all RCRA Subtitle C requirements, including 40 CFR part 266 subpart P, provided they meet two conditions: (1) They are combusted at a permitted large or small municipal waste combustor or a permitted or interim status hazardous waste combustor (incinerator or cement kiln) and (2) they are managed and disposed of in compliance with all applicable DEA regulations for controlled substances.

The first condition we proposed was to ensure that the controlled substances are destroyed in an environmentally protective manner by a high-temperature combustor, such as a large or small municipal waste combustor or a permitted or interim status hazardous waste combustor (incinerator or cement kiln). At the time of proposal, DEA had not specified or endorsed a method by which the controlled substances should be destroyed to meet the non-retrievable standard. Although many hazardous wastes/controlled substances were being destroyed by incineration, it was not required by DEA. At the time, EPA was concerned that in the future DEA might allow a technology that lacks environmental controls and permits. Therefore, combustion of the hazardous wastes/controlled substances, which requires permitting, operating and monitoring standards, was proposed as a condition of the exemption. However, EPA requested comment on whether there are additional technologies that would be appropriate to include for the destruction of hazardous waste pharmaceuticals that are also controlled substances.

The second condition we proposed was to ensure that dually regulated hazardous wastes/controlled substances are managed under another rigorous regulatory program since they will not be managed in accordance with the RCRA Subtitle C regulations. Although developed for different reasons, both EPA's hazardous waste and DEA's controlled substance regulatory programs are designed to track the regulated material from cradle to grave. EPA requested comment on whether the tracking that DEA requires for controlled substances is sufficient to act in lieu of the RCRA manifest.

We considered proposing a third condition that the hazardous waste pharmaceuticals that are also DEA controlled substances would be subject

[299] Note that EPA's U034 listing includes chloral hydrate, see memo dated April 6, 1998; Brandes to Knauss, RCRA Online #14175

[300] See memo dated February 17, 2012; from Devlin to RCRA Division Directors, RCRA Online #14831.

to the sewer prohibition of § 266.505. At the time of proposal, however, we concluded that because combustion in specific units was a condition of the exemption, that it was unnecessary to state that the hazardous waste/controlled substances may not be sewered.

EPA also proposed a related conditional exemption for household pharmaceuticals, including those that are collected in DEA authorized collection receptacles and commingled with DEA controlled substances. Specifically, we proposed that collected household pharmaceuticals will continue to be excluded from RCRA regulation as household hazardous waste, provided they comply with the same two conditions. The Agency has a long-standing recommendation that household hazardous waste collection programs manage the collected waste as hazardous waste.[301] As such, the Agency recommends that collected household waste pharmaceuticals be incinerated—preferably at a permitted hazardous waste incinerator, but when that is not feasible, at a large or small municipal waste combustor.[302] The Agency believes that this practice is already common among collection programs since one goal of many collection programs is to divert pharmaceuticals from municipal landfills. Additionally, incineration is commonly used to meet the "non-retrievable" standard of destruction required by DEA for controlled substances collected from consumers (ultimate users, as DEA refers to them). Nevertheless, the Agency proposed to make this recommendation a requirement for collected household waste pharmaceuticals in § 266.506.[303] We strongly believe that if a program goes to the expense of collecting the waste, including waste pharmaceuticals, it should manage the waste as hazardous waste, rather than manage it as municipal solid waste, which the household could do absent the collection program. However, the current household waste exemption does not *require* an entity that hosts a household hazardous waste collection event to manage the collected waste as hazardous waste. Typically, the parties conducting household hazardous waste collection events have been government entities—municipalities and counties. It is relatively new that retail pharmacies and others are becoming interested in performing this function. To encourage this practice, while at the same time ensuring that collection programs are managing the collected waste properly, we proposed to codify our policy that pharmaceuticals that are household hazardous waste (*i.e.*, "household waste pharmaceuticals") and are collected in DEA authorized collection receptacles where they may be commingled[304] with controlled substances continue to be excluded from RCRA regulation, provided they are (1) combusted at a municipal solid waste or hazardous waste combustor, and (2) managed in accordance with all applicable DEA regulations.[305]

B. Summary of Comments

Many of the commenters, including states, healthcare facilities, and waste management companies, supported both conditional exemptions as a way to eliminate the duplicative regulation by DEA and EPA and commenters thought that the DEA tracking, shipping and recordkeeping are sufficient to operate in lieu of RCRA. Several commenters suggested that we expand the types of treatment that are allowed to destroy the hazardous waste pharmaceuticals that are also controlled substances. In some cases, commenters suggested that we allow additional combustion units such as hospital, medical, infectious waste incinerators (HMIWIs); commercial, industrial solid waste incinerators (CISWIs); and other solid waste incinerators (OSWIs) to combust hazardous waste pharmaceuticals that are also controlled substances. Other commenters suggested that we allow forms of destruction beyond combustion, such as oxidation treatment[306] or chemical digestion,[307] or any technology that achieves DEA's standard of non-retrievable.[308]

C. Final Rule Provisions

We are finalizing both conditional exemptions for hazardous wastes that are also controlled substances, with some changes. First, we have amended the regulatory language in § 266.506(a)(2) to be more consistent with the preamble to the proposed rulemaking and to be more consistent with how the conditional exemption in § 266.506(a)(1) was crafted. In the preamble to the proposed rulemaking, we discussed the conditional exemption in terms of the waste pharmaceuticals from take-back events and programs, while in the proposed regulatory language, the conditional exemption was focused on the collector of the waste pharmaceuticals. We revised the regulatory language in § 266.506(a)(2) to conditionally exempt the collected household waste pharmaceuticals, as opposed to the collector of the household waste pharmaceuticals. Additionally, one commenter pointed out that the proposed regulatory language could be read to mean that if the household waste pharmaceuticals were not commingled with DEA controlled substances, then the requirement to combust them would not apply.[309] EPA did not intend to make this distinction. Although we understand that most, if not all, take-back events and programs do, in fact, commingle controlled substances with non-controlled substances, EPA proposed to place conditions on collectors of household waste pharmaceuticals with the understanding that this proposed regulatory language would capture all pharmaceuticals collected at take-back events and programs. The revised regulatory language in this final rule makes it clearer that the household waste pharmaceuticals collected during a take-back event or program must be destroyed by combustion or other DEA-approved method, whether or not the household waste pharmaceuticals are commingled with DEA controlled substances.

Also in response to comments, we are expanding the types of combustors that are allowed to destroy the conditionally exempt hazardous waste pharmaceuticals. Under the final rule, five types of combustors will be allowed to destroy hazardous waste pharmaceuticals that are also DEA controlled substances and the pharmaceuticals from take-back events and programs: (1) Permitted large municipal waste combustors (MWCs), (2) permitted small MWCs, (3) permitted HMIWIs, (4) permitted CISWIs and (5) permitted hazardous waste combustors (either an incinerator or other combustor, such as a cement kiln).

In addition to the five types of permitted combustors allowed to destroy the conditionally exempt

[301] See memo from J. Winston Porter to Regions, dated November 1, 1988; RCRA Online #11377.

[302] See memo September 26, 2012, Rudzinski to the Regional RCRA Division Directors (RCRA Online#14833) and memo October 2, 2015, Johnson to RCRA Division Directors (RCRA Online #14853).

[303] Since pharmaceutical collection programs typically commingle DEA controlled substances with non-controlled substances, this requirement is included in a section of the regulations that pertains to controlled substances.

[304] DEA does not prohibit co-mingling of controlled substances with non-controlled substances provided they are all then managed as controlled substances.

[305] See 40 CFR 26.506(a)(2).

[306] See Comment number EPA–HQ–RCRA–2007–0932–0287.

[307] See Comment number EPA–HQ–RCRA–2007–0932–0375.

[308] See Comment number EPA–HQ–RCRA–2007–0932–0333.

[309] See comment number EPA–HQ–RCRA–2007–0932–0261.

pharmaceuticals, EPA is building in flexibility to the final regulation to allow for the possibility that future technologies might be developed that meet the DEA non-retrievable standard. Specifically, we are allowing any method of destruction for the conditional exemption that DEA has publicly approved in writing as able to meet its non-retrievable standard. While it is reasonable to defer to the DEA's judgement in this matter to approve methods of destruction that are environmentally protective, we feel it is necessary to limit future allowable destruction technologies for the conditionally exempt pharmaceuticals to those that are publicly approved by the DEA as meeting the non-retrievable standard. This is intended to avoid a situation where parties might make unsubstantiated claims that their product is capable of meeting the DEA non-retrievable standard in order to qualify for the conditional exemption. Furthermore, any method that DEA might specify must not conflict with federal environmental laws or regulations. Also, because combustion is no longer specified as the only allowable method of destruction, we have concluded that an additional change to the regulations is needed to make it clear that the hazardous waste pharmaceuticals that are also DEA controlled substances are subject to § 266.505, and therefore, may not be sewered.

Both types of conditionally exempt hazardous waste pharmaceuticals (*i.e.,* those that are DEA controlled substances and those that are collected household waste pharmaceuticals) will be able to take advantage of the expanded list of allowable types of combustors. For healthcare facilities and reverse distributors that generate and manage the handful of hazardous waste pharmaceuticals that are also controlled substances, we think it will be helpful to have additional destruction methods for these previously dually regulated wastes. Also, the expanded list of allowable types of combustors will be helpful for those operating take-back programs and events. The Agency is a strong supporter of take-back programs and events for household pharmaceuticals as an alternative to disposing of leftover, unwanted medications in the trash or in the toilet or down the sink (except in cases where the FDA-approved labeling instructs patients to immediately flush the unneeded medication down the toilet if a take-back option is not readily available). In expanding the types of combustors that are allowed to burn the pharmaceuticals from take-back events, we strive to strike a balance between maximizing flexibility while still being protective of human health and the environment. Under the revised list in the final rule, the universe of allowable combustors will substantially increase in number. There are 77 municipal solid waste combustion facilities (also referred to as waste-to-energy facilities) in 22 states,[310] and 21 commercial hazardous waste combustion facilities (*i.e.,* those that accept waste from off-site) in 12 states.[311] There are currently 33 HMIWIs units in the U.S.: 11 of the 33 are commercial HMIWIs, while the other 22 HMIWI units only combust their own waste.[312] There are approximately 75 CISWIs facilities in the U.S.[313] We note that the types of combustors we are allowing to accept the conditionally exempt pharmaceuticals are not obligated to accept the conditionally exempt pharmaceuticals. Of course, we strongly encourage all the various types of allowable combustors to work with their communities and regulators in developing viable options for destroying the pharmaceuticals from take-back events. In particular, we encourage the "captive" combustors that currently only combust their own waste to consider amending their permits to allow them to accept pharmaceuticals from take-back events and programs.

We have concluded that it is reasonable to expand the list of allowable combustors able to accept the conditionally exempt pharmaceuticals because the combustion of pharmaceuticals that meet the definition of a RCRA solid waste but do not meet the definition of RCRA hazardous waste (*i.e.,* non-hazardous waste pharmaceuticals) is regulated by § 129 of the Clean Air Act. The statute requires EPA to establish emission limits for nine air pollutants (*i.e.,* particulate matter, carbon monoxide, dioxins/furans, sulfur dioxide, nitrogen oxides, hydrogen chloride, lead, mercury, and cadmium) from several categories of solid waste incineration units, including MWCs; HMIWIs; and CISWIs. EPA has established emission limits for each of the categories based on the application of maximum available control technology (MACT) which reflect the emission levels achieved by the best performers in each category.

In addition to complying with emission limitations, solid waste incineration units are also subject to comprehensive operating, monitoring and reporting requirements. In light of the common framework used to develop emission limits and requirements for MWC, CISWI, and HMIWI units, we believe that it is appropriate to include HMIWIs and CISWIs as types of combustors that are allowed to burn the pharmaceuticals from take-back events.

While the Agency has expanded the list of allowable combustors to include HMIWIs and CISWIs, we have not expanded the list to include other solid waste incinerators (OSWIs). OSWIs are small units that have fewer emission controls than other types of combustors. Further, there are only a handful of new OSWIs in operation and the legal status of existing OSWIs is uncertain due to litigation. EPA is also not expanding the list of allowable combustors to include human and pet crematoriums. Crematoriums are not regulated under the Clean Air Act and typically do not use air pollution control devices to limit toxic air pollutants such as mercury and dioxins and furans. We believe that crematoriums would not provide adequate public health and environmental protection when burning non-hazardous waste pharmaceuticals. If solid or hazardous wastes are burned in a crematorium, it would make the crematorium subject to the Clean Air Act.

D. Comments and Responses

In its comment, Cardinal Health included a list of pharmaceuticals that it manages as both RCRA hazardous waste and DEA controlled substances.[314] In most cases, their comments reinforced the list that we included in the proposed rulemaking. In two cases, Cardinal Health identified additional forms of drugs that were included in the table of DEA controlled substances and hazardous wastes in the preamble to the proposed rulemaking. First, Cardinal Health identified Axiron as the brand name of an additional form of testosterone that is a solution applied to the underarms that is also ignitable. Second, Cardinal Health identified Diastat as the brand name of an additional form of valium that is a gel intended for rectal administration that is also ignitable. We have amended our list of DEA controlled substances and RCRA hazardous wastes by including Axiron and Diastat in Table 6 below to be more

[310] Energy Recovery Council, 2016 Directory of Waste-to-Energy Facilities; *http://energyrecoverycouncil.org/wp-content/uploads/2016/06/ERC-2016-directory.pdf.*

[311] Memo from Rudzinski to Regions, dated September 26, 2012; RCRA Online #14833.

[312] See comment number EPA–HQ–RCRA–2007–0932–0280.

[313] See CISWI inventory EPA–HQ–OAR–2016–0664–0002.

[314] See comment number EPA–HQ–RCRA–2007–0932–0250.

complete and accurate. However, there is no corresponding regulatory change being made. The regulations conditionally exempt all RCRA hazardous wastes that are also DEA controlled substances; the table identifying which drugs are both is included in the preamble for informational purposes:

TABLE 6—PHARMACEUTICALS STILL USED IN HEALTHCARE THAT ARE DEA CONTROLLED SUBSTANCES & RCRA HAZARDOUS WASTES

[Amendments in bold based on comments]

Name of drug	Other name(s)	Medical uses	RCRA HW code	DEA CS schedule	Comment
Chloral; chloral hydrate.	Acetaldehyde, trichloro-; Aquachloral, Noctec, Somnote, Supprettes.	Sedative	U034 toxic	IV	Used in hospital pediatric units; common ingredient in vet anesthetics.
Fentanyl sublingual spray.	Subsys	Analgesic	D001 ignitable	II	Ignitable due to alcohol content.
Phenobarbital	Bellergal-S, Donnatal, Luminal,	Anticonvulsant	D001 ignitable	IV	Ignitable due to alcohol content.
Testosterone gels/solutions.	Androgel, Axiron, Fortesta, Testim	Hormone	D001 ignitable	III	Ignitable due to alcohol content.
Valium injectable/gel	Diazepam, Diastat	Anti-anxiety	D001 ignitable	IV	Ignitable due to alcohol content.

Cardinal Health's comment also indicated that the company manages Somatropin (brand names Humatrope and Genotropin) as a DEA controlled substance and a RCRA hazardous waste. M-cresol, which is a contaminant identified on the toxicity characteristic list in § 261.24 (D024), is used as a preservative in Somatropin. Per legislations, all anabolic steroids are considered controlled substances;[315] however, Somatropin is considered a human growth hormone, not an anabolic steroid.[316] Therefore, although Somatropin may be a RCRA hazardous waste for its m-Cresol content, it is not a DEA controlled substance.

The two conditional exemptions we are finalizing in this rule are intended to eliminate any duplicative regulations for pharmaceuticals that are RCRA hazardous wastes and DEA controlled substances. Nevertheless, there are several remaining areas where DEA and EPA regulations intersect, even if they are not duplicative. The Agency would like to address these intersecting areas in effort to reduce confusion and aid compliance.

1. Only Household (Ultimate User) Waste May Be Collected in DEA Authorized Collection Receptacles

It is important to note that in order to qualify for the conditional exemption, a retail pharmacy (or other DEA authorized collector pharmacy) can use the DEA authorized collection receptacle to collect waste generated only at households (DEA refers to this as waste from "ultimate users") and brought to the store for collection. The hazardous waste generated by the retail pharmacy and store, including hazardous waste pharmaceuticals, are not excluded household wastes under RCRA and may not be placed in the DEA authorized receptacle.[317] Depending on the amount generated, the hazardous waste pharmaceuticals generated by the retail pharmacy and store must be managed under either § 262.14 (as a VSQG) or under part 266 subpart P. Furthermore, states generally regulate non-hazardous waste and it is possible that they may have licensing or permitting requirements for the collection of solid waste. Because EPA would like to see the use of DEA authorized collection receptacles become widespread, we encourage states to streamline any requirements that may create a barrier to the use of the DEA authorized collection receptacles.

2. Sewer Prohibition, Conditional Exemption and Pharmaceutical Wastage

In response to comments, EPA has decided against making any exceptions to the sewer prohibition. Some commenters suggested that EPA should allow RCRA hazardous wastes that are also DEA controlled substances to be sewered. On the other hand, many commenters suggested, and EPA agrees, that it would be inappropriate to make exceptions to the sewer prohibition, even for the handful of hazardous wastes that are also controlled substances. In part, commenters thought it was bad environmental policy to allow sewering of any hazardous waste pharmaceuticals. Commenters were also concerned that it would send a mixed message to the regulated community about our goals and lead to confusion about which hazardous waste pharmaceuticals could and could not be sewered. As a result, all hazardous waste pharmaceuticals are prohibited from being sewered, including the handful that are also DEA controlled substances.

Under the DEA regulations, a registrant's inventory of controlled substances is already prohibited from being sewered as a means of meeting the non-retrievable standard.[318] Likewise, under the CWA regulations, RCRA ignitable hazardous wastes (D001) are prohibited from being discharged to the sewer.[319] As noted in Table 6, four out of the five RCRA hazardous wastes that are also DEA controlled substances are hazardous waste due to being ignitable and hence are already prohibited from being sewered by the CWA regulations. In effect, this new RCRA regulation only prohibits the sewering of one additional DEA controlled substance that is also a RCRA hazardous waste: Chloral hydrate, which is listed for toxicity. In summary, a RCRA hazardous waste that is also DEA controlled substance that is part of a DEA registrant's inventory may not be sewered.

[315] The Anabolic Steroids Control Act of 1990 placed anabolic steroids into Schedule III of the Controlled Substances Act (CSA) as of February 27, 1991.

[316] *https://www.fda.gov/Drugs/DrugSafety/ucm237839.htm;* accessed 8/24/2017.

[317] DEA also prohibits retail pharmacy stock/inventory from being placed in the collection receptacle or mail-back envelopes (see 21 CFR 1317.05(a)).

[318] See the preamble to DEA's final rule 79 FR 53548; September 9, 2014 and the preamble to DEA's proposed rule 77 FR 75803; December 21, 2012.

[319] See the Clean Water Act regulations at 40 CFR 403.5(b)(1).

DEA does allow controlled substance "pharmaceutical wastage" to be disposed of in accordance with applicable federal, state, and local laws, regulations, and healthcare facility policies, including sewering or putting down the drain.[320] DEA uses the term "pharmaceutical wastage" to refer to leftover, unadministered pharmaceuticals ("*e.g.*, some of the substance remains in a vial, tube, transdermal patch, or syringe after administration but cannot or may not be further utilized" [321]). While DEA allows pharmaceutical wastage of controlled substances to be sewered, the CWA regulations already prohibit the discharge of any RCRA ignitable hazardous waste and, under this RCRA rule, EPA is not creating any exceptions to the sewer prohibition. As a result, neither inventory nor pharmaceutical wastage of DEA controlled substances that are also RCRA hazardous wastes may be sewered.

Even though inventory and pharmaceutical wastage are prohibited from being sewered, both inventory and pharmaceutical wastage would be eligible for the conditional exemption being finalized in this rule in § 266.506 for RCRA hazardous wastes that are also DEA controlled substances. As discussed previously, EPA is finalizing the conditional exemption that the few RCRA hazardous waste pharmaceuticals that are also DEA controlled substances would be exempt from RCRA regulation, on the condition that they are (1) managed in accordance with DEA regulations and (2) incinerated by one of five types of permitted combustors or destroyed by another method that has been publicly approved by DEA, and (3) are not sewered.

Therefore, if inventory or pharmaceutical wastage is both a RCRA hazardous waste and a DEA controlled substance it would not be allowed to be sewered, it would have to be incinerated (or destroyed by another method publicly approved by DEA). Prior to incineration, however, the inventory and pharmaceutical wastage, both of which are conditionally exempt under RCRA, are regulated differently by DEA. The leftover inventory of DEA controlled substances remains fully subject to DEA regulations, which includes tracking and witnessed destruction. On the other hand, controlled substance pharmaceutical wastage is no longer regulated by DEA. Therefore, only pharmaceutical wastage could be collected in a container at the healthcare facility prior to incineration. If this container were used to collect only conditionally exempt pharmaceutical wastage prior to incineration, it would not be subject to the subpart P container standards. It is more likely, however, that a container used to collect the conditionally exempt pharmaceutical wastage would also be used to collect regulated hazardous waste, in which case the container would be subject to subpart P container standards. In either case, as DEA states in its guidance, "Although Part 1317 does not apply to pharmaceutical wastage, the DEA strongly encourages all practitioners to continue to adhere to security controls and procedures that ensure pharmaceutical wastage is not diverted. For example, most institutional practitioners have implemented policies that require two persons to witness and record destruction of pharmaceutical wastage." [322] In support of DEA's guidance, EPA strongly recommends that any container that is used to collect pharmaceutical wastage that will include DEA controlled substances contain some sort of absorbent or chemical reactant in order to bind or chemically alter the contents and thus deter the diversion of the collection container for controlled substance recovery.

3. Long-Term Care Facilities and the DEA Regulations

This section will discuss the intersection of the DEA regulations and the RCRA hazardous waste regulations that pertain to LTCFs.

Under the DEA regulations, most LTCFs are not registrants and until recently have had few options for properly and securely disposing of the controlled substances from its patients (ultimate users). DEA's 2014 final regulations to implement the Secure and Responsible Drug Disposal Act of 2010 are designed to help alleviate the problem that LTCFs face when discarding their patients' controlled substances. DEA's 2014 final rule allows, but does not require, retail pharmacies and hospital/clinics with an on-site pharmacy that are DEA registrants to modify their registrations to become "collectors" and to place collection receptacles at LTCFs (or at the retail pharmacy or hospital/clinic with an on-site pharmacy) for the collection of controlled substances from ultimate users. Per the DEA regulations, if a DEA authorized collection receptacle is placed in a LTCF, only the ultimate users' controlled substances may be placed in the DEA collection receptacle. If an LTCF is a DEA registrant and discards DEA controlled substances from its inventory, they may not be placed in the DEA authorized collection receptacle and must be otherwise destroyed to meet the non-retrievable standard.

Under the 2014 DEA final rule, LTCFs now have three options for managing their patients' controlled substances. First, if a DEA registered retail pharmacy or hospital/clinic with an on-site pharmacy places a collection container at an LTCF, the staff from the LTCF may place the patients' controlled substances in the collection receptacles. Second, although LTCFs are not allowed to conduct a facility-wide collection event for their patients' controlled substances for mail-back programs, they are allowed to assist patients who choose to use a mail-back program for their own controlled substances, on an individual-by-individual basis. And third, law enforcement can pick up patients' controlled substances for disposal. With these changes to DEA's regulation, LTCFs can now dispose of patients' controlled substances in a more environmentally protective way and EPA strongly encourages the use of any of these three collection methods. It should be noted that the 2014 DEA regulations do not mandate the placement of collection receptacles at long-term care facilities or patient participation in mail-back programs or take-back events.

As for the RCRA regulations, this rule finalizes the provision that hazardous waste from LTCFs will no longer be considered exempt as household hazardous waste. Instead, it will need to be managed as regulated hazardous waste. This interpretation will apply to all the hazardous waste generated by a LTCF, not just its hazardous waste pharmaceuticals (although the Agency expects that much of the hazardous waste generated by LTCFs consists of hazardous waste pharmaceuticals). Notwithstanding this revised interpretation, there are four other regulatory provisions that might affect how a LTCF will actually have to manage its hazardous waste pharmaceuticals under this final rule

First, we have added to the final rule a presumption that LTCFs with 20 beds or fewer will be VSQGs.[323] And those LTCFs that have more than 20 beds may still qualify as VSQGs (for all of their hazardous waste) if they generate less than 100 kg of hazardous waste and less

[320] See DEA letter to registrants re: Clarifying disposal of pharmaceutical wastage dated Oct 17, 2014; *http://www.deadiversion.usdoj.gov/drug_disposal/dear_practitioner_pharm_waste_101714.pdf.*

[321] Ibid.

[322] Ibid.

[323] See 40 CFR 266.504(d).

than 1 kg of acute hazardous waste per calendar month. In fact, based on the RIA for the final rule, EPA estimates that 98–99 percent of LTCFs that generate hazardous waste are VSQGs.[324] As VSQGs, the long-term care facilities will be subject to the reduced regulatory provisions of 40 CFR 262.14 for all of their hazardous waste (including those that are controlled substances), and only the sewer prohibition provision of this new subpart for their hazardous waste pharmaceuticals. Only the other 1–2 percent of LTCFs that generate hazardous waste will be subject to part 266 subpart P.

Second, this final rule allows an LTCF that is a VSQG (for all of its hazardous waste) to send its hazardous waste pharmaceuticals to an off-site healthcare facility that either supplies the LTCF with its pharmaceuticals (*e.g.*, a long-term care pharmacy) or is under the control of the same person and that is operating under subpart P.[325] Note that this provision is limited to hazardous waste pharmaceuticals and not to those that are also controlled substances because the DEA allows controlled substances to be returned to a long-term care pharmacy only when they are subject to a recall.

Third, this final rule also allows a healthcare facility, including a LTCF that is a VSQG, to use an on-site DEA authorized collection receptacle to dispose of its hazardous waste pharmaceuticals (see § 266.504(c)). It could be argued that VSQGs would already be allowed to use DEA authorized collection receptacles for their hazardous waste pharmaceuticals even without this new provision, provided the waste from the DEA authorized collection receptacles is treated or disposed at one of the types of facilities identified in § 262.14(a)(5) (*e.g.*, facilities that are permitted or have interim status to manage hazardous waste and facilities that are permitted, licensed or registered by a state to manage hazardous waste, municipal waste or non-municipal waste). Nevertheless, we did propose, and are finalizing the provision in § 266.504(c) making it clear that healthcare facilities that are VSQGs can place their hazardous waste pharmaceuticals in an on-site DEA collection receptacle. DEA already allows controlled substances to be commingled with non-controlled substances. Therefore, EPA believes it is consistent to allow VSQG hazardous waste pharmaceuticals that are not controlled substances to be placed in DEA collection receptacles with controlled substances. EPA believes that management of VSQGs' hazardous waste pharmaceuticals as DEA controlled substances is preferable because it provides greater protection to patients, visitors, and workers at healthcare facilities to have the hazardous waste pharmaceuticals accumulating in DEA-authorized collection receptacles rather than in the regular trash. However, it is important to note that the DEA regulations for controlled substances are much narrower in what may be placed in a collection receptacle; DEA only allows controlled substances from patients to be placed in collection receptacles that are at LTCFs. To reiterate, under the DEA regulations, if a LTCF, or any other healthcare facility, is a DEA registrant it may not place its own inventory of controlled substances in a collection receptacle, even if it is a VSQG under RCRA.

Fourth, for the LTCFs that are not VSQGs, the handful of RCRA hazardous waste pharmaceuticals that are also DEA controlled substances will not be subject to RCRA, provided they meet three conditions: (1) They are combusted at a small or large MWC, a HMIWI, a CISWI or a hazardous waste combustor (or destroyed by another method publicly approved by DEA), (2) they are managed and disposed of in compliance with all applicable DEA regulations for controlled substances, and (3) they are not sewered. DEA allows LTCFs to put their patients' controlled substances into an on-site collection receptacle; therefore, an LTCF could also place its patients' controlled substances that are also RCRA hazardous waste into a DEA authorized collection receptacle (alternatively, patients could use another allowable take-back method, such as mail-back envelopes) in order to meet the conditional exemption. However, we must stress that only LTCFs would be able to use collection receptacles (or another allowable take-back method) to meet the conditional exemption for RCRA hazardous wastes that are also DEA controlled substances, because they are the only type of facility that DEA allows to place their patients' wastes into an on-site collection container. Other healthcare facilities, such as hospitals, could not meet the conditional exemption by placing their DEA controlled substances that are also RCRA hazardous wastes in a collection receptacle because DEA does not allow patients at hospitals to use on-site collection receptacles. No registrant healthcare facility, including an LTCF, would be able to use the collection receptacle to meet the terms of the conditional exemption for any of its own inventory of DEA controlled substances that are also RCRA hazardous wastes because DEA does not allow registrants to use collection receptacles for their own inventory.

For those LTCFs that are not VSQGs, the hazardous waste pharmaceuticals that are not controlled substances (and therefore not conditionally exempt) will be subject to part 266 subpart P, while the other hazardous wastes will be subject to the SQG or LQG regulations, as applicable, in part 262.

See Table 7 for a summary of the intersection of RCRA and DEA regulations for the disposal of hazardous waste pharmaceuticals at LTCFs:

TABLE 7—INTERSECTION OF RCRA & DEA REGULATIONS AT LONG-TERM CARE FACILITIES

Types of pharmaceutical waste at long-term care facilities	RCRA regulatory requirements		
	How RCRA applies	DEA authorized collection methods allowed for HW pharmaceuticals?	Can be returned to an off-site HCF owned by the same person or LTC pharmacy?
Hazardous Waste Pharmaceuticals that are NOT Controlled Substances:			
if LTCF is a VSQG	§ 262.14 and sewer prohibition.	Yes. § 266.504(c)	Yes.
if LTCF is *not* a VSQG	part 266 subpart P	No	No.
Hazardous Waste Pharmaceuticals that are also Controlled Substances:			

[324] See the Regulatory Impact Analysis for this final rule in the docket EPA–HQ–RCRA–2007–0932.

[325] See 40 CFR 266.502(l) and 266.503(b) for non-creditable and creditable hazardous waste pharmaceuticals, respectively.

TABLE 7—INTERSECTION OF RCRA & DEA REGULATIONS AT LONG-TERM CARE FACILITIES—Continued

Types of pharmaceutical waste at long-term care facilities	RCRA regulatory requirements		
	How RCRA applies	DEA authorized collection methods allowed for HW pharmaceuticals?	Can be returned to an off-site HCF owned by the same person or LTC pharmacy?
if LTCF is a VSQG	§ 262.14 and sewer prohibition.	Yes. Only from patients	Only if subject to a recall.
if LTCF is *not* a VSQG	Conditionally exempt from RCRA (§ 266.506) if: • Combusted (or other DEA approved destruction method). • Comply with DEA regulations.	Yes. Only from patients (DEA collection methods meet the terms of the RCRA conditional exemption).	Only if subject to a recall.

XV. Management of Residues in Pharmaceutical Containers (§ 266.507)

A. Regulatory Background

Over the years, EPA has received numerous inquiries regarding the regulatory status of residues in various types of containers that once held pharmaceuticals that are considered hazardous waste when discarded. Stakeholders have been particularly concerned about residues in containers that once held pharmaceuticals that are on the "P-list" of acutely hazardous commercial chemical products in § 261.33(e) because a generator becomes an LQG if it generates more than 1 kg of acute hazardous waste per calendar month.[326] The regulatory status of acute and non-acute commercial chemical product residues remaining in a container are specifically addressed in § 261.33:

"The following materials or items are hazardous wastes if and when they are discarded or intended to be discarded . . . (c) Any *residue* remaining in a container or in an inner liner removed from a container that has held any commercial chemical product or manufacturing chemical intermediate having the generic name listed in paragraphs (e) or (f) of this section, unless the container is *empty* as defined in § 261.7(b)."

In § 261.7(b)(1), there are two ways a container that held a non-acute hazardous waste can be considered "empty." The container is considered empty if all wastes have been removed that can be removed using the practices commonly employed to remove materials from that type of container, *e.g.,* pouring, pumping, aspirating, *and* (1) no more than 2.5 centimeters (one inch) of residue remain on the bottom of the container or inner liner, *or* (2) No more than 3 percent by weight of the total capacity of the container remains in the container or inner liner if the container is less than or equal to 119 gallons in size; or no more than 0.3 percent by weight of the total capacity of the container remains in the container or inner liner if the container is greater than 119 gallons in size.

Therefore, it is important to note that if the container that held the non-acute hazardous waste pharmaceutical does not have its contents removed by a commonly employed practice even though it has one inch or less of residue remaining or has 3 percent or less by weight of the total capacity of the container remaining,[327] the container is still *not* considered "RCRA empty." If the container is not "RCRA empty," then the residues are regulated as hazardous waste (since the residues are within the container, the container must be managed as hazardous waste, as well, even if it is not itself hazardous waste).

According to § 261.7(b)(3), there are three ways that a container that held an acute hazardous waste can be considered empty:

(1) The container or inner liner has been triple rinsed using a solvent capable of removing the commercial chemical product or manufacturing chemical intermediate;

(2) The container or inner liner has been cleaned by another method that has been shown in the scientific literature, or by tests conducted by the generator, to achieve equivalent removal; or

(3) In the case of a container, the inner liner that prevented contact of the commercial chemical product or manufacturing chemical intermediate with the container, has been removed.

According to these requirements, if the container that held the P-listed pharmaceutical is not triple rinsed, or cleaned by another method that has been demonstrated to achieve equivalent removal, or had the inner liner removed, the container is not considered "RCRA empty," even though the pharmaceutical may have been fully removed. If the container is not "RCRA empty," then the residues are regulated as acute hazardous waste.

In November 2011, EPA issued guidance about containers that once held P-listed pharmaceuticals[328] that provides three possible regulatory approaches for generators:

(1) Count only the weight of the hazardous waste residues toward generator category

(2) Demonstrate an equivalent removal method to render containers RCRA empty

(3) In the case of warfarin, show that the concentration in the residue is below the P-listed concentration

This guidance was intended as a short-term solution that worked within the confines of the existing RCRA hazardous waste regulations. In 2015, we proposed to amend the regulations that pertain to residues in containers that once held pharmaceuticals that are RCRA hazardous wastes. EPA proposed different regulatory solutions for different types of containers found in healthcare settings. Specifically, the proposal addressed the following three categories of containers: (1) Unit-dose containers (*e.g.,* packets, cups, wrappers, blister packs, and delivery devices) and dispensing bottles and vials; (2) dispensed syringes; and (3) other containers, including delivery devices. Generally, commenters were supportive of the need for these new empty container standards specifically developed for the types of small containers used in the healthcare setting, although they did have suggestions for changes. Each category

[326] Additionally, acute hazardous wastes are included on the F-list of § 261.31; however, none of those acute hazardous wastes are pharmaceuticals.

[327] We are assuming that containers that hold pharmaceuticals are in containers less than 119 gallons in size.

[328] Rudzinski to RCRA Division Directors, November 11, 2011, RCRA Online #14827.

of container is discussed separately below. Today's new "empty container" regulations in § 266.507 will replace the November 2011 guidance as it pertained to residues of hazardous waste pharmaceuticals in containers, although the memo will remain in effect for non-pharmaceutical hazardous wastes.

B. Stock, Dispensing and Unit-Dose Containers (§ 266.507(a))

1. Summary of Proposal

We proposed that a dispensing bottle, vial, or ampule (not to exceed 1 liter or 1,000 pills) or a unit-dose container (*e.g.,* a unit-dose packet, cup, wrapper, blister pack or delivery device) would be considered empty and the residues would not be regulated as hazardous waste if the hazardous waste pharmaceuticals have been removed from the dispensing or unit-dose container by commonly employed methods.

This proposal applied to containers that once held acute or non-acute hazardous waste pharmaceuticals. Under the proposal, for containers that once held non-acute hazardous waste pharmaceuticals, it would not be necessary to measure the remaining contents. Likewise, under the proposal, for containers that once held acute hazardous waste pharmaceuticals, it would not be necessary to triple rinse the containers or demonstrate an equivalent removal method. Rather, we proposed that a dispensing or unit-dose container would be considered empty if all pharmaceuticals have been removed using the practices commonly employed to remove materials from that type of container—thus, the residues (and therefore the container as well) may be disposed of as non-hazardous waste.

We proposed this new "RCRA empty" standard for containers used within a healthcare setting for two reasons. First, this approach will help eliminate the sewering of pharmaceuticals. In a healthcare setting, if containers are triple rinsed, the rinsate will likely be poured down the drain, which is not a good environmental practice. We think it is important that the residues be managed in a more controlled manner—such as in municipal solid waste landfills— rather than poured down the drain. Second, although the "empty container" regulations of § 261.7 apply to all sizes of containers, they were developed with larger, industrial-sized containers in mind. For the most part, the containers that hold pharmaceuticals are smaller in size than a 55-gallon drum; therefore, the amount of residue will likely be much less in these containers. In the preamble to the proposed rulemaking, we explained that we selected the 1,000-pill/1-liter limit because, in our observation, EPA had rarely seen dispensing bottles larger than that. We specifically sought comment on whether larger containers are used for dispensing pharmaceuticals and, if so, which pharmaceuticals they are used for and what RCRA hazardous waste codes would apply.

In the proposal, EPA presented data from three stakeholders helping to confirm the assumption that very little residue remains in containers after the pharmaceuticals (*e.g.,* pills) have been removed. In addition, EPA's Office of Research and Development conducted similar research.[329] A summary of the results is in the preamble to the proposed rulemaking, while the full results from each of the four sources are included in the docket for the proposed rulemaking.[330] [331]

EPA is aware that there are certain limitations with the data from the four sources. For instance, in one of the studies, no replicate samples were tested. In another study, only warfarin residues were tested. However, given the size of the containers involved and the nominal quantities of residues involved, the Agency proposed to allow the residues in dispensing bottles, vials and ampules, and single-unit dose containers that once held hazardous waste pharmaceuticals to be managed as non-hazardous waste provided the pharmaceutical product has been removed (*e.g.,* all pills have been removed).

As part of the proposal, EPA raised the concern of potential diversion of the pharmaceutical containers that may occur when the pharmaceutical residues and containers are discarded in the municipal waste stream. The Agency proposed that RCRA-empty pharmaceutical containers that are original pharmaceutical packages (and therefore susceptible to diversion) should be destroyed prior to placing them in the trash. These types of containers would include dispensing bottles, vials, or ampules typically used in pharmacies, but would not include paper or plastic cups, or blister packs used for dispensing singles doses to patients. In the preamble to the proposal, we explained that the means of destruction could include crushing or shredding the container.

2. Summary of Comments

The comments for this section can be broken into two major groups. One group of comments expressed concern with the 1,000-pill/1-liter size limit to pharmaceutical dispensing containers and commenters asked EPA to consider allowing the new RCRA-empty standard for pharmaceutical dispensing containers to apply to larger pharmaceutical containers or even to all dispensing containers, regardless of size.

As part of its comments, CVS Health included results from an analysis conducted on containers that held warfarin.[332] Their tests included brand name and generic warfarin stock bottles, testing the largest stock bottles with the highest prescription strength warfarin typically found in a CVS Health Pharmacy, although their comments do not specify the size of the largest stock bottle, nor do they specify the highest prescription strength of warfarin. That said, their results do offer similar results as the studies used in support of the proposal, indicating the range of total residues detected was 0.0–19.8 mg (excluding outliers).

Another group of comments objected to the proposed requirement to destroy the containers before disposing of them in municipal solid waste landfills. Commenters objected to this proposed provision for several reasons. First, the most common reason given by commenters that objected to this provision was they disagreed with EPA that diversion of these containers is occurring. Many states commented that this has never been a problem in their state and that the issues with these types of containers arise from purchase of empty vials on the internet and counterfeit labels made on home computers, not from dumpster diving. Second, there was concern that this would be a costly option since many healthcare facilities would now need to hire someone or buy equipment to destroy the containers. Many commenters thought the same goals could be reached through more cost-effective means such as defacing the label to render the containers unusable for illicit purposes. Third, a few commenters were also concerned with the release of the residues in these containers upon destruction and the effect that could have on the workers. This set of commenters included the one state that favored destruction of the containers. Finally, some commenters noted that these empty containers are already being disposed of in locked

[329] Tolaymat, T. and A. El Badawy. Evaluation of P-Listed Pharmaceutical Residues in Empty Pharmaceutical Containers. U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-14/167, 2015.

[330] September 25, 2018; 80 FR 58052.

[331] EPA–HQ–RCRA–2007–0932–0153 through 0156.

[332] See comment number EPA–HQ–RCRA–2007–0932–0312.

dumpsters and there are adequate institutional controls to address any public health risk from use of discarded containers in counterfeit drug sales.

3. Final Rule Provisions

In response to comments, we have made three substantive changes to the regulations proposed in § 266.507(a) that define when a dispensing or unit-dose container is empty. First, based on comments, we now recognize that we used the term "dispensing" bottle, vial, or ampule incorrectly. Dispensing bottles are those that are provided to patients when they get a prescription filled. Although a healthcare facility such as a pharmacy may dispose of some dispensing bottles, they are more likely to dispose of the stock bottles that they use to fill the dispensing bottles provided to the patients. As a result, we have modified the regulatory language to include stock bottles in addition to dispensing bottles, vials or ampules, and unit-dose containers.

Second, after reviewing comments and asking for additional support and clarification from commenters, including the Army Public Health Center, CVS Health and the Department of Veterans Affairs, the Agency has increased the size of the dispensing containers from 1,000 pills to 10,000 pills.[333] The Army Public Health Center states that they "routinely procure containers containing 1K, 2K, and even 5K or 10K pill counts" for refilling the automated dispensing machines at their facilities.[334] This exceeds the size of dispensing containers that we and others tested, but given that the contents are solid pills, capsules and tablets, and that the residues we and others detected are very small, we determined that it is appropriate to increase the size of the stock or dispensing container to 10,000 pills.

However, we have kept the maximum volume for stock and dispensing containers at a maximum of 1 liter since this volume limit would apply to liquids (and other non-pill formulations), which are harder to fully remove, and commenters did not provide sufficient information to support increasing the volume limit. Further, it is not clear from comments or subsequent correspondence whether any containers larger than 1 liter are in use for pharmaceuticals that would be hazardous waste when discarded. Stock or dispensing containers that exceed 1 liter would be considered "other containers" under § 266.507(d). As such, under the final rule, if they held pharmaceuticals that are non-acute hazardous waste, then they would be able to use § 261.7(b)(1) to show that they are empty.

The third substantive change is that we have removed the proposed requirement to destroy the empty pharmaceutical containers prior to disposal. We share commenters' concerns about possible worker exposure during the process of crushing or shredding the containers. However, EPA remains concerned about the diversion of the empty containers for illicit purposes. Therefore, we strongly encourage healthcare facilities to use best management practices, such as locked dumpsters and defacing labels, to prevent the diversion of these containers, but the extra step of destroying these containers will not be required.

Thus, under the final rule, a stock bottle, dispensing bottle, vial, or ampule (not to exceed 1 liter or 10,000 pills); or a unit-dose container (*e.g.*, a unit-dose packet, cup, wrapper, blister pack, or delivery device) is considered empty and the residues are not regulated as hazardous waste provided the pharmaceuticals have been removed from the stock bottle, dispensing bottle, vial, ampule, or the unit-dose container using the practices commonly employed to remove materials from that type of container.

In § 261.33(c), we have also added a reference to the new empty container provisions for hazardous waste pharmaceuticals in § 266.507 as a conforming change. Previously, § 261.33(c) referenced only the empty container provisions of § 261.7(b).

4. Comments and Responses

One commenter asked us to add an explicit reference to acute/P-listed hazardous waste in this section of the regulations. We believe this is unnecessary since § 261.7(c) indicates that containers of hazardous waste pharmaceuticals (which includes acute and non-acute hazardous waste pharmaceuticals) are subject to § 266.507 in lieu of § 261.7 for determining when they are empty. Nevertheless, we agree with the commenter that all of the new empty container provisions in § 266.507 apply to containers that held either non-acute or acute hazardous waste pharmaceuticals. Under the new subpart P provisions, for containers that once held non-acute waste pharmaceuticals to be considered empty, it will not be necessary to measure the remaining contents, and for containers that once held acute hazardous waste pharmaceuticals, it will not be necessary to triple-rinse the containers or demonstrate an equivalent removal method.

C. Syringes (§ 266.507(b))

1. Summary of Proposal

EPA proposed that the residues remaining in a syringe would not be regulated as hazardous waste provided the syringe had been used to administer a pharmaceutical to a patient, the syringe is placed in a sharps container (if appropriate), and is managed in accordance with all applicable federal, state, and local medical waste or regulated waste regulations. As with all of the new empty container standards proposed in § 266.507, this proposed provision applied to syringes used to administer pharmaceuticals that are acute or non-acute hazardous waste when discarded.

Prior to the proposal, EPA issued guidance regarding the regulatory status of residues in syringes in December 1994 and April 2008.[335] [336] In the December 1994 RCRA/Superfund Hotline Q&A about whether epinephrine residues in a discarded syringe would be P042, EPA stated, "Drug residues often remain in a dispensing instrument after the instrument is used to administer medication. EPA considers such residues remaining in a dispensing instrument to have been used for their intended purpose. The epinephrine remaining in the syringe, therefore, is not a commercial chemical product and not a P042 hazardous waste. The epinephrine could be a RCRA hazardous waste, however, if it exhibits a characteristic of hazardous waste." [337] In the April 2008 memo, EPA clarified that the 1994 interpretation extends to other P- and U-listed pharmaceuticals that have been used to administer the pharmaceutical by syringe.

EPA thinks that it is important to clarify in regulation when syringes are considered RCRA empty as this has been a source of many questions over the years. As part of the decision making, EPA is aware of the need to

[333] See the email correspondence from Lisa Strutz (APHC); Donald Dempsey (CVS Health); and Peter Carbrey (VA) in the supporting materials of the docket for this final rulemaking (EPA–HQ–RCRA–2007–0932).

[334] See the email correspondence from Lisa Strutz (APHC) to Kristin Fitzgerald (EPA), dated February 9, 2017, in the supporting materials of the docket for this final rulemaking (EPA–HQ–RCRA–2007–0932).

[335] December 1994, RCRA Online #13718.

[336] Memo from Dellinger to Chilcott, April 14, 2008, RCRA Online #14788.

[337] Note that since this Q&A was issued, EPA issued guidance indicating that epinephrine salts are not included in the scope of the P042 listing and therefore, most, if not all, medical applications of epinephrine are not P042 (October 15, 2007; RCRA Online #14778).

minimize the potential for exposures of healthcare workers to the sharps, which may be contaminated with bloodborne pathogens, as well as to the contents of the syringes.

The preamble to the proposed rulemaking also noted that sharps containers containing syringes are typically autoclaved prior to disposal. EPA expressed concern that the residues remaining in the syringes could be aerosolized during autoclaving and inadvertently expose workers to the aerosolized hazardous waste residues, posing risks via pulmonary exposure to those present during venting of the autoclave. Research suggests that autoclaving may even increase the toxicity of certain drugs.[338] As a result, EPA requested comment on whether it is necessary to place a limit on the volume of residue or the volume of the syringe to which this new provision would apply or whether any other conditions would be appropriate.

2. Summary of Comments

As noted above, commenters generally supported EPA's goal of codifying new standards for defining when containers are considered empty, including syringes. EPA received many comments requesting that the Agency clarify what it means when it uses the term "dispensed." Further, they noted that although the proposed regulations used the term "dispensed," in several cases in the preamble, we used the term "fully dispensed" and they requested clarification about which was correct. Commenters also noted that EPA used the term "dispensed" inappropriately and stated that the term "administered" was more appropriate. The Agency received mixed comments on whether any residues or contents should be left in the syringes when disposing of the syringe. In the case of autoclaving residues in syringes, almost all commenters agreed that the hazardous waste pharmaceutical residues should not be autoclaved. Some commenters believed that the contents should be disposed of in a gauze pad or equivalent while others argued that this was in contradiction to NIOSH recommendations for minimizing exposure to hazardous drugs. Some commenters were comfortable with leaving contents in the syringes, suggesting that would be in compliance with OSHA [339] and DOT.[340]

3. Final Rule Provisions

We have made two substantive changes to this section of the regulations that define when syringes are considered empty for the sake of RCRA regulation. First, EPA agrees with commenters that we used the term "dispensed" inappropriately in the proposed rulemaking. FDA defines "dispense to patients to mean the act of delivering a prescription drug product to a patient or an agent of the patient." [341] Dispensed pharmaceuticals are then administered directly to the patient. EPA has revised the regulations to address commenters' concerns. In the final rule, to avoid confusion, when discussing syringes we do not use the term dispensed, fully dispensed, or administered. Instead, under the final rule, a syringe is considered empty and the residues are not regulated as hazardous waste provided the contents have been removed by fully depressing the plunger of the syringe. Thus, the final regulations convey an intent that is more similar to the proposed preamble use of the term "fully dispensed." This reflects commenters' and EPA's desire to avoid the possibility of autoclaving syringes that may have a large portion of their hazardous waste pharmaceutical contents remaining.

Commenters affirmed EPA's concerns about aerosolizing the autoclaved hazardous waste in sharps containers and we have concluded that hazardous waste incineration of hazardous waste pharmaceuticals remaining in non-empty syringes is more appropriate. A recent literature search also supports this position. The NIOSH and the American Society of Hospital Pharmacists (ASHP) have both published articles regarding autoclaving of sharps. The 2004 NIOSH alert states, "Do not place hazardous drug-contaminated sharps in red sharps containers that are used for infectious wastes, since these are often autoclaved or microwaved." [342] The ASHP article states, "Sharps used in the preparation of hazardous drugs should not be placed in red sharps containers or needle boxes, since these are most frequently disinfected by autoclaving or microwaving, not by incineration, and pose a risk of aerosolization to waste-handling employees." [343]

A syringe with a fully depressed plunger will have a minute amount of residue and the syringe can be considered empty under the final rule. Thus the residue in the empty syringe (as well as the syringe) will not be regulated as hazardous waste. A syringe that does not have a fully depressed plunger could have anything from a small amount to 99% of hazardous waste pharmaceutical contents still left in it. Therefore, we have concluded that it is impracticable to impose an alternate bright line for determining whether a partially administered syringe is empty. Further, we concur with ASHP and NIOSH regarding concerns about the safety of autoclave operators and believe the standard in this final rule will help prevent exposing workers to volatilized hazardous waste pharmaceutical residues during the autoclaving process.

The second substantive change we made in the final rule is to clarify that if a syringe contains a pharmaceutical that is a hazardous waste and it is not empty because the plunger is not fully depressed, the syringe must be placed with its remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non-creditable hazardous waste pharmaceutical under this subpart as well as any applicable federal, state, and local requirements for sharps containers and medical or regulated waste. We note that the new empty syringe provisions being finalized today supersedes the previous EPA interpretations expressed in guidance memos in December 1994 and April 2008.[344] [345]

We note that a syringe can become empty in three ways: (1) Fully depressing the plunger of the syringe by administering the contents of the syringes to a patient, or (2) fully depressing the plunger by injecting the contents of the syringe into another delivery device such as an IV bag, or (3) fully depressing the plunger of the syringe by emptying the remaining contents into a hazardous waste collection container.

[338] Daughton CG, Drugs and the Environment: Stewardship & Sustainability, National Exposure Research Laboratory, Environmental Sciences Division, US EPA, Las Vegas, NV; NERL–LV–ES 10/081, EPA/600/R–10/106; September 2010 (*https://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryID=228503*).

[339] OSHA Title 29 CFR 1910.1030 Bloodborne Pathogens.

[340] DOT Title 49 CFR 172.343 subpart D—Marking; 172 subpart E—Labeling Standards; 172.432 Subpart E.

[341] See 21 CFR 208.3.

[342] NIOSH. "Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings." Publication Number 2004–165, Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH), Cincinnati, OH, 2004. 58 pp; *http://www.cdc.gov/niosh/docs/2004-165/pdfs/2004-165.pdf.*

[343] ASHP. "ASHP guidelines on handling hazardous drugs." American Journal of Health-System Pharmacy 2006, 63:1172–1193; *http://dx.doi.org/10.2146/ajhp050529.*

[344] December 1994, RCRA Online #13718.

[345] Memo from Dellinger to Chilcott, April 14, 2008, RCRA Online #14788.

4. Consultation With OSHA

As part of the final rule process, EPA consulted with OSHA to gain a better understanding of its Bloodborne Pathogens standard and how it interacts with other regulations for the disposal of sharps and the contents within the syringes. The Bloodborne Pathogens standard states that "[u]niversal precautions shall be observed to prevent contact with blood or other potentially infectious materials. Under circumstances in which differentiation between body fluid types is difficult or impossible, all body fluids shall be considered potentially infectious materials." [346] It also states that disposal of a sharp shall be done "immediately or as soon as feasible." [347] Further, OSHA requires that containers for contaminated sharps shall be "easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can reasonably anticipated to be found." [348] When workers travel to a remote location to discard a sharp, it increases the possibility of an accidental needlestick, increases the chances that needles and other sharps will be improperly discarded, and creates potential hazards for other staff members. The determination of whether or not a sharps disposal container is as close as feasible should be made on a case-by-case basis by OSHA.[349]

Therefore, the practice of emptying the contents of the syringe would not violate the OSHA standard if the containers are as close as feasible. Any related work practices must also be such that they do not create additional hazards to workers (*e.g.,* containers are located in close proximity to the work area to avoid employees travelling with used sharps to disposal receptacles located outside the point of use). Furthermore, nothing in this new subpart requires workers to recap needles or other sharps, or otherwise manually manipulate the sharp or needle during emptying, such as unscrewing the needle from the syringe.

As part of this consultation, OSHA addressed the issue of waste disposal. OSHA's Bloodborne Pathogens compliance directive states: "[W]hile OSHA specifies certain features of the regulated waste containers, including appropriate tagging, the ultimate disposal method (landfilling, incinerating, and so forth) for medical waste falls under the purview of the EPA and possibly State and local regulations" ("Disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories" (1910.1030(d)(4)(iii)(C))).[350]

The Agency also received comment that we should recommend the extra protective step that all syringes/sharps be incinerated. Any sharps container that contains hazardous waste must be treated to meet the LDR requirements in part 268. In most cases, the LDR treatment standard for hazardous waste pharmaceuticals is incineration. On the other hand, if a sharps container does not contain hazardous waste pharmaceuticals because all the syringes have been emptied by fully depressing the plunger, then the RCRA hazardous waste regulations would not apply to these sharps containers (although these sharps containers are still solid wastes).

Regardless of whether sharps containers have regulated hazardous waste pharmaceutical residues, they could contain bloodborne pathogens or other infectious materials. Thus, OSHA's Bloodborne Pathogens standard requires that "disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories." [351] Many states have medical waste regulations that require the treatment of regulated medical waste, including sharps containers, to render it non-infectious, which is often achieved by autoclaving, prior to disposal as solid waste.

D. Other Containers, Including Delivery Devices (§ 266.507(c) & (d))

1. Summary of Proposal

EPA proposed that the residues remaining in other types of unused or used containers, including delivery devices, such as IV bags and tubing, inhalers, aerosols, nebulizers, tubes of ointments, gels, or creams, would be regulated as hazardous waste if the residues are acute or non-acute hazardous waste. In some cases, such as with IV bags, the volume of hazardous waste being disposed is much larger than with residues contained in syringes or unit-dose containers. It is extremely difficult to determine how much residue remains in tubes of ointments, gel, or cream. In the case of aerosols, it would be inadvisable to remove the contents of the container. Since EPA proposed that hazardous waste pharmaceuticals managed under subpart P would not be counted towards a facility's generator category, we argued that managing these residues and containers as hazardous waste under the proposed provisions should not pose the same burden that generators had been facing in with keeping track of the monthly amount of residues in containers that are not "RCRA empty."

2. Summary of Comments

Comments were mixed in this section. Some commenters agreed with EPA that it is difficult to determine if containers such as inhalers, aerosol cans, tubes of ointments, gels, or creams meet the RCRA empty standards within § 261.7 and, therefore, managing them under the streamlined requirements of subpart P would be protective. Other commenters wanted EPA to allow these other containers to continue to meet the definition of empty within § 261.7 or develop specific empty container standards for them within subpart P. One commenter recommended that EPA revise the regulations to state that IV bags and their tubing, inhalers, aerosols, nebulizers, tubes of ointments, and gels or creams are RCRA empty and not subject to hazardous waste regulations if they contain non-acute hazardous waste and their contents are fully administered.

3. Final Rule Provision

In response to comments, the final rule contains an empty container standard for IV bags separate from other containers, including delivery devices. The Agency stated in the proposal that it is very hard to determine if aerosols, tubes of ointments, gels and creams, inhalers, and nebulizers are empty due to their containers and contents. As commenters pointed out, this is not the case for IV bags and tubing since they are transparent and the liquids inside can be easily observed.

Taking approaches suggested from commenters, EPA is finalizing in § 266.507(c) that an IV bag is considered empty and the residues are not regulated as hazardous waste provided the pharmaceuticals in the IV bag have been fully administered to a patient. In cases where the IV bag has not been fully administered and the IV bag held non-acute hazardous waste pharmaceuticals, then IV bag can be shown to be empty and the remaining residues not regulated as hazardous waste per § 261.7(b)(1). If an IV bag is not empty through either of these means because it either has not been fully

[346] See 29 CFR 1910.1030(d)(1).

[347] See 29 CFR 1910.1030(d)(4)(iii)(A)(*1*).

[348] See 29 CFR 1910.1030(d)(4)(iii)(A)(*2*)(*i*).

[349] OSHA Compliance Directive CPL 02–02–069 Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens *https://www.osha.gov/OshDoc/Directive_pdf/CPL_02-02-069.pdf.*

[350] Ibid.

[351] See 29 CFR 1910.1030(d)(4)(iii)(C).

administered or cannot meet the requirements of § 261.7(b)(1) or because it contained an acute hazardous waste pharmaceutical, the IV bag must be placed with its remaining hazardous waste pharmaceuticals into a container that managed and disposed of as a non-creditable hazardous waste pharmaceutical under this subpart.

In the final rule, EPA has also altered the requirements for other types of containers including delivery devices. Commenters pointed out that a healthcare facility should not be precluded from proving that these containers meet the RCRA-empty standards in § 261.7 simply due to the type of container or contents. EPA agrees with the commenters that these types of containers which held non-acute hazardous waste pharmaceuticals should be able to use the RCRA empty container standards under § 261.7 and has changed the final rule to allow this. If the containers meet the RCRA empty standard under § 261.7 then the non-acute hazardous waste pharmaceutical residues (and the container) are not regulated as hazardous waste and can be managed as solid waste.

If these other containers, a category that includes but is not limited to inhalers, aerosols, nebulizers, tubes of ointments, gels or creams, once held an acute hazardous waste pharmaceutical or if they held a non-acute hazardous waste pharmaceutical but cannot meet the RCRA empty container standard of § 261.7, then the residues of these hazardous waste pharmaceuticals (and their containers) must be managed as non-creditable hazardous waste pharmaceuticals under this subpart.

4. Comments and Responses

One commenter was concerned that managing all other containers that held hazardous waste pharmaceuticals as non-empty could cause a VSQG healthcare facility to bump up in generator category to an LQG. This will no longer be a concern since a healthcare facility now has the option to prove that their other containers that held non-acute hazardous waste pharmaceuticals meet the RCRA empty container standards in § 261.7 and they can manage the residues (and containers) as non-hazardous waste. Otherwise, if these other containers are not considered empty, then the residues (and containers) must be managed as non-creditable hazardous waste pharmaceuticals under subpart P and hazardous waste pharmaceuticals managed under subpart P do not count towards determining the generator category. Further, we note that a healthcare facility can use the new empty container provisions in § 266.507 when determining whether they generate enough hazardous waste to become subject to part 266 subpart P.

XVI. Shipping Standards for Hazardous Waste Pharmaceuticals (§§ 266.508 and 266.509)

A. Shipping Non-Creditable Hazardous Waste Pharmaceuticals From Healthcare Facilities to Treatment, Storage, and Disposal Facilities (§ 266.508(a))

1. Summary of Proposal

Under part 266 subpart P, hazardous waste pharmaceuticals generated in a healthcare facility fall into two categories: (1) Non-creditable hazardous waste pharmaceuticals (*e.g.*, partially administered for patient care), and (2) potentially creditable hazardous waste pharmaceuticals (*e.g.*, unused, unadministered). This section discusses the proposed requirements for shipping non-creditable hazardous waste pharmaceuticals. For information regarding the shipment of potentially creditable hazardous waste pharmaceuticals from healthcare facilities and reverse distributors, see section XVI.D. of this preamble.

Generally, non-creditable hazardous waste pharmaceuticals differ from potentially creditable hazardous waste pharmaceuticals in that they have been partially administered and often are not in their original packaging. In addition, since there is not a reasonable expectation that prescription non-creditable hazardous waste pharmaceuticals are eligible to receive manufacturer credit, they are shipped off site to a TSDF rather than a reverse distributor. Due to concerns that a healthcare facility might send all of its hazardous waste pharmaceuticals to a reverse distributor even if there is not a reasonable expectation of receiving manufacturer credit—essentially using the reverse distributor as a TSDF—EPA proposed that non-creditable hazardous waste pharmaceuticals generated at healthcare facilities, when shipped off site, must be shipped to a designated facility (*e.g.*, an interim status or permitted hazardous waste TSDF), as was required under part 262 (unless the healthcare facility has interim status or a RCRA permit to store or treat hazardous waste and chooses to store or treat the non-creditable hazardous waste pharmaceuticals on site instead of shipping them to a designated facility).

Specifically, EPA proposed that healthcare facilities shipping non-creditable hazardous waste pharmaceuticals to a designated facility for treatment or disposal must continue to comply with the existing Department of Transportation (DOT) pre-transport requirements for packaging, labeling and marking, and that the non-creditable hazardous waste pharmaceuticals must continue to be shipped using a hazardous waste transporter and be tracked with a hazardous waste manifest. However, to avoid unnecessarily burdening the healthcare facility staff, who the Agency assumes are typically unfamiliar with RCRA, EPA proposed that the hazardous waste numbers (often called hazardous waste codes) are not required to be entered into the hazardous waste manifest for non-creditable hazardous waste pharmaceuticals. In lieu of hazardous waste codes, EPA proposed that the words, "hazardous waste pharmaceuticals" must be entered in the "special handling and additional information" box on the manifest (this box was called Item 14 at the time of the proposal).

We also proposed that all existing RCRA recordkeeping requirements regarding hazardous waste manifesting as well as all applicable DOT shipping requirements continue to apply to healthcare facilities shipping non-creditable hazardous waste pharmaceuticals to a TSDF for treatment or disposal (see section X.K).

2. Summary of Comments

Comments on this section of the proposed rulemaking were mixed. Commenters generally agreed with the proposed standards for packaging, labeling, marking, placarding, and shipping papers. Adverse comments were mostly in regard to the decision to not require individual waste codes on the manifest for a healthcare facility sending non-creditable hazardous waste pharmaceuticals to a TSDF for disposal. In fact, commenters were generally concerned about the proposal to not require individual waste codes anywhere in the management standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals. Whether the comments were regarding waste code determinations, labeling containers with waste codes, or including waste codes on the manifest, the overarching concern was that TSDFs would not know the specific contents of shipments received, resulting in an increase to their burden, and possibly would be detrimental to human health and the environment. Therefore, the adverse comments regarding the lack of a proposed requirement to input individual waste codes on the manifest are applicable more broadly to the subject of whether or not the

information that individual waste codes convey should somehow be provided to a TSDF by the healthcare facility shipping non-creditable hazardous waste pharmaceuticals.

Some states agreed with the proposal to not require individual waste codes on the manifest, while others commented that it is important to have waste codes at all steps where they would otherwise be required under previous RCRA regulations. Comments from waste management companies were also mixed, with some supporting the proposal to not require individual hazardous waste codes on the manifest, while others agreed with the proposal but suggested including a profile of likely constituents to alert TSDFs of potential waste contents to aid in LDR compliance.

Those waste management companies that disagreed with the proposed standards cited the added burden imposed by not knowing the specific waste constituents included in a shipment, which would make compliance with LDR standards more difficult. They were primarily concerned about the added burden of having to either begin testing their ash for wastes that have a numeric treatment standard, or modify existing testing protocols. One commenter from the healthcare industry disagreed with the elimination of individual hazardous waste codes on manifests from healthcare facilities shipping non-creditable hazardous waste pharmaceuticals, arguing that healthcare workers are capable of making accurate hazardous waste determinations. They also stated that hazardous waste codes are integral to properly managing hazardous waste. One waste management commenter stated that continuing to require waste codes on LDR notices altogether negates any actual relief because healthcare facilities will have to determine appropriate waste codes before sending hazardous waste pharmaceuticals off site to a TSDF whether or not they are required on the container label or manifest.

One reverse distributor also agreed with the proposed standards under the condition that the Agency agree that pharmaceuticals being sent to a reverse distributor are not waste.

3. Final Rule Provisions

The agency is finalizing the majority of the proposed requirements in this section. Before being shipped off site, all shipments of non-creditable hazardous waste pharmaceuticals must comply with applicable DOT pre-transport requirements for packaging (49 CFR parts 173, 178, and 180), labeling (49 CFR part 172 subpart E), and marking (49 CFR part 172 subpart D). There are, however, three notable changes being finalized.

First, § 266.508(a)(1)(v) has been removed and a healthcare facility shipping hazardous waste pharmaceuticals to a TSDF for disposal must instead comply with § 266.508(a)(2)'s manifest requirement to meet DOT's shipping papers requirement.

Second, the agency has decided to modify the proposal to not require any hazardous waste codes in Item 13 (Waste Codes) of the hazardous waste manifest for shipments of non-creditable hazardous waste pharmaceuticals being sent to a TSDF, and write the words "Hazardous Waste Pharmaceuticals" in Item 14 (Special Handling Instructions and Additional Information). The Agency is instead finalizing a requirement to write only one waste code— "PHARMS"—in Item 13, and not impose any requirements for what must be written in Item 14. After further consideration of the impacts this proposed requirement would impose on implementation and data collection, the Agency decided it had to be modified. During the development of this rule, the Agency has also been developing the electronic manifest system (e-Manifest) which requires that some code be written in Item 13. We chose the PHARMS code because it both meets the required number of characters and communicates the nature of the waste. Since the waste will now be sufficiently characterized in Item 13, the Agency feels there is no longer the need to require the words "hazardous waste pharmaceuticals" in Item 14.

This new PHARMS code is for manifesting and reporting purposes only and is not an official EPA hazardous waste code. Because it will be written in the same place as other official EPA hazardous waste codes, it may also be referred to colloquially as a "hazardous waste code." However, it does not modify any existing LDR treatment standards, nor does it enact any new or alternate LDR treatment standards for hazardous waste pharmaceuticals. Many commenters throughout the proposed rulemaking suggested that EPA promulgate an alternative treatment standard of the "CMBST" code specifically for hazardous waste pharmaceuticals with numeric treatment standards. The agency considered incorporating these suggestions into the proposed rulemaking, but did not receive the necessary data to support such an action. The Agency does, however, generally agree that implementing a new alternative treatment standard for hazardous waste pharmaceuticals might help mitigate burden on the regulated community while remaining protective of human health and the environment. The Agency remains open to considering the addition of an alternative treatment standard for hazardous waste pharmaceuticals in future rulemakings.

Although the Agency is now requiring the PHARMS code in Item 13 for shipments of non-creditable hazardous waste pharmaceuticals from a healthcare facility to a TSDF, hazardous waste codes are not required on the manifest, which was preferred by some commenters. As a result, TSDFs treating hazardous waste pharmaceuticals will have to assume that shipments of hazardous waste pharmaceuticals contain the few that have numeric treatment standards in order to demonstrate compliance with LDRs.

The third change made to the regulations was to modify the regulatory language in § 266.508(a) slightly to clarify that shipments of non-creditable hazardous waste pharmaceuticals being sent from a healthcare facility for disposal must be sent to a designated facility and accompanied by a hazardous waste manifest. As part of the manifest requirements in 40 CFR part 262 subpart B, shipments of non-creditable and evaluated hazardous waste pharmaceuticals must be sent to a designated facility via a hazardous waste transporter. One commenter noted that the proposed language could have been interpreted to mean that such shipments are also allowed to go elsewhere, which was not the Agency's intent.

Another substantive change to the regulatory language that resulted from incorporating commenters' concerns was to remove the requirements for shipping papers in § 266.508(a)(1)(v). A commenter pointed out that the requirement is unnecessary given the requirements in § 266.508(a)(2) and the Agency agreed. Section 266.508(a)(1)(v) would have required a healthcare facility shipping non-creditable hazardous waste pharmaceuticals to a TSDF to prepare shipping papers in accordance with 49 CFR 172 subpart C; however, the subsequent paragraph (§ 266.508(a)(2)) outlines the requirements for manifesting a shipment of non-creditable hazardous waste pharmaceuticals. Requiring both shipping papers and a manifest is redundant and could have possibly resulted in confusion and contradictory requirements. The hazardous waste manifest requirements, if complied

with, duly satisfy DOT's shipping paper requirements.

The wording in § 266.508(a) was modified slightly to clarify that healthcare facilities and reverse distributors that ship non-creditable and evaluated hazardous waste pharmaceuticals off site, respectively, are required to send them to a designated facility.

Finally, to be consistent with the Hazardous Waste Generator Improvements final rule, we have added paragraph 266.508(a)(1)(iii)(C) to mirror § 262.32(d), which addresses marking for lab packs. Specifically, lab packs of hazardous waste pharmaceuticals that will be treated using the alternative treatment standard of incineration, as allowed by § 268.42(c), do not have to marked or labeled with EPA hazardous waste numbers. However, lab packs that contain D004 (arsenic), D005 (barium), D006 (cadmium), D007 (chromium), D008 (lead), D010 (selenium) or D011 (silver), the EPA hazardous waste number must be marked or labeled with the EPA hazardous waste numbers (or electronic means may be used). These specific metals must be identified because § 268.42(c)(4) requires any incinerator residues from lab packs that contain any of these specific metals to undergo further treatment prior to land disposal.

B. Shipping Evaluated Hazardous Waste Pharmaceuticals From Reverse Distributors to Treatment, Storage, and Disposal Facilities (§ 266.508(a))

1. Summary of Proposal

For reverse distributors, once a potentially creditable hazardous waste pharmaceutical has been evaluated and it has been determined that it is not destined for another reverse distributor for further evaluation or verification of credit, EPA proposed that the hazardous waste pharmaceuticals be referred to as "evaluated hazardous waste pharmaceuticals." As with shipping non-creditable hazardous waste pharmaceuticals, when evaluated hazardous waste pharmaceuticals are shipped off-site, EPA proposed that they must be shipped in accordance with the existing DOT pre-transport requirements under 49 CFR parts 172–80 for packaging, labeling, marking, placarding, and shipping papers. We also proposed that they must be shipped in accordance with the existing RCRA manifest requirements of 40 CFR part 262 subpart B, which requires all relevant waste codes be listed in Item 13 and that they be shipped via a hazardous waste transporter to a designated facility. This continues current practices under existing regulations for this type of hazardous waste pharmaceutical and does not represent an increase in burden. EPA argued that the use of a hazardous waste manifest and a hazardous waste transporter are appropriate at this point for two reasons. First, once credit for the hazardous waste pharmaceuticals 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. Second, TSDFs are accustomed to receiving hazardous waste via a hazardous waste transporter with a hazardous waste manifest and it would place administrative and compliance burdens on the receiving TSDF to accept shipments of hazardous waste with alternative tracking.

EPA proposed that a reverse distributor must list all appropriate hazardous waste codes on the manifest when shipping evaluated hazardous waste pharmaceuticals to a TSDF. This differs from the requirements for a healthcare facility shipping non-creditable hazardous waste pharmaceuticals to a TSDF. Unlike non-creditable hazardous waste pharmaceuticals generated at a healthcare facility, hazardous waste pharmaceuticals received by reverse distributors are typically in the manufacturer's original, intact, and labeled packaging (if not, they are likely non-creditable hazardous waste pharmaceuticals and should be sent to a TSDF), so the information needed to determine the appropriate hazardous waste codes once evaluated should be readily available to the reverse distributor. Also, reverse distributors are currently required to include hazardous waste codes on the manifest and it is expected that they have the necessary expertise in the management of these hazardous wastes that healthcare personnel lack. Under the reverse distributor standards in § 266.510(c)(10)(ii), EPA also proposed that reverse distributors must keep copies of hazardous waste manifests for three years from the date evaluated hazardous waste pharmaceuticals are shipped to a TSDF.

2. Summary of Comments

Comments in this section were mixed. Many commenters addressed the standards for healthcare facilities sending shipments of non-creditable hazardous waste pharmaceuticals to a TSDF but did not specifically mention the standards for shipping evaluated hazardous waste pharmaceuticals to a TSDF. Nevertheless, many of the concerns expressed by commenters with the standards for healthcare facilities shipping non-creditable hazardous waste pharmaceuticals to a TSDF are relevant because the standards in § 266.508 are the same for healthcare facilities shipping non-creditable hazardous waste pharmaceuticals as they are for reverse distributors shipping evaluated hazardous waste pharmaceuticals, with the exception of § 266.508(a)(2)(i) and (ii). The few that commented directly on the proposed shipping standards for evaluated hazardous waste pharmaceuticals being shipped from a reverse distributor to a TSDF agreed with the standards as proposed.

Reverse distributor and waste management industry commenters were in agreement with the proposed standards for shipping evaluated hazardous waste pharmaceuticals to a TSDF, but to reiterate, did not agree with the standards for shipping non-creditable hazardous waste pharmaceuticals from a healthcare facility to a TSDF (no waste codes on the manifest). Many commenters on this section simply stated that waste codes should be included on a manifest, referring to the requirements in § 266.508(a)(2)(i) and (ii) which do not require waste codes on the manifest for healthcare facilities shipping non-creditable hazardous waste pharmaceuticals to a TSDF. Since those standards only apply to healthcare facilities shipping non-creditable hazardous waste pharmaceuticals to a TSDF and not reverse distributors sending evaluated hazardous waste pharmaceuticals to a TSDF, the agency assumes that those same commenters are generally in agreement with the requirement for reverse distributors shipping evaluated hazardous waste pharmaceuticals to a TSDF to comply with all of the manifest standards in 40 CFR part 262 subpart B, which includes a requirement to list all applicable EPA hazardous waste codes on the manifest.

3. Final Rule Provisions

The Agency is finalizing the standards for shipping evaluated hazardous waste pharmaceuticals from a reverse distributor to a TSDF with minor changes. First, § 266.508(a)(1)(v) has been removed. The standards for shipping papers for reverse distributors sending evaluated hazardous waste pharmaceuticals to a TSDF are contained instead in subparagraph § 266.508(a)(2) (*i.e.*, the manifest).

Second, the clarification to the regulatory language mentioned previously, which specifies that non-creditable hazardous waste

pharmaceuticals must go only to a TSDF, also applies to evaluated hazardous waste pharmaceuticals. As mentioned above, commenters were concerned that the proposed regulatory language appeared to make it optional for a reverse distributor to ship evaluated hazardous waste pharmaceuticals to a TSDF for disposal, although it was not intended to read that way. The finalized regulatory language was modified to clarify that a reverse distributor shipping evaluated hazardous waste pharmaceuticals must send them to a TSDF for treatment and disposal. This change pertains to both evaluated pharmaceuticals being shipped from a reverse distributor as well as non-creditable hazardous waste pharmaceuticals being shipped from a healthcare facility.

To summarize, reverse distributors sending evaluated hazardous waste pharmaceuticals to a TSDF for disposal are required to comply with all standards in § 266.508(a), which includes a requirement to list all applicable waste codes in Item 13 of the manifest, even though healthcare facilities sending non-creditable hazardous waste pharmaceuticals to a TSDF do not. They are not, however, required to write the word PHARMS in Item 13 or on the container label in addition to all other applicable waste codes.

C. Shipping Non-Creditable or Evaluated Hazardous Waste Pharmaceuticals for Import or Export (§§ 266.508(b) and 266.508(c))

1. Summary of Proposal

Under part 262, a healthcare facility or reverse distributor may not import hazardous waste pharmaceuticals unless it has a RCRA permit or interim status that allows it to accept hazardous waste from off site and complies with the requirements for importing hazardous waste in 40 CFR part 262 subpart H. Under part 266, EPA did not propose to change the regulations as they apply to the import of non-creditable or evaluated hazardous waste pharmaceuticals. Likewise, under part 262, a healthcare facility or reverse distributor may not export (non-creditable nor evaluated) hazardous waste pharmaceuticals unless it complies with requirements for exporting hazardous waste in 40 CFR part 262 subpart H. Under part 266, EPA did not propose to change the regulations as they apply to the export of (non-creditable or evaluated) hazardous waste pharmaceuticals.[352]

EPA requested comment on the likelihood that non-creditable hazardous waste pharmaceuticals that are shipped from a healthcare facility to a domestic TSDF, would then be exported to a TSDF in a foreign country. In addition, EPA did not anticipate that hazardous waste pharmaceuticals would be destined for transboundary shipments for purposes of recovery operations and therefore potentially subject to 40 CFR part 262 subpart H; however, we also requested comment on whether this is the case.

2. Summary of Comments

We received no comments on the proposed standards for importing and exporting non-creditable or evaluated hazardous waste pharmaceuticals.

3. Final Rule Provisions

Since part 266 subpart P was proposed, the hazardous waste import and export regulations under part 262 have been revised.[353] The export regulations which had been in part 262 subpart E are now in part 262 subpart H. Likewise, the import regulations which had been in part 262 subpart F are also now in part 262 subpart H. The requirements for both importing and exporting non-creditable hazardous waste pharmaceuticals are being substantially finalized as proposed. The only change being made from the proposed requirements is to update the reference to the revised part 262 regulations, in order to conform to the changes implemented in the Hazardous Waste Imports and Exports Improvement Rule. Whereas the proposed § 266.508(b) and (c) refer to the standards in 40 CFR part 262 subpart E and F, they now refer to 40 CFR part 262 subpart H.

D. Shipping Potentially Creditable Hazardous Waste Pharmaceuticals (§ 266.509).

1. Summary of Proposal

This section discusses the proposed requirements for shipping potentially creditable hazardous waste pharmaceuticals from a healthcare facility to a reverse distributor and between reverse distributors. The return of potentially creditable waste pharmaceuticals (hazardous and non-hazardous) to a reverse distributor can involve multiple shipping steps before the pharmaceuticals are transported for ultimate treatment and disposal. In comments on the 2008 Pharmaceutical Universal Waste proposal and in response to EPA's request for information,[354] reverse distributors described various scenarios. For example, a healthcare facility typically sends waste pharmaceuticals to the reverse distributor with which it has a contract. However, some manufacturers will only provide manufacturer credit after the pharmaceuticals have been returned to the reverse distributor with which the manufacturer has a contract. Thus, if the reverse distributor with which the healthcare facility has a contract differs from the reverse distributor with which the manufacturer has a contract, then the healthcare facility's reverse distributor must send the pharmaceuticals on to the manufacturer's reverse distributor for the manufacturer credit to be given to the healthcare facility. In some cases, a pharmaceutical manufacturer may require the reverse distributor to ship the pharmaceuticals back to them so they can perform the verification and issue credit themselves. The estimated amount of pharmaceuticals transported from reverse distributors to manufacturers for verification varies. Based on our request for information, reverse distributors indicated that the percent of potentially creditable hazardous waste pharmaceuticals transported to manufacturers ranged from an estimated 25 percent to 93 percent of total volume, depending on the contractual agreement between the reverse distributor and the manufacturer. The scenarios described previously occur routinely and are an integral part of the process by which manufacturers issue credit.

As explained in section IV.A, EPA proposed that all pharmaceuticals transported to reverse distributors for manufacturer credit are solid wastes, some of which would also be considered hazardous wastes. The finalized regulations have been modified, however, such that only prescription pharmaceuticals going through reverse distribution for manufacturer credit are solid wastes, while OTC pharmaceuticals going through reverse logistics are outside of this rule. Under the part 262 regulations, hazardous waste, including hazardous waste pharmaceuticals, must be manifested to a permitted or interim

[352] In the proposed rule we referenced part 262 subparts E and F when discussing this provision. Part 262 subparts E and F have since been replaced by part 262 subpart H; see the Hazardous Waste Export-Import Revisions final rule, 81 FR 85696; December 31, 2016.

[353] See the final Hazardous Waste Export-Import Revisions rule, 81 FR 85696; December 31, 2016.

[354] See the survey of reverse distributors in docket number: EPA–HQ–RCRA–2007–0932–0158 through 0160.

status TSDF and shipped using a hazardous waste transporter to ensure the cradle-to-grave system of RCRA is maintained. However, compared to other hazardous wastes, EPA believes that the risk of environmental release posed by most potentially creditable hazardous waste pharmaceuticals during accumulation and transport is relatively low. The risk is low because of the form and packaging of most potentially creditable hazardous waste pharmaceuticals, which is typically in small, individually packaged doses (such as with many tablets and capsules) or small vials. These small volumes of individually wrapped or packaged pharmaceuticals, when aggregated in a larger container, are unlikely to spill or be released into the environment since they are essentially double-packed when transported to a reverse distributor. Potentially creditable hazardous waste pharmaceuticals that are in liquid and aerosol forms may pose more of a risk during accumulation and transport due to possible spillage or leakage, but the small quantities in which they are generated, along with the DOT packaging requirements of 49 CFR parts 173, 178, and 180, would likely mitigate this risk (see EPA's recommendation regarding liquids and aerosols in section XI.C.1). Further, the 2008 Pharmaceutical Universal Waste proposal specifically sought comment regarding the risks of transportation of hazardous waste pharmaceuticals and no commenters identified environmental risks.

Due to the low risk to human health and release to the environment, EPA proposed to allow potentially creditable hazardous waste pharmaceuticals to be shipped without a hazardous waste manifest and without the use of hazardous waste transporters when the healthcare facility is sending potentially creditable hazardous waste pharmaceuticals to a reverse distributor or when a reverse distributor is sending potentially creditable hazardous waste pharmaceuticals to another reverse distributor. The same DOT shipping requirements would continue to apply to shipments of potentially creditable hazardous waste pharmaceuticals (provided they are classified as DOT hazardous materials) that applied prior to this final rule. Nothing in this final rule changes how DOT shipping requirements apply to shipments of prescription pharmaceuticals to reverse distributors.

EPA proposed an alternate tracking method for potentially creditable hazardous waste pharmaceuticals—with two requirements in lieu of requiring a hazardous waste manifest and the use of hazardous waste transporters. First, EPA proposed that for each shipment, healthcare facilities and reverse distributors must provide in writing (via letter or electronic communication), advance notice of the intent to send a shipment to the receiving reverse distributor. We also proposed that the receiving reverse distributor must provide acknowledgement to the shipper that they received the advance notice. This requirement was intended to function like a manifest, tracking the potentially creditable hazardous waste pharmaceuticals en route to the reverse distributor. Second, EPA proposed that for each shipment, the receiving reverse distributor must provide confirmation to the healthcare facility or reverse distributor that initiated the shipment, that the shipment of potentially creditable hazardous waste pharmaceuticals has been received. The Agency proposed this requirement in direct response to concerns expressed by commenters over the lack of tracking of pharmaceutical waste in the 2008 Pharmaceutical Universal Waste proposal.

The Agency proposed that, if a healthcare facility or reverse distributor initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor and does not receive delivery confirmation within seven calendar days, that the healthcare facility or reverse distributor that initiated the shipment must contact the shipper and the intended recipient promptly to (1) report that the confirmation was not received, and (2) to determine the status and whereabouts of the potentially creditable hazardous waste pharmaceuticals that were shipped.

The Agency proposed that if a healthcare facility or reverse distributor exports potentially creditable hazardous waste pharmaceuticals, it must generally comply with 40 CFR part 262 subpart E, except that it is not required to manifest the potentially creditable hazardous waste pharmaceuticals. The Agency also proposed that any person that imports potentially creditable hazardous waste pharmaceuticals, must comply with the proposed requirements for the shipment of potentially creditable hazardous waste pharmaceuticals, in lieu of the requirements for hazardous waste imports found at 40 CFR part 262 subpart F.[355]

[355] Part 262 subparts E and F have since been replaced by part 262 subpart H; see the Hazardous Waste Export-Import Revisions final rule, 81 FR 85696; December 31, 2016.

EPA proposed to require healthcare facilities (§ 266.503(d)) and reverse distributors (§ 266.510(b)(4)) to keep records of the shipments of potentially creditable hazardous waste pharmaceuticals to reverse distributors. Specifically, we proposed that healthcare facilities and reverse distributors that initiate a shipment to a reverse distributor must keep (1) records of advance notification regarding shipments of potentially creditable hazardous waste pharmaceuticals, (2) delivery confirmation for three years after the shipment was initiated, and (3) shipping papers or bills of lading. The Agency argued that these records are necessary to ensure that potentially creditable hazardous waste pharmaceuticals reach their intended destination and are not diverted.

In most cases, retaining records for three years should be sufficient for inspection purposes; however, we proposed that the periods of retention would be automatically extended during unresolved enforcement activity, or at the request of the EPA Regional Administrator. The Agency sought comment on whether additional recordkeeping is necessary to document the cases when the reverse distributor does not receive a shipment of potentially creditable pharmaceuticals within seven calendar days and the steps must be taken to locate the shipment.

2. Summary of Comments

The majority of comments focused on the provision to allow shipments of potentially creditable hazardous waste pharmaceuticals to be sent via carrier (*i.e.*, not by hazardous waste transporter), the requirements for advance notice of shipment and delivery confirmation, and the time frame within which delivery confirmation is received before the shipper must take action to locate a missing shipment.

Comments on whether the Agency should allow shipments of potentially creditable hazardous waste pharmaceuticals to be sent via carriers such as USPS, UPS, and FedEx without a manifest were mixed. Only a few states commented on this provision specifically. The majority of states agreed that shipping via carriers provides sufficiently low risk of release or illicit diversion. However, one state was concerned that we did not propose a requirement to reconcile the contents of what was shipped with what was received. That same commenter, as well as a handful of others, also voiced concern about whether DOT regulations would permit hazardous waste

pharmaceuticals to be lawfully shipped via carrier in the first place. Manufacturers, waste management companies, healthcare industry groups, and pharmacy trade associations were all generally in agreement with the proposed shipping standards for potentially creditable hazardous waste pharmaceuticals.

One of the primary points of contention in this subsection was the proposed standard that would require a shipper to provide advance notice of its intent to ship potentially creditable hazardous waste pharmaceuticals to a reverse distributor. Reverse distributors objected, arguing it would impart undue financial and administrative burden, which would require them to hire additional staff to adequately process advance notices, track, and confirm the delivery of thousands of shipments per year. A national trade association of retailers expressed similar concerns. They did not support the proposed advance notice and delivery confirmation requirements and argued the requirements would add undue burden due to the high volume of shipments large retailers send per year. The commenters suggested that the proposed notification and delivery standards either be removed or modified to match current inventory and accounting practices.[356] One pharmaceutical manufacturer also disagreed with the proposed standard, but gave no reasoning as to why, other than they thought it was unnecessary. States generally agreed with the proposed standard and a few suggested the Agency finalize additional requirements like reconciling what was in the notice with the contents of the package after delivery which would also require an inventory of each container. One state was concerned about its ability to confirm that a shipment has reached its final destination (TSDF) in scenarios where a shipment is sent to an out-of-state reverse distributor or a second reverse distributor. Healthcare facilities and pharmacist trade groups either agreed with the proposed standards or did not mention these standards specifically. One pharmacist trade group said they want some clarification about what constitutes advance notice.[357]

There were numerous comments both in agreement with and opposition to the proposed requirement to take action to locate a shipment of potentially creditable hazardous waste pharmaceuticals if no delivery confirmation is received within seven days from the day the shipment leaves the shipper's facility. Most comments were related to the time frame within which the shipper must receive delivery confirmation, but a few commenters from the retail and reverse distribution industries opposed the requirement altogether because of the added financial, procedural, and administrative burden they argue it would impose. Many commenters were concerned that the proposed time frame was too short and would result in frequent situations in which the shipper would be required to undertake efforts to locate a shipment that eventually arrives without intervention sometime after the seven days. Some commenters noted that seven days is the minimum transit time for a standard cross-country shipment under ideal conditions, which provides no buffer for unforeseen circumstances that may cause delays such as inclement weather or some other service disruption. One state suggested a 35-day time frame as an alternative because it would be the same as the time frame specified for delivery confirmation of universal waste shipped via carrier per the universal waste rule.[358]

There were limited comments regarding the proposed standards for healthcare facilities and reverse distributors importing and/or exporting potentially creditable hazardous waste pharmaceuticals. The only concern raised was whether shipments sent to or received from U.S. territories (*e.g.*, Puerto Rico, Guam) are considered exports/imports, and if so, they recommended that the Agency confer with other appropriate federal agencies and their reverse distributor contractors.

3. Final Rule Provisions

In response to comments, the Agency has made several changes to the proposed standards for shipping potentially creditable hazardous waste pharmaceuticals. First, we have made a minor change to make our regulatory language more consistent with DOT's terminology and clarify to whom the regulations refer. Specifically, in § 266.509(c), we changed the word shipper to carrier. As originally proposed, the word shipper could have been interpreted to refer to the party that prepares and offers a shipment of potentially creditable hazardous waste pharmaceuticals, whereas the regulations apply to the company providing transportation of a shipment of potentially creditable hazardous waste pharmaceuticals. To clarify, a shipper is the party that prepares and offers a shipment to be transported by a carrier.

Second, we have eliminated the requirement in § 266.509(a)(1) for a healthcare facility or reverse distributor that ships potentially creditable hazardous waste pharmaceuticals to provide advance notice of the shipment. The Agency believes that the proposed advance notice requirement goes beyond the manifest requirements and would have resulted in undue burden on both the shippers and the receiving reverse distributors while only nominally more protective of human health and the environment. We would, however, recommend that, as a best practice, shippers of potentially creditable hazardous waste pharmaceuticals provide advance notice to the recipients to the extent practicable. Conforming changes have been made throughout the regulations that reflect the elimination of the requirement to provide advance notice of shipments of potentially creditable hazardous waste pharmaceuticals.

Third, the proposed requirement that a reverse distributor that receives a shipment of potentially creditable hazardous waste pharmaceuticals must provide delivery confirmation to the facility that initiated the shipment is being finalized as proposed, with the added clarification that the shipment is not considered delivered until it is under the custody and control of the receiving reverse distributor. Requiring delivery confirmation provides assurance that the shipment was actively received by the reverse distributor and the chain of custody maintained. Without this confirmation from the receiving reverse distributor personnel, it is possible for a shipment to be delivered to the destination location but not necessarily taken into their custody and control (*e.g.*, left unattended outside the building).

Under this final rule, healthcare facilities and reverse distributors may use carriers, such as USPS, UPS, and FedEx for shipments of potentially creditable hazardous waste pharmaceuticals to and between reverse distributors, as long as personnel are present to receive and take control of the shipments upon arrival. EPA believes that carriers are able to provide safe shipment since these potentially creditable hazardous waste pharmaceuticals present low risk of release during transport.

In addition, all of the carriers EPA is aware of offer services that meet the delivery confirmation requirement.

[356] See comment number EPA–HQ–RCRA–2007–0932–0295.

[357] See comment number EPA–HQ–RCRA–2007–0932–0284.

[358] See comment number EPA–HQ–RCRA–2007–0932–0238.

Delivery confirmation can be paper-based or electronic and must indicate that personnel from the receiving reverse distributor have taken the shipment into their custody and control. One way for healthcare facilities and reverse distributors sending shipments of potentially creditable hazardous waste pharmaceuticals to a reverse distributor via carrier may comply with the delivery confirmation requirement would be to utilize the delivery confirmation service provided by most carriers (*e.g.,* Return Receipt from USPS, Delivery Confirmation from UPS, or Signature Proof of Delivery from FedEx). Typically, personnel at the receiving reverse distributor will sign for a shipment confirming that it is now in their custody and control. That signature will then be made available to the shipper, which satisfies the delivery confirmation requirement.

EPA has learned that some stakeholders use alternative electronic tracking methods outside of those offered by carriers. One alternative electronic tracking method is to apply barcoding on pharmaceutical packaging or on containers containing multiple pharmaceutical packages. A barcode is a unique identifier that links the container to a database with detailed information about its contents and includes the exact quantities of each item included in the shipment (inventories). Typically, when a reverse distributor receives a barcoded shipment, it will scan the barcodes upon receipt, and the sender will receive electronic notification that the shipment has arrived at its destination and is in the custody and control of the reverse distributor. This type of barcode tracking would meet the delivery confirmation requirement of this final rule. Another type of alternative electronic tracking that would satisfy the delivery confirmation requirement is radio frequency identification (RFID). Similar to barcodes, RFID tags are placed inside a container, or integrated into the container itself, and linked to inventories and other detailed information. The RFID tags are read when they arrive at the receiving facility and that information is made available to the shipper, confirming that the shipment has been taken into the custody and control of the receiving reverse distributor.[359]

Fourth, we have eliminated the regulatory language that was proposed in § 266.509(a)(2). We had referenced the DOT pre-transport regulations that apply to shipments of non-creditable hazardous waste pharmaceuticals. However, in 2016, DOT revised the Hazardous Materials Regulations (HMR) as they apply to shipments of items in reverse logistics.[360] As a result, many of the DOT pre-transport requirements we had referenced no longer apply to shipments of hazardous materials in reverse logistics. In response, we have eliminated the reference to the DOT pre-transport requirements and instead modified our final regulations in § 266.509(a) to refer to the entire HMR, rather than specific provisions within the HMR. Healthcare facilities and reverse distributors that send shipments of potentially creditable hazardous waste pharmaceuticals to reverse distributors need only comply with the applicable sections of DOT's HMR for shipments in reverse logistics.

We note that healthcare facilities and reverse distributors must meet the applicable DOT hazardous material shipping requirements only when shipping potentially creditable hazardous waste pharmaceuticals that meet the definition of DOT hazardous material. Under the DOT regulations, a RCRA hazardous waste that requires a manifest is considered a Class 9 hazardous material. Potentially creditable hazardous waste pharmaceuticals do not require a manifest; therefore, the DOT shipping requirements will apply when potentially creditable hazardous waste pharmaceuticals are shipped to reverse distributors only when the hazardous wastes are otherwise classified as DOT hazardous materials (*i.e.,* DOT hazard class 1–8). We added regulatory language (that was adapted from the Universal Waste regulations) to reflect this.

Fifth, the Agency has finalized the requirement that the shipper of potentially creditable hazardous waste pharmaceuticals must receive a delivery confirmation from the reverse distributor, however, the Agency has extended the time frame within which the shipper must receive the delivery confirmation from the reverse distributor from the proposed seven days to 35 days, after which the shipper must begin taking actions to locate a shipment if the delivery confirmation is not received. Many commenters suggested 14 days as an alternative to the proposed seven-day time frame, while others suggested far longer or to eliminate the time frame altogether. Upon reconsideration of the issue and how it pertains more generally to other RCRA hazardous waste programs, the Agency decided that 35 days was more appropriate, while remaining duly protective of human health and the environment and reducing burden on the regulated community. The time frame to receive delivery confirmation for shipments of potentially creditable hazardous waste pharmaceuticals is also now in line with the standard for delivery confirmation under universal waste, which is also 35 days. In addition, one of the overarching goals of this rule was to enact universal waste-like standards for hazardous waste pharmaceuticals, to which this provision conforms. Some states wanted the Agency to go further and require that the EPA Regional Administrator be notified whenever a shipment has not been received within the allotted time frame. Although the Agency understands the utility of such a provision, it is not being adopted because of the added burden it would impose on both states and the regulated community. In addition, the Agency prefers, in this instance, to allow states the flexibility to implement more stringent reporting standards for missing shipments of potentially creditable hazardous waste pharmaceuticals according to their individual circumstances and preferences.

After considering these comments, the Agency determined that it is necessary to require a delivery confirmation in order to ensure shipments of potentially creditable hazardous waste pharmaceuticals have been received and taken into the custody and control of the destination facility as a way to approximate the manifest system without requiring the use of hazardous waste transporters or manifests. In response to comments, we have reconsidered the proposed seven-day time frame for the shipper to receive delivery confirmation; the Agency decided that 35 days is more appropriate. It strikes a balance between being duly protective of human health and the environment, reducing burden, and is now in line with universal waste standards.

Sixth, we have made several changes to the pre-transport requirements that we proposed in § 266.509(a)(1) and (2). Because of the removal of the requirement for advance notice of shipments of potentially creditable hazardous waste pharmaceuticals, we renumbered the section such that it all appears in § 266.509(a) now. What was proposed in § 266.509(a)(2) and is now in § 266.509(a), has been modified to reflect the removal of § 266.508(a)(1)(v) which previously contained a requirement that DOT shipping papers be generated. The Agency believes that the shipping papers requirement—

[359] See comment number EPA–HQ–RCRA–2007–0932–0268.

[360] March 31, 2016; 62 FR 18527.

although duplicative for shipments of non-creditable hazardous waste pharmaceuticals from a healthcare facility or evaluated hazardous waste pharmaceuticals from a reverse distributor—is appropriate for shipments of potentially creditable hazardous waste pharmaceuticals given that they are not manifested. Therefore, the requirement for DOT shipping papers has been added to § 266.509(a). Language was also added to clarify that shipments of potentially creditable hazardous waste pharmaceuticals from a healthcare facility or reverse distributor to a reverse distributor do not require a manifest. This language was taken from the universal waste standards in § 273.52(a) which is consistent with the goal of developing universal waste-like shipping standards for potentially creditable hazardous waste pharmaceuticals.

As with the export of non-creditable hazardous waste pharmaceuticals, the proposed standards for healthcare facilities or reverse distributors that export potentially creditable hazardous waste pharmaceuticals to a foreign destination have also been modified to reflect the changes made to the import/export rules of part 262. Specifically, the Agency is finalizing requirements that exporters of potentially creditable hazardous waste pharmaceuticals must comply will all applicable sections of 40 CFR part 262 subpart H, except for the manifest requirements of § 262.83(c), in addition to the requirements for shipping potentially creditable hazardous waste pharmaceuticals in § 266.509(a) through (c).

Subsequent to when this rule was proposed in September 2015, the Hazardous Waste Import-Export Revisions rule was finalized in 2016.[361] As a result, the Agency has had to make conforming changes to this final rule to reflect the changes made by the Import-Export Revisions final rule. Because the regulations for importing and exporting hazardous waste were previously located in separate subparts—exports in subpart E and imports in subpart F—the proposed requirements in this rule were also separated into discreet subsections and referred to their respective subparts (exporting and importing) of 40 CFR part 262. A significant change enacted by the Import-Export Revisions Rule was to consolidate into subpart H the multiple related subparts in 40 CFR 262 regarding import, export, and transboundary movements of hazardous waste that had been in subparts E and F.

The essence of the proposed regulations has not changed in the finalized requirements. That is, a healthcare facility or reverse distributor exporting potentially creditable hazardous waste pharmaceuticals is still subject to the same or similar provisions as were proposed, only now they must comply with 40 CFR part 262 subpart H instead, except for the manifesting requirements, and paragraphs (a) through (c) of § 266.509.

For healthcare facilities and reverse distributors that import potentially creditable hazardous waste pharmaceuticals, the requirements are being finalized as proposed, except that due to the conforming changes necessitated by the Hazardous Waste Export-Import Revisions Final Rule, they must now comply with the shipping standards for potentially creditable hazardous waste pharmaceuticals in lieu of 40 CFR part 262 subpart H (instead of part 262 subpart F). One other clarification was added to the regulatory language specifying that potentially creditable hazardous waste pharmaceuticals are subject to all applicable provisions in this subpart immediately after entering the United States.

4. Comments and Responses

The commenter that requested an official definition of advance notice also requested an official definition for delivery confirmation.[362] The Agency is purposely leaving this standard sufficiently broad as to allow the implementing agencies discretion to determine the best implementation strategies on a case-by-case basis.

EPA notes that a reverse distributor is not required to segregate the potentially creditable hazardous waste pharmaceuticals from the potentially creditable non-hazardous waste pharmaceuticals when they are destined for another reverse distributor. However, if the potentially creditable pharmaceuticals are not segregated, the reverse distributor must follow the tracking procedures for the entire shipment. On the other hand, if a reverse distributor chooses to segregate the potentially creditable hazardous waste pharmaceuticals from the non-hazardous waste pharmaceuticals prior to shipping to another reverse distributor, only the potentially creditable hazardous waste pharmaceutical portion would have to be shipped according to these standards.

XVII. Standards for Reverse Distributors (§ 266.510)

A. Background on Reverse Distributor Operations

Reverse distributors act as intermediaries between healthcare facilities and pharmaceutical manufacturers. They receive shipments of potentially creditable hazardous waste pharmaceuticals from healthcare facilities and, on behalf of manufacturers, facilitate the process of crediting healthcare facilities for these pharmaceuticals. From stakeholder input, EPA site visits, and comments on the proposed rulemaking, EPA's understanding is that when a reverse distributor receives a shipment of potentially creditable hazardous waste pharmaceuticals, the reverse distributor sorts through the shipment and often uses barcodes to scan items into its computer system. Based on manufacturers' "business rules" (*i.e.,* manufacturers' return policies), the reverse distributors determine which potentially creditable hazardous waste pharmaceuticals can receive manufacturer credit, as well as which must be sent on to another reverse distributor for completion of the crediting process. "Business rules" (*i.e.* manufacturers' return policies) refers to the rules that govern the disposition of retail items agreed to by the manufacturer, retailer, and reverse distributor or reverse logistics center.[363]

In many cases, there is more than one reverse distributor involved in establishing and verifying manufacturer credit for a particular potentially creditable hazardous waste pharmaceutical. For instance, reverse distributors may have contracts with specific pharmaceutical manufacturers such that only a specific reverse distributor may facilitate credit for a particular manufacturer's pharmaceuticals. If the receiving reverse distributor has a contract with the healthcare facility, but not with the pharmaceutical manufacturer, then the receiving reverse distributor sends the returned pharmaceutical on to the reverse distributor that has a contract with the pharmaceutical manufacturer in order to facilitate the manufacturer credit process.

Because manufacturers' business rules change over time, sometimes a reverse distributor receives a potentially creditable hazardous waste

[361] See the Hazardous Waste Export-Import Revisions final rule, 81 FR 85696; December 31, 2016.

[362] See comment number EPA–HQ–RCRA–2007–0932–0284.

[363] This definition is derived from the definition of "business rules" in the "Surplus Household Consumer Products and Wastes: Report to the Legislature." Available at: *http://www.dtsc.ca.gov/HazardousWaste/Retail_Industry/upload/SB423_Final-Rpt.pdf.*

pharmaceutical that is not eligible for credit immediately, and the reverse distributor retains the potentially creditable hazardous waste pharmaceutical on site until it is credit eligible (often called "aging" a pharmaceutical). For example, manufacturers only issue credit for expired pharmaceuticals. As a result, sometimes a reverse distributor receives an unexpired hazardous waste pharmaceutical that is otherwise creditable but awaiting its expiration date. The reverse distributor then retains the potentially creditable hazardous waste pharmaceutical on site until after it has expired and thus becomes eligible for manufacturer credit. In some cases, even after the reverse distributor has awarded manufacturer credit, a pharmaceutical manufacturer may request that the hazardous waste pharmaceuticals be transported back to the manufacturer to verify the amount of pharmaceuticals and manufacturer credit.

On the other hand, if the potentially creditable hazardous waste pharmaceuticals are not sent on to another reverse distributor and the reverse distributor awards the manufacturer credit to the healthcare facility itself, it then manages the hazardous waste pharmaceuticals on site until they are sent off site for treatment and disposal. As discussed previously, after a potentially creditable hazardous waste pharmaceutical has been evaluated and no additional reverse distributors will be involved in the manufacturer's crediting process, EPA uses the term "evaluated hazardous waste pharmaceutical." This is to distinguish between the potentially creditable hazardous waste pharmaceuticals awaiting determination within the reverse distribution system versus the evaluated hazardous waste pharmaceuticals that will not be sent to another reverse distributor for evaluation. Both are considered hazardous waste pharmaceuticals, but they are managed differently under this subpart.

EPA is not aware of any reverse distributor that facilitates manufacturer credit that also has interim status or a permit to treat or dispose of hazardous waste on-site.[364] Therefore, EPA anticipates that reverse distributors eventually send all evaluated hazardous waste pharmaceuticals off site for treatment and disposal.

[364] Several DEA reverse distributors have RCRA interim status or a permit to treat or dispose of hazardous waste, but these DEA reverse distributors do not facilitate manufacturer credit.

B. EPA's Rationale for Finalizing New RCRA Management Standards for Reverse Distributors

This final rule establishes standards for the management of both potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that reverse distributors receive and manage. The management standards discussed in this section apply only to reverse distributors of prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals. The management standards discussed in this section do not apply to the reverse logistics systems that may exist for other retail items. In response to comments, EPA is codifying our existing interpretation that nonprescription pharmaceuticals 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 (*e.g.*, lawfully redistributed for their intended purpose) or reclaimed (see the definition of hazardous waste pharmaceutical under section VIII and section IX, the applicability section). Additionally, EPA is establishing a policy that other retail items that are sent through reverse logistics are not solid waste at the retail store if they have a reasonable expectation of being legitimately used/reused or reclaimed (see section VI). Therefore, reverse logistics centers that receive and manage nonprescription pharmaceuticals will not be regulated under this subpart and will not be subject to the standards for reverse distributors.

The current federal RCRA hazardous waste generation regulations at 40 CFR part 262 provide that only designated facilities, such as RCRA-permitted and interim status TSDFs, may receive hazardous waste from off site for treatment, storage, or disposal. However, the Agency does not believe it is necessary for reverse distributors to obtain permits or have interim status to store hazardous waste pharmaceuticals in order to protect human health and the environment. Thus, EPA is finalizing a new category of hazardous waste management facilities under RCRA called a "reverse distributor," which is defined as any person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit. The definition specifies that any person, including forward distributors, third-party logistics providers, and pharmaceutical manufacturers, that processes prescription hazardous waste pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor. EPA is finalizing that reverse distributors are not required to have interim status or a RCRA permit to accumulate hazardous waste pharmaceuticals and they may only accept potentially creditable hazardous waste pharmaceuticals from off site provided they comply with the standards in this final rule. Reverse distributors may not treat or dispose of hazardous waste on-site unless authorized to do so as a RCRA-permitted or interim status TSDF.

As discussed earlier in this document, EPA's previous interpretation allows reverse distributors to be generators of hazardous waste pharmaceuticals after a decision is made about whether the pharmaceuticals will be repurposed. As a hazardous waste generator, a reverse distributor had to comply with the LQG, SQG, or VSQG generator regulations, depending on the total volume of hazardous waste generated in a calendar month. Some smaller reverse distributors might have stayed under the hazardous waste quantity limits for VSQGs, which would mean that under the federal RCRA regulations, these VSQG reverse distributors would not have had to notify EPA as a generator and their hazardous waste pharmaceuticals could be disposed of with municipal and non-municipal solid waste (see § 262.14). However, the Agency has concerns with VSQG reverse distributors not notifying EPA that they are managing hazardous waste. EPA is even more concerned about reverse distributors that currently qualify as VSQGs placing the hazardous waste pharmaceuticals into the municipal and non-municipal solid waste stream and sending them to non-hazardous waste landfills. Some studies have shown active pharmaceutical ingredients present in landfill leachate that is collected in municipal solid waste landfill leachate systems.[365] [366] Landfill leachate is generally transported to a wastewater treatment

[365] Barnes, K.K., Christenson, S.C., Kolpin, D.W., Focazio, M.J., Furlong, E.T., Zaugg, S.D., Meyer, M.T. and Barber, L.B. (2004), Pharmaceuticals and Other Organic Waste Water Contaminants Within a Leachate Plume Downgradient of a Municipal Landfill. Groundwater Monitoring & Remediation, 24: 119–126.

[366] Buszka, P.M., Yeskis, D.J., Kolpin, D.W., Furlong, E.T., Zaugg, S.D., and Meyer, M.T. (2009), Waste-Indicator and Pharmaceutical Compounds in Landfill-Leachate-Affected Ground Water near Elkhart, Indiana, 2000–2002. Bulletin of Environmental Contamination and Toxicology. 82.6:635–659.

plant to be treated before discharge; however, some pharmaceutical compounds pass through treatment and are discharged, becoming a potential contributor of the pharmaceutical compounds detected in our nation's waters.

In this final rule, EPA is revising its position regarding prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals, such that they will be considered discarded at the healthcare facilities, not at the reverse distributors. This revision is based on new information demonstrating to EPA that prescription pharmaceuticals returned to a reverse distributor are rarely, if ever, recycled or reused, and therefore the decision to send a potentially creditable hazardous waste pharmaceutical to a reverse distributor is a decision to discard the pharmaceutical (as discussed previously in section VI). Comments on the December 2008 Pharmaceutical Universal Waste proposal indicated that notification to EPA by reverse distributors and tracking of shipments of potentially creditable hazardous waste pharmaceuticals are critical and must be included in any regulatory scheme to ensure the safe management of potentially creditable hazardous waste pharmaceuticals.

Although EPA maintains its position as stated in the proposed rulemaking preamble that hazardous waste pharmaceuticals going to reverse distributors are solid wastes at the healthcare facility, there are important differences between reverse distributors and traditional TSDFs. Only between 2–6 percent of the potentially creditable pharmaceuticals that are received by reverse distributors are listed or characteristic hazardous wastes.[367] Therefore, the vast majority of the potentially creditable pharmaceutical waste that a reverse distributor receives is not considered a characteristic or listed hazardous waste pharmaceutical under the existing definition of hazardous waste. This stands in contrast to a typical TSDF, whose primary function is to manage hazardous waste. As a result, a reverse distributor generally manages a smaller volume of hazardous waste than a typical permitted TSDF.

In addition, because the pharmaceuticals in the reverse distribution system are receiving manufacturer credit, they are moved through the system efficiently. In fact, one national pharmacy retail chain informed EPA that the value of the credit they receive from manufacturers for returned pharmaceuticals is approximately $1 billion a year.[368] Healthcare facilities and reverse distributors have a vested interest in having potentially creditable hazardous waste pharmaceuticals processed and credited quickly and managed appropriately so money is not lost in the process.

Furthermore, potentially creditable hazardous waste pharmaceuticals generally present a low risk of release to the environment as they typically are still in the manufacturer's packaging, which in some cases includes inner and outer packaging (*e.g.*, plastic bottle inside a box). Since there is a relatively low human health and environmental risk of release associated with the low volumes of potentially creditable hazardous waste pharmaceuticals shipped to reverse distributors for crediting purposes, and because EPA is not aware of any incidents of mismanagement resulting in environmental harm or releases of hazardous waste pharmaceuticals by reverse distributors, EPA believes that it is not necessary to require reverse distributors to obtain RCRA hazardous waste storage permits with respect to typical reverse distribution operations, such as receiving, sorting, consolidating, and reshipping potentially creditable hazardous waste pharmaceuticals.

Thus, EPA is taking a tailored approach to regulating reverse distributors by regarding them as a new type of RCRA hazardous waste entity—a reverse distributor. This approach balances EPA's revised interpretation that the point of generation for prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals is at the healthcare facility, not the reverse distributor, with the fact that potentially creditable hazardous waste pharmaceuticals have value which provides an incentive for proper management.

EPA is establishing new management standards for reverse distributors in 40 CFR part 266 subpart P. These entities will not be subject to 40 CFR parts 262, 264, 265, or 270. Generally, EPA is finalizing that reverse distributors comply with standards that are similar to the current federal LQG standards, in combination with certain requirements that permitted or interim status hazardous waste TSDFs must meet. We are establishing one set of requirements for all reverse distributors, regardless of the amount of potentially creditable hazardous waste pharmaceuticals they receive. EPA believes this uniform set of standards will make it easier for reverse distributors to comply with the new subpart, in part because the burden of having to count hazardous waste pharmaceuticals on a monthly basis, especially the 1 kg of acute hazardous waste pharmaceuticals, will be removed.

EPA is finalizing that a reverse distributor will not be required to have a hazardous waste permit or interim status for on-site accumulation of creditable and evaluated hazardous waste pharmaceuticals provided it follows the final reverse distributor standards. As mentioned previously, the on-site accumulation of creditable and evaluated hazardous waste pharmaceuticals generally presents low risk of release to the environment because they are typically in the manufacturer's packaging. However, for activities such as treatment or disposal of hazardous waste pharmaceuticals or other hazardous waste, a reverse distributor must either obtain a RCRA permit or have interim status, as these activities pose a higher risk of release. EPA has determined that requirements similar to LQG standards for on-site accumulation of hazardous waste that are found in § 262.17 are appropriate. As discussed previously, the value of the potentially creditable pharmaceuticals creates an incentive for proper management and the risk of release is low. Furthermore, many reverse distributors are already LQGs and, therefore, this final rule should not represent a large shift in current practices or increased burden.[369] However, once credit is provided, the value of the pharmaceuticals is eliminated and therefore the evaluated hazardous waste pharmaceuticals have a greater potential for mismanagement. As a result, EPA is finalizing additional standards for the management of evaluated hazardous waste pharmaceuticals at reverse distributors.

EPA received numerous comments that expressed concern that the standards for reverse distributors would be burdensome for reverse logistics

[367] See EPA's request of information from reverse distributors, as well as their responses to EPA in the docket for this rulemaking: EPA–HQ–RCRA–2007–0932–0157, EPA–HQ–RCRA–2007–0932–0158, EPA–HQ–RCRA–2007–0932–0159, EPA–HQ–RCRA–2007–0932–0160, EPA–HQ–RCRA–2007–0932–0161, EPA–HQ–RCRA–2007–0932–0162, EPA–HQ–RCRA–2007–0932–0163, EPA–HQ–RCRA–2007–0932–0164.

[368] Meeting with representatives from CVS (August 11, 2012); see the docket for meeting notes (EPA–HQ–RCRA–2007–0932–0188).

[369] See the Regulatory Impact Analysis in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

centers that handle nonprescription pharmaceuticals. For example, one commenter expressed concern that the reverse distributor inventory requirements for both potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals would be burdensome for facilities that receive and manage nonprescription pharmaceuticals because these reverse logistics centers do not currently maintain an inventory for these retail items.[370] EPA is codifying our existing interpretation that nonprescription pharmaceuticals 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 (*e.g.,* lawfully redistributed for their intended purpose) or reclaimed (see section VI for more discussion). Therefore, reverse logistics centers will not be regulated under part 266 subpart P and will not be subject to the standards for reverse distributors. As a result, comments received on the impact of the reverse distributor standards on reverse logistics centers that receive and manage nonprescription pharmaceuticals are outside the scope of the final rule and are not discussed in this section. EPA also received numerous general comments expressing concern that finalizing new RCRA management standards for reverse distributors would be burdensome. However, some specific provisions included in the proposed reverse distributor standards received few comments.

C. Detailed Discussion of Final Reverse Distributor Standards

The final standards for reverse distributors are organized into three sections. The first section applies to the reverse distributor for the management of all potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals (§ 266.510(a)). The second section includes additional standards that would apply to the management of the potentially creditable hazardous waste pharmaceuticals that will be sent to another reverse distributor for further evaluation or verification of credit and therefore continue to be regulated as potentially creditable hazardous waste pharmaceuticals (§ 266.510(b)). The third section includes additional standards that apply to the management of the evaluated hazardous waste pharmaceuticals that will not be sent to another reverse distributor, but instead will be sent to a permitted or interim status TSDF (§ 266.510(c)).

1. Standards for Reverse Distributors Managing Potentially Creditable Hazardous Waste Pharmaceuticals and Evaluated Hazardous Waste Pharmaceuticals (§ 266.510(a))

This portion of the preamble discusses the standards that apply to reverse distributors for the management of all hazardous waste pharmaceuticals on site, including potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals. Unlike the following two sections, the standards discussed in this section apply to all prescription hazardous waste pharmaceuticals at a reverse distributor, regardless of the subsequent destination of the hazardous waste pharmaceuticals. We note that a reverse distributor must follow these standards for the management of hazardous waste pharmaceuticals even if it generates other, non-pharmaceutical hazardous waste that is managed under 40 CFR part 262. Note that we have reorganized § 266.510(a) since the proposal to more accurately reflect the flow of hazardous waste pharmaceuticals at a reverse distributor. The subsequent preamble section follows the organization of the final regulations.

a. Notification

Summary of Proposal. EPA proposed that a reverse distributor must notify EPA of its hazardous waste pharmaceutical activities using the Site ID Form (EPA Form 8700–12). Under the RCRA Subtitle C program, SQGs, LQGs, and TSDFs must submit a Site ID Form to EPA. EPA proposed that a reverse distributor that does not have an EPA ID number will be required to submit the Site ID Form to obtain one and that a reverse distributor that already has an EPA ID number will need to notify EPA as a reverse distributor.

Summary of Comments. EPA received two comments in support of the proposed notification requirements. One state supported all of the proposed notification requirements.[371] Inmar, Inc. supported the requirement that reverse distributors must notify EPA using EPA Form 8700–12.[372]

Final Rule Provisions. EPA is finalizing in § 266.510(a)(1) that a reverse distributor must notify EPA of its hazardous waste pharmaceutical activities using the Site ID Form (EPA Form 8700–12). The Agency will revise the Site ID Form to include a box to allow notifications by reverse distributors. EPA believes it is appropriate, and in line with comments received on the proposal, to require reverse distributors to notify EPA. Under the final rule, a reverse distributor that does not have an EPA ID number will be required to submit the Site ID Form to obtain one. A reverse distributor that already has an EPA ID number will need to notify EPA as a reverse distributor. The time frame in both cases is within 60 days of the effective date of this subpart or within 60 days of becoming subject to this subpart. Some reverse distributors may also be generators of other types of hazardous waste (*e.g.,* from cleaning and maintenance operations). Therefore, it is possible that a reverse distributor may notify on the same notification form as both a generator of hazardous waste and as a reverse distributor.

b. Inventory

Summary of Proposal. EPA proposed that reverse distributors must keep an inventory of the potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that are on site. EPA proposed that the inventory must include the identity (*e.g.,* name or National Drug Code) and quantity of each potentially creditable hazardous waste pharmaceutical and evaluated hazardous waste pharmaceutical. EPA also proposed that a reverse distributor must inventory each potentially creditable hazardous waste pharmaceutical upon arrival at the reverse distributor.

Summary of Comments. EPA received comments from states and industry in support of the proposed inventory requirement.[373] One state suggested that EPA also require reverse distributors to include the name of the healthcare facility that shipped the potentially creditable hazardous waste pharmaceuticals to the reverse distributor.[374]

Retail Industry Leaders Association argued that the inventory requirements for reverse distributors should be reduced.[375] Inmar, Inc. did not support the inventory requirements and argued

[370] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[371] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[372] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[373] See comment numbers EPA–HQ–RCRA–2007–0932–0235, EPA–HQ–RCRA–2007–0932–0257, EPA–HQ–RCRA–2007–0932–0280, EPA–HQ–RCRA–2007–0932–0296, EPA–HQ–RCRA–2007–0932–0300, and EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[374] See comment number EPA–HQ–RCRA–2007–0932–0235 in the docket for this rulemaking.

[375] See comment number EPA–HQ–RCRA–2007–0932–0295 in the docket for this rulemaking.

that they are duplicative because reverse distributors must already inventory and track prescription pharmaceuticals.[376] Inmar, Inc. wrote that at least four states currently require the maintenance of drug inventories by law.[377] Both Inmar, Inc. and RILA expressed concern that the inventory requirements would be particularly burdensome for their facilities that handle nonprescription pharmaceuticals. Inmar, Inc. pointed out that their reverse logistics centers do not maintain an inventory for nonprescription pharmaceuticals.[378]

EPA received multiple comments from industry that expressed concern that the reverse distributor must inventory each potentially creditable hazardous waste pharmaceutical upon arrival.[379] One commenter expressed concern that the reverse distributor must complete an inventory upon arrival because packages of potentially creditable hazardous waste pharmaceuticals can remain unopened for up to 5 business days.[380] Healthcare Distribution Management Association [381] pointed out that reverse distributors sometimes receive tens of thousands of products in a day and do individual product accounting when the credit determination is made.[382]

Commenters on the proposed rulemaking also pointed out that reverse distributors are already required to inventory and track prescription pharmaceuticals under licensing and accreditation programs overseen by the National Association of Boards of Pharmacy.[383]

Final Rule Provisions. EPA is finalizing in § 266.510(a)(2) that reverse distributors must keep an inventory of the potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that are on site. In response to comments, we have made several changes to what was proposed but have determined that an inventory is a key requirement to protect public health by helping to prevent the diversion of hazardous waste pharmaceuticals. An inventory will allow the reverse distributor to know which hazardous waste pharmaceuticals they have on-site at any time. Based on stakeholder input and site visits, the Agency believes that in many cases, reverse distributors already maintain inventories of pharmaceuticals and this requirement is not expected to be burdensome for the reverse distributors to implement. According to responses from reverse distributors to a 2011 request for information, four out of eight of them indicated that they already keep inventories as best management practices or because it is required by the Board of Pharmacy in their state.[384] The inventory must include the identity (*e.g.,* name or National Drug Code) and quantity of each potentially creditable hazardous waste pharmaceutical and evaluated hazardous waste pharmaceuticals. In response to commenter concern that the inventory requirement would be duplicative, EPA clarified in the regulatory language of the final rule that if the reverse distributor already meets the inventory requirements because of other regulatory requirements, such as State Board of Pharmacy regulations, the facility is not required to provide a separate inventory.

EPA proposed that a reverse distributor must inventory each potentially creditable hazardous waste pharmaceutical upon arrival at the reverse distributor. The final rule has been revised to state that reverse distributors must inventory each potentially creditable hazardous waste pharmaceutical within 30 calendar days of arriving at the reverse distributor. EPA made this change in response to commenter concern that the Agency did not provide enough time for reverse distributors to inventory potentially creditable hazardous waste pharmaceuticals. As previously mentioned, comments pointed out that reverse distributors sometimes receive tens of thousands of products in one day and need additional time to inventory each potentially creditable hazardous waste pharmaceutical.[385] EPA is also aware that many reverse distributors inventory the potentially creditable hazardous waste pharmaceutical at the same time that they evaluate the potentially creditable hazardous waste pharmaceutical to determine if it will receive manufacturer credit. When a reverse distributor receives a shipment of potentially creditable hazardous waste pharmaceuticals, the reverse distributor sorts through the shipment and often uses barcodes to scan items into its system and make a credit determination. EPA believes that 30 days is an adequate amount of time for the reverse distributor to sort through shipments of hazardous waste pharmaceuticals and inventory the potentially creditable hazardous waste pharmaceuticals. The Agency has determined that because of the value of the potentially creditable hazardous waste pharmaceuticals, and the low risk these materials present, increasing the amount of time reverse distributors have to complete the inventory will not increase risk of release to the environment.

c. Evaluating Potentially Creditable Hazardous Waste Pharmaceuticals Within 30 Days

Summary of Proposal. The key role the reverse distributor plays in managing the issuing of credit from a manufacturer to a healthcare facility is sorting through shipments of potentially creditable hazardous waste pharmaceuticals and evaluating them to determine which must be transported to another reverse distributor for further evaluation of manufacturer credit and which will be sent off site for treatment and disposal. The reverse distributors often use barcodes to scan items into their systems.

EPA proposed that this evaluation process must be completed within 21 days of arriving at the reverse distributor. Likewise, EPA proposed that if the reverse distributor is a manufacturer, the manufacturer must finish verifying the appropriate credit within 21 calendar days of receiving the shipment of potentially creditable hazardous waste pharmaceuticals. The Agency proposed that the 21 calendar days for evaluating the potentially creditable hazardous pharmaceuticals counts as part of the total 90 calendar days that each reverse distributor is allowed to accumulate hazardous waste pharmaceuticals on site.

Summary of Comments. The most frequent comment EPA received on the proposed requirement that reverse distributors complete the evaluation process within 21 days of arriving at the reverse distributor is that the proposed time frame was too short. Waste Management National Services, Inc.

[376] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[377] See the EPA correspondence with Inmar dated March 29, 2017 in the docket for this rulemaking EPA–HQ–RCRA–2007–0932.

[378] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[379] See comment numbers EPA–HQ–RCRA–2007–0932–0295, EPA–HQ–RCRA–2007–0932–0276, EPA–HQ–RCRA–2007–0932–0352, and EPA–HQ–RCRA–2007–0932–0340 in the docket for this rulemaking.

[380] See comment number EPA–HQ–RCRA–2007–0932–0278 in the docket for this rulemaking.

[381] Now renamed Heathcare Distribution Alliance.

[382] See comment number EPA–HQ–RCRA–2007–0932–0276 in the docket for this rulemaking.

[383] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[384] See EPA's request of information from reverse distributors, as well as their responses to EPA in the docket for this rulemaking: EPA–HQ–RCRA–2007–0932–0157, EPA–HQ–RCRA–2007–0932–0158, EPA–HQ–RCRA–2007–0932–0159, EPA–HQ–RCRA–2007–0932–0160, EPA–HQ–RCRA–2007–0932–0161, EPA–HQ–RCRA–2007–0932–0162, EPA–HQ–RCRA–2007–0932–0163, EPA–HQ–RCRA–2007–0932–0164.

[385] See comment number EPA–HQ–RCRA–2007–0932–0276 in the docket for this rulemaking.

requested that EPA allow additional time for reverse distributors to evaluate potentially creditable hazardous waste pharmaceuticals.[386] One state requested that EPA allow reverse distributors to have 30 days to complete the evaluation process.[387] RILA and PharmaLink, Inc. requested that EPA allow reverse distributors to have 60 days to complete the evaluation process.[388] GENCO, Qualanex, LLC, and Healthcare Waste Institute of the National Waste and Recycling Association requested that there be no time limit set for reverse distributors to complete the evaluation process.[389] One state suggested that it is not critical to require the evaluation to take place in a certain number of days if the days count toward the total number of days that hazardous waste pharmaceuticals are allowed to accumulate on site.[390]

EPA also received multiple comments in support of the requirement that reverse distributors complete the evaluation process in a short time frame. One state supported the requirement that reverse distributors complete the evaluation process in a short time frame.[391] Clean Harbors Environmental Services argued that 21 days is more than adequate for a reverse distributor to evaluate potentially creditable hazardous waste pharmaceuticals.[392]

Final Rule Provisions. Under the final rule, EPA is requiring in § 266.510(a)(3) that reverse distributors evaluate potentially creditable hazardous waste pharmaceuticals within 30 calendar days of arriving at the reverse distributor. Likewise, EPA is finalizing in § 266.510(a)(4) that if the reverse distributor is a manufacturer, the manufacturer must finish verifying the appropriate credit within 30 calendar days of receiving the shipment of potentially creditable hazardous waste pharmaceuticals.

EPA is now aware that reverse distributors sometimes receive tens of thousands of products in one day and that sometimes reverse distributors need more than 21 days to evaluate the potentially creditable hazardous waste pharmaceuticals.[393] As mentioned previously, commenters pointed out that many reverse distributors inventory the potentially creditable hazardous waste pharmaceuticals at the same time that they evaluate the potentially creditable hazardous waste pharmaceuticals to determine if they will be credited.[394] Therefore, the Agency is finalizing that both the inventory and the evaluation process must be completed in 30 days to ensure that reverse distributors have adequate time to sort through shipments of potentially creditable hazardous waste pharmaceuticals.[395] In the case where healthcare facilities do not segregate hazardous waste pharmaceuticals from non-hazardous waste pharmaceuticals as part of the evaluation process, reverse distributors will effectively make a hazardous waste determination in order to determine which pharmaceuticals are hazardous waste pharmaceuticals and thus subject to this subpart.

The Agency is finalizing that the 30 calendar days for evaluating the potentially creditable hazardous pharmaceuticals do not count as part of the total 180 calendar days that the hazardous waste pharmaceuticals are allowed to accumulate on site at the reverse distributor. The Agency has determined that because of the value of the potentially creditable hazardous waste pharmaceuticals and the low risk these materials present, increasing the amount of time reverse distributors have to evaluate shipments of potentially creditable hazardous waste pharmaceuticals will not increase risk of release to the environment. Additionally, because most potentially creditable hazardous waste pharmaceuticals are in their original packaging, if the original packaging for gels or liquids is intact and sealed or the pharmaceuticals have been repackaged (*e.g.,* for unit dosing) and the repackaged packaging for gels and liquids is intact and sealed, they are considered to meet the closed container standard, and therefore EPA has determined that having a longer accumulation time is not a hazard to human health and the environment.[396]

EPA is finalizing that once an evaluation is made on the incoming potentially creditable hazardous waste pharmaceuticals, if they are destined for another reverse distributor, they are still considered potentially creditable hazardous waste pharmaceuticals. There are additional regulations in this subpart at § 266.510(b) that pertain to these potentially creditable hazardous waste pharmaceuticals. If, however, they are destined for an interim status or permitted TSDF, they are considered "evaluated hazardous waste pharmaceuticals." There are additional regulations in this rule at § 266.510(c) that pertain to these evaluated hazardous waste pharmaceuticals.

d. Accumulation Time Limit

Summary of Proposal. EPA proposed that, like LQGs, reverse distributors may accumulate potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals on-site for up to 90 calendar days without having interim status or a permit. However, because of the value of the potentially creditable hazardous waste pharmaceuticals, and the low risk these materials present because they are in original manufacturer's packaging that would meet our typical requirement for closed containers, the Agency decided not to propose specific container management standards.

The Agency proposed that the 90-day time limit begin when the potentially creditable hazardous waste pharmaceuticals initially arrive at the reverse distributor. The Agency also proposed that there is a 90-day accumulation limit for the hazardous waste pharmaceuticals at each reverse distributor. Some potentially creditable hazardous waste pharmaceuticals travel through more than one reverse distributor to receive manufacturer credit. The Agency proposed that in such cases, each reverse distributor that receives the potentially creditable hazardous waste pharmaceuticals has a 90-day accumulation limit.

EPA did not propose a specific method that reverse distributors must use to document that accumulation does not exceed 90 calendar days. EPA

[386] See comment number EPA–HQ–RCRA–2007–0932–0257 in the docket for this rulemaking.

[387] See comment number EPA–HQ–RCRA–2007–0932–0313 in the docket for this rulemaking.

[388] See comment numbers EPA–HQ–RCRA–2007–0932–0295 and EPA–HQ–RCRA–2007–0932–0349 in the docket for this rulemaking.

[389] See comment numbers EPA–HQ–RCRA–2007–0932–0336, EPA–HQ–RCRA–2007–0932–0352, and EPA–HQ–RCRA–2007–0932–0296 in the docket for this rulemaking.

[390] See comment number EPA–HQ–RCRA–2007–0932–0235 in the docket for this rulemaking.

[391] See comment number EPA–HQ–RCRA–2007–0932–0315 in the docket for this rulemaking.

[392] See comment number EPA–HQ–RCRA–2007–0932–0333 in the docket for this rulemaking.

[393] See comment numbers EPA–HQ–RCRA–2007–0932–0276 and EPA–HQ–RCRA–2007–0932–0257 in the docket for this rulemaking.

[394] See comment number EPA–HQ–RCRA–2007–0932–0276 in the docket for this rulemaking.

[395] Although RILA requested that EPA allow reverse distributors to have 60 days to complete the evaluation process, RILA was primarily concerned that it would be difficult for reverse distributors to sort through over-the-counter pharmaceuticals and dietary supplements within the proposed time frame (see comment number EPA–HQ–RCRA–2007–0932–0295 in the docket for this rulemaking). However, the Agency thinks that 30 days is a sufficient amount of time for reverse distributors to sort through shipments of potentially creditable hazardous waste pharmaceuticals, which does not include over-the-counter pharmaceuticals and dietary supplements under the final regulations (see the definition of "potentially creditable hazardous waste pharmaceuticals" in 266.500).

[396] For more discussion of the closed container standard see memo from Devlin to RCRA Division Directors, November 3, 2011 (RCRA Online #14826).

anticipated that most reverse distributors would use the inventory system to verify the 90-calendar day time frame rather than taking the extra step of labeling containers with dates for verification. EPA also proposed to allow a reverse distributor to request from EPA an extension of the 90-day accumulation time limit for situations when the hazardous waste pharmaceuticals are involved in litigation, a recall, or in unforeseen circumstances beyond the control of the reverse distributor. Under the part 262 generator regulations, the extension of time typically allowed is limited to an extra 30 days for LQGs. However, due to the complex nature of pharmaceutical litigation and recalls, EPA proposed to allow the EPA Regional Administrator to grant a time extension at their discretion on a case-by-case basis.

Summary of Comments. The most frequent comment EPA received on the proposed on-site accumulation time limit was that the 90-day accumulation limit was too short. Waste Management National Services, Inc. did not support the 90-day accumulation limit, arguing that there are many reasons why a reverse distributor would experience significant changes in the volumes of returns it receives, including recalls.[397] Inmar, Inc. did not support the 90-day accumulation limit, arguing that its facilities receive thousands of shipments every day and it would be impractical to ensure a 90-day accumulation limit.[398] Healthcare Distribution Management Association pointed out that the 90-day accumulation limit is too short because manufacturers frequently take longer than 90 days to make credit determinations.[399] Waste Management National Services, Inc., Qualanex, LLC, and PharmaLink, Inc. requested that EPA not require the 90-day accumulation to begin until the potentially creditable hazardous waste pharmaceuticals become evaluated hazardous waste pharmaceuticals.[400] Stericycle, Inc. requested that EPA extend the accumulation time limit from 90 days to 180 days and suggested that there should not be an accumulation time limit for hazardous waste pharmaceuticals being held due to recall.[401] GENCO and Healthcare Waste Institute of the National Waste and Recycling Association also requested that EPA extend the accumulation time limit from 90 days to 180 days.[402] RILA Association requested that EPA extend the accumulation time limit from 90 days to one year.[403] National Pharmaceutical Returns requested that EPA place no accumulation time limit on potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.[404]

EPA received multiple comments suggesting that the accumulation time limits did not accommodate situations where reverse distributors receive unexpired pharmaceuticals that are otherwise creditable but are awaiting their expiration date or situations where reverse distributors "age" potentially creditable pharmaceuticals until they are eligible for manufacturer credit.[405]

One state supported the 90-day accumulation limit.[406] One state agreed that the 90-day accumulation limit is reasonable but did not support allowing each reverse distributor to have a 90-day accumulation period because it increases the potential for mismanagement.[407]

Final Rule Provisions. In response to comments, EPA is providing additional time for reverse distributors accumulating hazardous waste pharmaceuticals. Specifically, EPA is finalizing in § 266.510(a)(5) that reverse distributors may accumulate potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals on site for up to 180 calendar days without having interim status or a permit as long as they meet the conditions of this subpart. The Agency is finalizing that the 180-day time limit begins once the reverse distributor evaluates the potentially creditable hazardous waste pharmaceutical and determines if the potentially creditable hazardous waste pharmaceuticals must be transported to another reverse distributor for further evaluation of manufacturer credit or if it will be sent off site for treatment and disposal. As mentioned in the previous section, reverse distributors are required to inventory and evaluate potentially creditable hazardous waste pharmaceuticals within 30 calendar days of arriving at the reverse distributor. Therefore, the potentially creditable hazardous waste pharmaceuticals can be accumulated at each reverse distributor for no more than 210 days in total after arrival.

The Agency is finalizing that there is a 180-day accumulation limit for the hazardous waste pharmaceutical at each reverse distributor. Some potentially creditable hazardous waste pharmaceuticals travel through more than one reverse distributor to receive manufacturer credit. Under the final rule, each reverse distributor that receives the potentially creditable hazardous waste pharmaceuticals has a new 180-day accumulation limit. Under the final rule, the 180-day time limit begins when the reverse distributor evaluates potentially creditable hazardous waste pharmaceuticals and to determine which potentially creditable hazardous waste pharmaceuticals must be transported to another reverse distributor and which ones will be sent off site for treatment and disposal.

Under the final rule, EPA is not requiring a specific method that reverse distributors must use to document that accumulation does not exceed 180 calendar days. EPA anticipates that most reverse distributors will use the inventory system to verify the 180-calendar day time frame rather than taking an addition step of labeling containers with dates for verification. As discussed previously, EPA is finalizing that a reverse distributor must inventory potentially creditable hazardous waste pharmaceuticals within 30 calendar days of arriving at the reverse distributor. Many reverse distributors utilize barcoding and scanners to log potentially creditable pharmaceuticals into a database upon arrival or soon after a shipment arrives.

Because of the value of the potentially creditable hazardous waste pharmaceuticals, and the low risk these materials present, the Agency is not requiring specific container management standards in the final rule. Furthermore, potentially creditable hazardous waste pharmaceuticals are typically still in the manufacturer's packaging, which would meet our typical requirement for closed containers.

Under the final rule, EPA has eliminated the proposed provision allowing reverse distributors to request an extension of the accumulation time limit. In order to accommodate situations where hazardous waste

[397] See comment number EPA–HQ–RCRA–2007–0932–0257 in the docket for this rulemaking.

[398] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[399] See comment number EPA–HQ–RCRA–2007–0932–0276 in the docket for this rulemaking.

[400] See comment numbers EPA–HQ–RCRA–2007–0932–0257, EPA–HQ–RCRA–2007–0932–0352, and EPA–HQ–RCRA–2007–0932–0349 in the docket for this rulemaking.

[401] See comment number EPA–HQ–RCRA–2007–0932–0280 in the docket for this rulemaking.

[402] See comment numbers EPA–HQ–RCRA–2007–0932–0336 and EPA–HQ–RCRA–2007–0932–0296 in the docket for this rulemaking.

[403] See comment number EPA–HQ–RCRA–2007–0932–0295 in the docket for this rulemaking.

[404] See comment number EPA–HQ–RCRA–2007–0932–0310 in the docket for this rulemaking.

[405] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[406] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[407] See comment number EPA–HQ–RCRA–2007–0932–0300 in the docket for this rulemaking.

pharmaceuticals are involved in unforeseen circumstances beyond the control of the reverse distributor, the Agency increased the accumulation time limit from 90 days to 180 days. As discussed previously, the Agency also increased the amount of time reverse distributors can take to evaluate potentially creditable hazardous waste pharmaceuticals from 21 to 30 days. Additionally, in order to accommodate situations when hazardous waste pharmaceuticals are involved in litigation or a recall, under the final rule, the Agency decided that hazardous waste pharmaceuticals that are either involved in an investigation or judicial proceeding or are subject to a voluntary or federally-mandated recall are not required to be managed under subpart P (see section IX for a detailed discussion). As a result, we do not anticipate the need for reverse distributors to seek accumulation time extensions and therefore we have deleted proposed § 266.510(a)(5).

In order to accommodate situations when reverse distributors receive unexpired pharmaceuticals that are otherwise creditable but are awaiting their expiration date (*i.e.*, aging in a holding morgue), EPA has added a provision in § 266.510(a)(5)(ii) to allow reverse distributors to accumulate these unexpired pharmaceuticals for up to 180 days after the expiration date provided that the unexpired pharmaceuticals are managed in accordance with the container labeling and management standards for evaluated hazardous waste pharmaceuticals found at § 266.510(c)(4)(i)–(vi) while they are aging. This includes labeling containers with the words "hazardous waste pharmaceuticals;" ensuring the containers are in good condition, managed to prevent leaks and compatible with the contents; and keeping containers closed.

Once a reverse distributor evaluates a hazardous waste pharmaceutical and determines that it is not destined for another reverse distributor, the reverse distributor must manage that hazardous waste pharmaceutical according to the standards for evaluated hazardous waste pharmaceuticals (unless, as previously mentioned, the hazardous waste pharmaceuticals are unexpired pharmaceuticals that are otherwise creditable but are awaiting their expiration date). The evaluated hazardous waste pharmaceuticals can be accumulated for up to 180 calendar days without having interim status or permits and they must be managed in accordance with the standards for evaluated hazardous waste pharmaceuticals in § 266.510(c). Although reverse distributors must manage the hazardous waste pharmaceuticals that are not destined for another reverse distributor in accordance with the standards for evaluated hazardous waste pharmaceuticals, the reverse distributor can decide at any point during the accumulation time that the evaluated hazardous waste pharmaceuticals have become eligible for manufacturer credit. If the evaluated hazardous waste pharmaceuticals become eligible for manufacturer credit, the reverse distributor does not get additional calendar days beyond the 180-day accumulation time limit to accumulate the hazardous waste pharmaceuticals. If the evaluated hazardous waste pharmaceutical becomes eligible for manufacturer credit, and the hazardous waste pharmaceutical will still not be sent to another reverse distributor for further evaluation, the reverse distributor must continue to manage the hazardous waste pharmaceutical in accordance with the standards for evaluated hazardous waste pharmaceuticals.

EPA does not anticipate a scenario where an evaluated hazardous waste pharmaceutical becomes eligible for manufacturer credit and the reverse distributor needs to send the hazardous waste pharmaceutical to another reverse distributor for further evaluation. A reverse distributor is unlikely to utilize resources to accumulate a pharmaceutical that another reverse distributor is required to evaluate due to contractual arrangements with pharmaceutical manufacturers. Although EPA does not anticipate this scenario, if an evaluated hazardous waste pharmaceutical becomes eligible for manufacturer credit and the reverse distributor determines that it should go to another reverse distributor to be further evaluated for manufacturer credit, the reverse distributor can then resume managing the hazardous waste pharmaceutical pursuant to the standards for potentially creditable hazardous waste pharmaceuticals that are going on to another reverse distributor (§ 266.510(b)). However, the reverse distributor does not get additional time to accumulate the hazardous waste pharmaceuticals. That is, the reverse distributor can only accumulate the hazardous waste pharmaceuticals for a total of 180 days after the initial evaluation process is complete. Overall, this approach balances the requests from commenters to accommodate situations where reverse anticipate that a manufacturer's policy might change and that evaluated hazardous waste pharmaceuticals might become eligible for manufacturer credit with EPA's belief that it is necessary to limit total accumulation time to 180 days.

e. Security

Summary of Proposal. EPA proposed that reverse distributors must meet a performance-based security requirement which is based on the existing interim status TSDF security requirements found at § 265.14. Due to increased thefts of pharmaceuticals from pharmacies reported in recent years in major media outlets, EPA was concerned that reverse distributors could face such thefts since they accumulate unused pharmaceuticals.[408] Further, commenters on the 2008 Pharmaceutical Universal Waste proposal suggested that pharmaceutical universal waste handlers should meet the TSDF facility security requirement. EPA agreed with the commenters that the requirements in the interim status TSDF security regulations would be appropriate to adopt and apply to reverse distributors to prevent the illicit use of these pharmaceuticals, thereby safeguarding human health. EPA's proposal required that they must prevent unknowing entry, and minimize the possibility for the unauthorized entry into the portion of the facility where potentially creditable and evaluated hazardous waste pharmaceuticals are kept (*e.g.*, a receiving area and accumulation area).

Summary of Comments. Inmar, Inc. and RILA did not support the proposed security requirements and argued that they are duplicative because protective security measures are already required by other state and federal laws.[409] One state and two industry commenters expressed support that reverse distributors must meet a performance-based security standard.[410] One industry commenter pointed out that this requirement should not be an added burden since reverse distributors should already have significant security systems in place and one industry commenter pointed out that the requirements are consistent with the

[408] "Pharmacies Besieged by Addicted Thieves" by Abby Goodnough Published: February 6, 2011 *http://www.nytimes.com/2011/02/07/us/07pharmacies.html.*

[409] See comment numbers EPA–HQ–RCRA–2007–0932–0377 and EPA–HQ–RCRA–2007–0932–0295 in the docket for this rulemaking.

[410] See comment numbers EPA–HQ–RCRA–2007–0932–0257, EPA–HQ–RCRA–2007–0932–0280, and EPA–HQ–RCRA–2007–0932–0315 in the docket for this rulemaking.

way that reverse distributors operate.[411] [412]

Final Rule Provisions. EPA is finalizing in § 266.510(a)(6) that reverse distributors must meet a performance-based security requirement which is based on the existing interim status TSDF security requirements found at § 265.14. EPA believes that the requirements that appear in the interim status TSDF security regulations are appropriate to adopt and apply to reverse distributors to prevent the illicit use of these pharmaceuticals thereby safeguarding human health. The security requirement of § 265.14(a) requires a facility to "prevent the unknowing entry, and minimize the possibility for the unauthorized entry, of persons or livestock onto the active portion of his facility." EPA is finalizing a similar requirement for reverse distributors: they must prevent unknowing entry and minimize the possibility for the unauthorized entry into the portion of the facility where potentially creditable and evaluated hazardous waste pharmaceuticals are kept (*e.g.,* a receiving area and accumulation area).

Based on site visits and comments received on the proposed rulemaking, EPA recognizes that many reverse distributors may already meet the proposed security standard through the use of key cards that allow only authorized personnel into specific areas of the reverse distributor, camera surveillance systems, and cages for storing pharmaceuticals. Some reverse distributors may use fences and signs. EPA is including several examples of acceptable security measures in the regulatory text, but reverse distributors are not limited to the examples provided. Further, EPA does not believe this requirement is duplicative because we included a provision in the regulations that if a reverse distributor already meets the performance-based security standard by complying with other regulations, such as DEA's regulations, then the reverse distributor would not need to install additional security. Furthermore, in response to comments we added a reference to the State Board of Pharmacy regulations as a second example of other regulations that could be used to fulfill the performance based security requirement.

f. Contingency Plan and Emergency Procedures

Summary of Proposal. The Agency proposed to require that reverse distributors meet standards that are the same as those that appear in the federal LQG regulations for developing a contingency plan and emergency procedures at 40 CFR part 265 subpart D. EPA noted in the proposal that a reverse distributor should be prepared to respond to potential emergencies just like LQGs and TSDFs. Since many reverse distributors are already LQGs, they should already have contingency plans to address the hazards on site. It may be possible that the reverse distributors would have to amend their contingency plans to include the potentially creditable hazardous waste pharmaceuticals, which have been considered products, not hazardous waste, but the Agency pointed out in the proposal that such modifications should not impose much burden.

Summary of Comments. One state and two industry commenters supported the requirement that reverse distributors meet the same contingency planning standards as LQGs at 40 CFR part 265 subpart D.[413] Inmar, Inc. supported the proposed contingency plan and emergency procedures requirements and pointed out that most of their facilities are LQGs and already follow these requirements.[414] RILA argued that the contingency planning and emergency procedures requirements should not apply to reverse distributors that handle lower volumes of hazardous waste than an SQG generates because the nature of the waste does not warrant the more stringent requirements.[415]

Final Rule Provisions. EPA is finalizing in § 266.510(a)(7) that reverse distributors meet standards that are the same as those that appear in the federal LQG regulations for developing a contingency plan and emergency procedures. Since this rule was proposed, the 2016 Hazardous Waste Generator Improvements rule has been finalized and has placed the contingency plan and emergency procedures for LQGs in part 262 subpart M, entitled "Preparedness, Prevention and Emergency Procedures for Large Quantity Generators." As a result, this final rule now references the LQG standards in part 262 subpart M rather than the interim status TSDF standards part 265 subpart D. EPA believes that a reverse distributor should be prepared to respond to potential emergencies just like LQGs and TSDFs. Reverse distributors that are LQGs should already have contingency plans to address the hazards on-site. Commenters pointed out that reverse distributors that currently operate as SQGs will face a burden under this requirement, but EPA's data shows that most reverse distributors are already LQGs.[416] It is possible that the reverse distributors will have to amend their contingency plans to include the potentially creditable hazardous waste pharmaceuticals, which have been considered products, not hazardous waste, but EPA does not believe that such modifications will impose much burden.

Comments and Responses. One state recommended that EPA establish a similar requirement to 40 CFR 264.31 (failure of a facility owner or operator to maintain or operate facility to minimize possibility of fire, explosion or releases of hazardous waste or hazardous waste constituents) for reverse distributors.[417] EPA included similar language in the regulations at § 266.510(c)(4)(v).

g. Closure

Summary of Proposal. Due to the generally low risk of release to the environment of the hazardous waste pharmaceuticals that reverse distributors will accumulate on site, as well as the value of the hazardous waste pharmaceuticals, EPA proposed a performance-based closure standard for reverse distributors that incorporated the federal LQG closure standard found at § 265.111. Specifically, when a reverse distributor closes its operations related to hazardous waste pharmaceuticals, EPA proposed that it must control or minimize post-closure releases of hazardous waste into the environment. EPA expected that this would entail removing the containers of both potentially creditable hazardous waste pharmaceuticals as well as evaluated hazardous waste pharmaceuticals from the facility before closure.

Summary of Comments. Waste Management National Services, Inc., the California Department of Toxic Substances Control, and the Connecticut Department of Energy and Environmental Protection support the requirement for a performance-based closure standard that is based on the

[411] See comment number EPA–HQ–RCRA–2007–0932–0257 in the docket for this rulemaking.

[412] See comment number EPA–HQ–RCRA–2007–0932–0280 in the docket for this rulemaking.

[413] See comment numbers EPA–HQ–RCRA–2007–0932–0257, EPA–HQ–RCRA–2007–0932–0341, and EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[414] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[415] See comment number EPA–HQ–RCRA–2007–0932–0295 in the docket for this rulemaking.

[416] See the Regulatory Impact Analysis in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[417] See comment number EPA–HQ–RCRA–2007–0932–0235 in the docket for this rulemaking.

federal LQG closure standard.[418] Inmar, Inc. requested that EPA clarify that the reverse distributor closure requirement only apply to the closure of the facility and not to the closure of accumulation areas.[419]

Final Rule Provisions. Under the final rule at § 266.510(a)(8), EPA is requiring a performance-based closure standard that is based on the federal LQG closure standard. Since the rule was proposed, the 2016 Hazardous Waste Generator Improvements rule has been finalized and has incorporated the LQG closure standards into the new LQG regulations in § 262.17. As a result, this final rule now references the LQG closure standard in §§ 262.17(a)(8)(ii) and (iii) rather than incorporating the regulatory language of § 265.111. The LQG closure standards are substantially the same as before. Therefore, when a reverse distributor closes its operations related to hazardous waste pharmaceuticals, it must control or minimize post-closure releases of hazardous waste constituents into the environment. This will entail removing the containers of both potentially creditable hazardous waste pharmaceuticals as well as evaluated hazardous waste pharmaceuticals from the facility before closure. The closure standards apply when the reverse distributor closes its operations related to hazardous waste pharmaceuticals rather than when the reverse distributor closes an accumulation area.

h. Reporting

Summary of Proposal. In some instances, a shipment arriving at a reverse distributor may inadvertently include items that are not potentially creditable pharmaceuticals. These shipments can include wastes that are clearly not eligible to receive credit, such as patient care waste (*e.g.,* IV bags and tubing), contaminated personal protective equipment (PPE), medical waste, or other inappropriate wastes. Reverse distributors are not the appropriate waste management facility for medical or infectious wastes and these wastes must be managed and transported from the healthcare facility to an appropriate waste disposal facility. In some cases, these non-creditable wastes may be hazardous waste. These non-creditable hazardous wastes are prohibited from being transported from a healthcare facility to a reverse distributor and should have been manifested from the healthcare facility to a designated facility, such as a permitted or interim status TSDF.

EPA proposed that if a shipment including these unauthorized wastes arrives at a reverse distributor from a healthcare facility, the reverse distributor must submit an unauthorized waste report to the EPA Regional Administrator within 15 days. EPA adapted the existing requirement for situations when permitted and interim status TSDFs receive unmanifested hazardous waste (§ 264.76 and § 265.76, respectively) to make it appropriate for situations when unauthorized waste arrives at a reverse distributor. EPA also proposed additional requirements for when inappropriate hazardous waste arrives at a reverse distributor.

First, EPA proposed that the reverse distributor must send a copy of the unauthorized waste report to the healthcare facility that sent the unauthorized waste. This requirement was intended to alert the healthcare facility of its mistake in order to prevent further shipments of non-creditable hazardous waste or non-pharmaceutical hazardous waste.

Second, EPA proposed that the reverse distributor must manage the unauthorized waste that it receives in accordance with all applicable regulations. Third, the Agency proposed that the EPA Regional Administrator may require reverse distributors to furnish additional reports concerning the quantities and disposition of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

Summary of Comments. The most frequent comment that EPA received on the proposed reporting requirements is that 15 days is not enough time to submit an unauthorized waste report to the EPA Regional Administrator. Four commenters argued that 15 days is not enough time to submit an unauthorized waste report to the EPA Regional Administrator.[420] Two industry commenters pointed out that it may take up to 30 days for shipments to be processed.[421] Healthcare Waste Institute of the National Waste and Recycling Association suggested that reverse distributors be required to submit an unauthorized waste report within 15 days of processing a shipment of hazardous waste rather than within 15 days of receiving the hazardous waste.[422]

CT DEEP supported the reporting requirements and wrote that the requirement might incentivize healthcare facilities not to ship unauthorized wastes to reverse distributors.[423] RILA did not support the reporting requirements and wrote that reverse distributors should not be required to submit an unauthorized waste report when shipments of non-creditable hazardous waste pharmaceuticals arrive at the reverse distributors because the healthcare facilities are not capable of evaluating creditworthiness.[424] Waste Management National Services, Inc. requested that EPA only require reverse distributors to send a copy of the unauthorized waste report to a specific healthcare facility three times, arguing that it is not the reverse distributor's responsibility to continue this reporting.[425] National Pharmaceutical Returns pointed out that reverse distributors receive a large amount of unauthorized waste pharmaceuticals that healthcare facilities think are potentially creditable and therefore the reporting requirements will be time consuming.[426] One state requested the EPA clarify if a reverse distributor may refuse to take a shipment.[427]

Final Rule Provisions. In response to comments, EPA is finalizing at § 266.510(a)(9) that if a shipment from a healthcare facility arrives at a reverse distributor that includes hazardous waste that it is not authorized to receive, the reverse distributor must submit an unauthorized waste report to the EPA Regional Administrator within 45 days of receiving the hazardous waste rather than the proposed 15 days. However, EPA is finalizing, as proposed, the additional requirements for when shipments of unauthorized waste arrive at reverse distributors. First, the reverse distributor must send a copy of the unauthorized waste report to the healthcare facility that sent the unauthorized waste. Second, the reverse distributor cannot reject the shipment of non-creditable hazardous waste and must manage the unauthorized waste in accordance with all applicable

[418] See comment numbers EPA–HQ–RCRA–2007–0932–0257, EPA–HQ–RCRA–2007–0932–0315, and EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[419] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[420] See comment numbers EPA–HQ–RCRA–2007–0932–0257, EPA–HQ–RCRA–2007–0932–0278, EPA–HQ–RCRA–2007–0932–0296, and EPA–HQ–RCRA–2007–0932–0352 in the docket for this rulemaking.

[421] See comment numbers EPA–HQ–RCRA–2007–0932–0257 and EPA–HQ–RCRA–2007–0932–0352 in the docket for this rulemaking.

[422] See comment number EPA–HQ–RCRA–2007–0932–0296 in the docket for this rulemaking.

[423] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[424] See comment number EPA–HQ–RCRA–2007–0932–0295 in the docket for this rulemaking.

[425] See comment number EPA–HQ–RCRA–2007–0932–0257 in the docket for this rulemaking.

[426] See comment number EPA–HQ–RCRA–2007–0932–0310 in the docket for this rulemaking.

[427] See comment number EPA–HQ–RCRA–2007–0932–0259 in the docket for this rulemaking.

regulations (*e.g.*, part 262 or medical waste regulations). Healthcare facilities are not equipped as well as reverse distributors to manage the hazardous waste and EPA is concerned that rejecting shipments of non-creditable hazardous waste will prolong mismanagement. Third, the Agency is finalizing as proposed that the EPA Regional Administrator may require reverse distributors to furnish additional reports concerning the quantities and disposition of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals. This provides the Agency with some flexibility in what reports may be required.

Comments and Responses. The Agency believes that commenters understood this provision to apply more broadly than we intended. We are aware that healthcare facilities often do not know whether a hazardous waste pharmaceutical will receive manufacturer credit at the reverse distributor. EPA did not intend for a reverse distributor to generate an unauthorized waste report each time a hazardous waste does not receive credit. Rather, a reverse distributor must generate an unauthorized waste report when it receives waste that it is not authorized to receive or manage. EPA reworded the regulations to include better examples of unauthorized waste, which includes, but is not limited to, non-pharmaceutical hazardous waste and medical or infectious waste.

In order to prevent exposing employees to unnecessary risk, EPA recommends as a best management practice that reverse distributors keep to a minimum the sorting of shipments that contain unauthorized waste since the shipment may include hazardous waste, including infectious or radioactive healthcare 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. Further, we recommend that reverse distributors work with their clients to reduce the occurrence of further inappropriate shipments.

i. Recordkeeping

Summary of Proposal. EPA proposed three recordkeeping requirements to provide transparency for the movement of potentially creditable hazardous waste pharmaceuticals and as a means of verification upon inspection. First, EPA proposed that a reverse distributor must keep a copy of its notification (EPA Form 8700–12) to EPA to indicate that it is a reverse distributor operating under 40 CFR part 266 subpart P. EPA proposed that a reverse distributor must keep the record of notification for as long as it is subject to these requirements. Second, EPA proposed that a reverse distributor must keep copies of the records associated with shipments of potentially creditable hazardous waste pharmaceuticals that it receives. This included a copy of the proposed advance notification from the healthcare facility or other reverse distributor, a copy of delivery confirmation, shipping papers or bills of loading, and any unauthorized waste reports. The Agency proposed that these shipping records must be kept for three years from the date the reverse distributor receives the shipment. Third, EPA proposed that a reverse distributor must keep a copy of its inventory at all times as long as the reverse distributor remains subject to this subpart. Finally, EPA proposed that periods of record retention indicated previously for a reverse distributor will be automatically extended during an enforcement action, or as requested by the EPA Regional Administrator to ensure that the appropriate records are available and can be reviewed as part of any enforcement action.

Summary of Comments. EPA received multiple comments on the recordkeeping requirements. GENCO did not support the recordkeeping requirements, arguing the requirements would impose burden.[428] Inmar, Inc. argued that reverse distributors are already required to keep records under other regulatory requirements related to receipt, storage, duration, and shipping of controlled and uncontrolled substances.[429]

Stericycle, Inc., the Healthcare Waste Institute of the National Waste and Recycling Association, and Waste Management National Services, Inc. expressed concern about the requirement that a reverse distributor must keep a copy of its inventory for as long as the facility is subject to this subpart.[430] Stericycle, Inc. argued that it is not reasonable to require the inventory be maintained for the life of the facility.[431] The Illinois Council of Health-System Pharmacists requested that EPA clarify whether reverse distributors must maintain only a current inventory or that all inventories as they change must be maintained.[432]

Final Rule Provisions. EPA is finalizing the proposed recordkeeping requirements at § 266.510(a)(10) with some minor changes in order to provide transparency for the movement of potentially creditable hazardous waste pharmaceuticals and as a means of verification upon inspection. First, EPA is finalizing that a reverse distributor must keep a copy of its notification (EPA Form 8700–12) to EPA to indicate that it is a reverse distributor operating under 40 CFR part 266 subpart P. A reverse distributor must keep the record of notification for as long as it is subject to these requirements.

Second, EPA is finalizing that a reverse distributor must keep copies of the records associated with shipments of potentially creditable hazardous waste pharmaceuticals that it receives. This includes a copy of delivery confirmation, shipping papers or bills of lading, and any unauthorized waste reports. We have revised the regulation language such that these shipping records must be kept for three years from the date the shipment arrives at the reverse distributor rather than when the reverse distributor "receives" the shipment since this standard is more precise.

Third, EPA is finalizing that a reverse distributor must keep a copy of its current inventory at all times as long as the reverse distributor remains subject to this subpart. The inventory is a living document that will constantly be updated and must be available for inspection. In order to clarify that a reverse distributor must maintain only a current inventory rather than all inventories even if they have changed, EPA revised the final regulatory language in § 266.510(a)(2) such that a reverse distributor must keep a copy of its current inventory. This recordkeeping change is being made to be consistent with that change in § 266.510(a)(2).

Finally, EPA is finalizing that periods of record retention referred to in this section are automatically extended during an enforcement action, or as requested by the EPA Regional Administrator to ensure that the appropriate records are available and can be reviewed as part of any

[428] See comment number EPA–HQ–RCRA–2007–0932–0336 in the docket for this rulemaking.

[429] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[430] See comment numbers EPA–HQ–RCRA–2007–0932–0280, EPA–HQ–RCRA–2007–0932–0296, and EPA–HQ–RCRA–2007–0932–0257 in the docket for this rulemaking.

[431] See comment number EPA–HQ–RCRA–2007–0932–0280 in the docket for this rulemaking.

[432] See comment number EPA–HQ–RCRA–2007–0932–0228 in the docket for this rulemaking.

enforcement action. The Agency recommends reverse distributors keep electronic versions of these records rather than paper or hard copy versions of these records.

Note that additional recordkeeping requirements may also pertain to reverse distributors. For example, a reverse distributor that manifests its non-pharmaceutical hazardous waste is subject to the manifest recordkeeping requirements of § 262.40. Further, as discussed in subsequent sections, there are additional recordkeeping requirements that apply to reverse distributors for the management of potentially creditable hazardous waste pharmaceuticals destined for another reverse distributor (§ 266.510(b)) and others that apply to reverse distributors for the management of evaluated hazardous waste pharmaceuticals (§ 266.510(c)).

2. Additional Standards for Reverse Distributors Managing Potentially Creditable Hazardous Waste Pharmaceuticals Destined for Another Reverse Distributor (§ 266.510(b))

This section discusses the additional standards that apply to a reverse distributor for the management of potentially creditable hazardous waste pharmaceuticals that require further evaluation or verification of manufacturer credit at another reverse distributor. Since these pharmaceuticals retain their value and there is greater incentive to manage them carefully in order to receive full manufacturer credit, EPA is requiring few regulatory standards for the management of the potentially creditable hazardous waste pharmaceuticals that are destined for another reverse distributor.

a. *Where potentially creditable hazardous waste pharmaceuticals can be sent.*

Summary of Proposal. EPA proposed a limit of three transfers of potentially creditable hazardous waste pharmaceuticals before the hazardous waste pharmaceuticals are ultimately transported to a permitted or interim status TSDF. The Agency proposed that the three possible types of transfers were:[433]

(1) A healthcare facility may send potentially creditable hazardous waste pharmaceuticals to a reverse distributor, which may or may not be a manufacturer;

(2) the first reverse distributor may send the potentially creditable hazardous waste pharmaceuticals to another reverse distributor, which may or may not be a manufacturer;

(3) the second reverse distributor can only send the potentially creditable hazardous waste pharmaceuticals on to a reverse distributor that is a manufacturer.

Because EPA proposed that each reverse distributor could accumulate hazardous waste pharmaceuticals up to 90 days after arriving at the reverse distributor, this proposed chain of transfers ensured that the potentially creditable hazardous waste pharmaceuticals would be accumulated for no more than 270 days in total after leaving a healthcare facility and before being transported to a RCRA-permitted or interim status TSDF for treatment and disposal.[434] As described previously, this is consistent with current practice among reverse distributors because of the contractual arrangements that reverse distributors have with specific manufacturers.

Summary of Comments. One state did not support allowing three transfers of potentially creditable hazardous waste pharmaceuticals before the hazardous waste pharmaceuticals are required to be transported to a TSDF and requested that EPA consider a maximum of two transfers prior to transportation to a TSDF.[435] Two industry commenters opposed EPA's proposed limit on the number of times a potentially creditable hazardous waste pharmaceutical may be transferred before it must be transported to a TSDF.[436] One of the industry commenters argued that reverse distributors have no knowledge about the pedigree of products prior to receipt and as such cannot be held accountable as to how many times a product is handled before transport to a TSDF.[437]

Final Rule Provisions. The final regulations for reverse distributors continue to be structured so that there is a limit to the number of transfers of potentially creditable hazardous waste pharmaceuticals that may occur before they are ultimately transported to a TSDF for treatment and disposal. Stakeholders expressed concern that the 2008 Pharmaceutical Universal Waste proposal would have allowed hazardous waste pharmaceuticals to be shipped repeatedly and indefinitely from one universal waste handler to another. From discussions with reverse distributors and reviewing comments received on the proposed rulemaking, the Agency believes a reasonable limit is three transfers of potentially creditable hazardous waste pharmaceuticals before the hazardous waste pharmaceutical is ultimately transported to a TSDF. The three possible types of transfers are:[438]

(1) A healthcare facility may send potentially creditable hazardous waste pharmaceuticals to a reverse distributor, which may or may not be a manufacturer;

(2) the first reverse distributor may send the potentially creditable hazardous waste pharmaceuticals to another reverse distributor, which may or may not be a manufacturer (§ 266.510(b)(1)); and

(3) the second reverse distributor can only send the potentially creditable hazardous waste pharmaceuticals on to a reverse distributor that is a manufacturer (§ 266.510(b)(2)).

Therefore, if a reverse distributor receives potentially creditable hazardous waste pharmaceuticals from a healthcare facility, the reverse distributor must send those potentially creditable hazardous waste pharmaceuticals to another reverse distributor (which may or may not be a manufacturer) or must manage them as evaluated hazardous waste pharmaceuticals under § 266.510(c). However, a reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from another reverse distributor is more limited in where it can send the potentially creditable hazardous waste pharmaceuticals. It can send potentially creditable hazardous waste pharmaceuticals to a reverse distributor that is the manufacturer or else must manage them as evaluated hazardous waste pharmaceuticals under § 266.510(c).

The Agency disagrees with the commenter who argued that reverse distributors cannot be accountable for how many times a hazardous waste pharmaceutical is transferred because reverse distributors do not have a record of transfers of the potentially creditable hazardous waste pharmaceuticals prior to receipt.[439] It is not necessary for a reverse distributor to have a record of previous transfers. It is only necessary for a reverse distributor to know

[433] A healthcare facility or reverse distributor also has the option of sending its hazardous waste pharmaceuticals to a RCRA-permitted or interim status TSDF.

[434] Although the proposal did allow for the possibility to request an accumulation time limit, the final rule does not.

[435] See comment number EPA–HQ–RCRA–2007–0932–0261 in the docket for this rulemaking.

[436] See comment numbers EPA–HQ–RCRA–2007–0932–0349 and EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[437] See comment number EPA–HQ–RCRA–2007–0932–0349 in the docket for this rulemaking.

[438] A healthcare facility or reverse distributor also has the option of sending its hazardous waste pharmaceuticals to a RCRA-permitted or interim status TSDF.

[439] See comment number EPA–HQ–RCRA–2007–0932–0349 in the docket for this rulemaking.

whether a shipment of potentially creditable hazardous waste pharmaceuticals originated from a healthcare facility or another reverse distributor. EPA believes it is reasonable for a reverse distributor to know the origin of a shipment that arrives at their facility.

Regardless of the origin or the destination of the potentially creditable hazardous waste pharmaceuticals, each reverse distributor must make an evaluation of them within 30 calendar days and may only accumulate the hazardous waste pharmaceuticals on site for no more than 180 calendar days after the evaluation before it ships them off-site to another reverse distributor or a RCRA-permitted or interim status TSDF (resulting in a maximum of 210 days). The 180 calendar day accumulation time starts after the 30 calendar days to make an evaluation. In the proposal, reverse distributors only had 90 days to accumulate hazardous waste pharmaceuticals on-site, including the 21 calendar days to make an evaluation. EPA made this conforming change to align with the change in § 266.510(a)(5) that allows reverse distributors to accumulate hazardous waste pharmaceuticals on-site for up to 180 calendar days without having interim status or a permit. In addition, all shipments of evaluated hazardous waste pharmaceuticals are subject to § 266.508 and shipments of all potentially creditable hazardous waste pharmaceuticals are subject to § 266.509.

Although this chain of transfers will allow potentially creditable hazardous waste pharmaceuticals to be accumulated for up to 630 days in total after leaving a healthcare facility and before being transported to a RCRA-permitted or interim status TSDF for treatment and disposal, EPA does not expect that potentially creditable hazardous waste pharmaceuticals will be accumulated for this time period in practice. First, it is unlikely that a reverse distributor will expend resources to accumulate potentially creditable hazardous waste pharmaceuticals on site for the full 180 calendar days if the potentially creditable hazardous waste pharmaceuticals are destined for another reverse distributor. Second, the desire to receive manufacturer credit in a timely manner will also make it unlikely that reverse distributors will accumulate potentially creditable hazardous waste pharmaceuticals for the full 180 days.

EPA anticipated that some healthcare facilities that are VSQGs will send their potentially creditable hazardous waste pharmaceuticals directly to reverse distributors. We allow for this under § 266.504(a). On the other hand, healthcare facilities that are VSQGs may choose to consolidate all their hazardous waste pharmaceuticals (both creditable and non-creditable) at an off site healthcare facility, as allowed by § 266.504(b). In this later case, the consolidated potentially creditable hazardous waste pharmaceuticals at an off-site VSQG in § 266.504(b) are not counted as one of the 3 allowable transfers of potentially creditable hazardous waste pharmaceuticals under § 266.510(b).

Under the final rule, manufacturers cannot send hazardous waste pharmaceuticals to a reverse distributor because the hazardous waste pharmaceuticals are no longer considered potentially creditable hazardous waste pharmaceuticals. Since manufacturers are unable to issue credit to themselves, it is not possible for the hazardous waste pharmaceuticals to be considered potentially creditable hazardous waste pharmaceuticals.

b. *Recordkeeping for reverse distributors shipping potentially creditable hazardous waste pharmaceuticals to another reverse distributor.*

Summary of Proposal. EPA proposed that reverse distributors must keep records (paper or electronic) for each shipment of potentially creditable hazardous waste pharmaceuticals that it initiates to another reverse distributor (whether it is a manufacturer or not). This included a copy of the advance notification provided to the other reverse distributor, a copy of delivery confirmation, as well as shipping papers or bill of lading. EPA proposed that the reverse distributor must keep these shipping records for three years from the date it initiates the shipment.

Summary of Comments. EPA received few comments on the recordkeeping requirements for reverse distributors that ship potentially creditable hazardous waste pharmaceuticals to another reverse distributor. One state asked EPA to clarify what it means by "shipping papers."[440]

Final Rule Provisions. EPA is finalizing in § 266.510(b)(4) that reverse distributors must keep records (paper or electronic) readily available upon request by an inspector for each shipment of potentially creditable hazardous waste pharmaceuticals that it initiates to another reverse distributor (whether it is a manufacturer or not). This includes a copy of delivery confirmation, as well as DOT shipping papers. EPA has clarified in the regulations that it is the DOT shipping papers prepared in accordance with 49 CFR part 172 subpart C we are referring to as "shipping papers"; EPA is not adding a requirement for additional shipping papers. The regulations do not specifically mention that reverse distributors keep a copy of a bill of lading, as this is only one type of shipping paper that reverse distributors can use to comply with 49 CFR part 172 subpart C. EPA is finalizing that these shipping records must be kept for three years from the date of shipment.

3. Additional Standards for Reverse Distributors Managing Evaluated Hazardous Waste Pharmaceuticals (§ 266.510(c))

This section discusses the additional standards that apply to a reverse distributor for the management of evaluated hazardous waste pharmaceuticals. In general, the term evaluated hazardous waste pharmaceuticals refers to hazardous waste pharmaceuticals that were potentially creditable hazardous waste pharmaceuticals but have been evaluated by a reverse distributor to establish whether they are eligible for manufacturer credit and will not be sent to another reverse distributor for further evaluation or verification. While potentially creditable hazardous waste pharmaceuticals have value in the form of manufacturer credit, evaluated hazardous waste pharmaceuticals do not. Therefore, in order to minimize the potential for their mismanagement, EPA believes it is necessary to have additional standards for the evaluated hazardous waste pharmaceuticals. These standards generally resemble the standards for LQG CAAs.

a. *Accumulation area.*

Summary of Proposal. EPA proposed that once a reverse distributor completes its evaluation of a potentially creditable hazardous waste pharmaceutical and the reverse distributor knows that the hazardous waste pharmaceutical is destined for treatment and disposal at a RCRA-permitted or interim status TSDF, rather than another reverse distributor, the pharmaceutical is considered an evaluated hazardous waste pharmaceutical. EPA proposed that a reverse distributor must establish an on-site accumulation area where it will accumulate these evaluated hazardous waste pharmaceuticals. An on-site accumulation area is needed so that the evaluated hazardous waste pharmaceuticals are segregated and clearly distinguished from the

[440] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

potentially creditable hazardous waste pharmaceuticals.

Summary of Comments. One state supported the requirement for reverse distributors to establish on-site accumulation areas for evaluated hazardous waste pharmaceuticals.[441]

Final Rule Provisions. EPA is finalizing as proposed that a reverse distributor must establish an on-site accumulation area where it will accumulate evaluated hazardous waste pharmaceuticals in § 266.510(c)(1). An on-site accumulation area is needed so that the evaluated hazardous waste pharmaceuticals are segregated and clearly distinguished from the potentially creditable hazardous waste pharmaceuticals that have fewer requirements and are destined for another reverse distributor.

b. *Weekly inspections.*

Summary of Proposal. EPA proposed that the accumulation area for evaluated hazardous waste pharmaceuticals must be inspected at least weekly to ensure containers are not leaking and that diversion of the evaluated hazardous waste pharmaceuticals is not occurring. Under the recordkeeping requirements for reverse distributors, the Agency proposed that a reverse distributor must keep a log of the weekly inspections of the on-site accumulation area and that the log must be retained for at least three years from the date of inspection. The log is necessary to validate the weekly inspections.

Summary of Comments. One state commented that weekly inspections are not sufficient to determine whether or not diversion of evaluated hazardous waste pharmaceuticals is occurring and requested EPA require additional security provisions.[442] Washington State Department of Ecology requested that EPA clarify the intent of "at least weekly" and argued that they interpret "at least weekly" to mean once within every seven days.[443]

Final Rule Provisions. In response to comments, EPA is finalizing that the accumulation area for evaluated hazardous waste pharmaceuticals must be inspected at least once every seven days to ensure containers are not leaking and that diversion of the hazardous waste pharmaceuticals is not occurring. We agree with the commenter that phrasing the standard as "at least once every seven days" is more precise than "at least weekly" and will avoid the situation where a reverse distributor could inspect early in one week and late the following week and still claim it is inspecting weekly. Under the recordkeeping requirements for reverse distributors in § 266.510(c)(10), the Agency is finalizing that a reverse distributor must keep a log of the weekly inspections of the on-site accumulation area and that the log must be retained for at least three years from the date of inspection. The log is necessary to validate the weekly inspections.

c. *Personnel training.*

Summary of Proposal. EPA proposed to require that reverse distributors meet the same federal classroom or on-the-job personnel training regulations that LQGs must meet (§ 265.16). However, the Agency specified in the proposal that the personnel that need to be trained are those persons who handle the evaluated hazardous waste pharmaceuticals in the on-site accumulation area. EPA argues that these personnel are the individuals handling and managing the evaluated hazardous waste pharmaceuticals and must have appropriate hazardous waste training.

Summary of Comments. Two industry commenters and one state supported the personnel training criteria for reverse distributors.[444] One state argued that the training requirements should be applied to the personnel who handle potentially creditable hazardous waste pharmaceuticals in addition to the personnel who handle evaluated hazardous waste pharmaceuticals on site.[445] Inmar, Inc. pointed out that personnel at reverse distributors are already required to receive training under other regulatory requirements.[446]

Final Rule Provisions. Under the final rule, reverse distributors must meet the same classroom or on-the-job personnel training requirements that LQGs must meet. EPA is finalizing that the personnel that need to be trained are those persons who handle the evaluated hazardous waste pharmaceuticals. Since these personnel are the individuals handling and managing the hazardous waste pharmaceuticals, they must have appropriate hazardous waste training. As mentioned previously, EPA received multiple comments in support of the training requirements for reverse distributors. Additionally, EPA does not believe the training requirements will add burden because EPA believes most reverse distributors currently operate as LQGs.[447] Since the proposed rulemaking, the 2016 Hazardous Waste Generator Improvement rule was finalized. As part of its reorganization, the personnel training regulations for LQGs are now incorporated into § 262.17(a)(7) and no longer refer to § 265.16. As a result, the § 266.510(c)(3) training requirements for personnel managing evaluated hazardous waste pharmaceuticals at reverse distributors now reference § 262.17(a)(7) instead of § 265.16.

d. *Labeling and management of containers in on-site accumulation area.*

Summary of Proposal. EPA proposed that while containers of evaluated hazardous waste pharmaceuticals are in the on-site accumulation area, they must be marked with the words, "hazardous waste pharmaceuticals." EPA proposed this term in order to distinguish them from the non-hazardous waste pharmaceuticals and from the hazardous waste pharmaceuticals that are still considered potentially creditable. The Agency did not propose to require an accumulation start date on the label for the containers of evaluated hazardous waste pharmaceuticals.

In terms of container management standards, the Agency proposed requirements that are similar to the container management standards for LQGs, but the Agency proposed to include some requirements specific to evaluated hazardous waste pharmaceuticals. For example, LQGs must keep all containers of hazardous waste closed. However, EPA proposed to require that only containers with hazardous waste pharmaceuticals that are liquids or gels be kept closed during accumulation due to the low potential for release to the environment for those hazardous waste pharmaceuticals that are in a solid form. The Agency did not propose to require other containers of evaluated hazardous waste pharmaceuticals to be closed during accumulation, although we expect that reverse distributors would choose to do so as a best management practice. Further, because most evaluated hazardous waste pharmaceuticals are in their original packaging, we proposed that if the original packaging for gels or liquids is intact and sealed or the pharmaceuticals have been repackaged (*e.g.,* for unit dosing) and the repackaged packaging for gels and liquids is intact and sealed, they are

[441] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[442] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[443] See comment number EPA–HQ–RCRA–2007–0932–0272 in the docket for this rulemaking.

[444] See comment numbers EPA–HQ–RCRA–2007–0932–0280, EPA–HQ–RCRA–2007–0932–0296, and EPA–HQ–RCRA–2007–0932–0304 in the docket for this rulemaking.

[445] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[446] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[447] See the Regulatory Impact Analysis in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

considered to meet the proposed closed container standard.

As with LQGs, EPA proposed that containers of evaluated hazardous waste pharmaceuticals must be maintained in good condition to prevent leaks and the container material must be compatible with the evaluated hazardous waste pharmaceuticals placed in the container. Another requirement that was tailored to reverse distributors was the proposal that reverse distributors that accumulate evaluated hazardous waste pharmaceuticals must segregate the pharmaceuticals that are prohibited from being combusted because of the dilution prohibition of § 268.3(c) and accumulate them in separate containers from other evaluated hazardous waste pharmaceuticals.

The LQG regulations in part 262 include management standards for several types of accumulation units that EPA did not propose to include for the management of evaluated hazardous waste pharmaceuticals. For instance, the proposal only set standards for the accumulation of evaluated hazardous waste pharmaceuticals in containers. EPA did not think it was necessary to include standards for accumulation units such as tanks, containment buildings, or drip pads because reverse distributors do not currently use these types of accumulation units. In addition, the Agency did not propose to require reverse distributors to meet the air emission standards found in 40 CFR part 265 subpart CC as required in § 262.34(a)(1)(i) for LQGs because the Agency anticipated that they will not be applicable. Additionally, 40 CFR part 265 subpart AA—air emissions standards for process vents—and subpart BB—air emission standards for equipment leaks—are not applicable to the activities of a reverse distributor.

Summary of Comments. EPA received numerous comments on the proposed requirements for labeling and management of containers of evaluated hazardous waste pharmaceuticals in on-site accumulation areas at reverse distributors. One state supported that containers be marked with the words "hazardous waste pharmaceuticals," but three states and one industry commenter requested that EPA require reverse distributors to label containers with the accumulation start date.[448] Stericycle, Inc. agreed that there is not a need to include standards for accumulation units such as tanks, containment buildings, or drip pads.[449] Clean Harbors argued that the only way to prevent diversion of hazardous waste pharmaceuticals is for all containers to be closed and sealed.[450] One state requested that EPA prohibit reverse distributors from mixing or commingling incompatible hazardous waste pharmaceuticals in the same container rather than only requiring reverse distributors to manage containers to prevent dangerous situations, such as fire explosion or release of toxic fumes.[451] One commenter agreed that the 40 CFR part 265 subpart AA—air emissions standards for process vents—and subpart BB—air emission standards for equipment leaks—are not applicable to the activities of a reverse distributor and its management of hazardous waste pharmaceuticals.[452]

Final Rule Provisions. Final standards for labeling and management of containers at an on-site accumulation area are found at § 266.510(c)(4). EPA is finalizing that while containers of evaluated hazardous waste pharmaceuticals are in the accumulation area, they must be marked with the words, "hazardous waste pharmaceuticals." Under the final rule, reverse distributors are not required to mark an accumulation start date on the label for the containers, because the reverse distributor's inventory will likely be used to verify the accumulation start date. However, a reverse distributor may choose an alternate method, such as marking the date on each container, to ensure that the containers of evaluated hazardous waste pharmaceuticals are not accumulated at the reverse distributor for more than 180 days. As explained previously, EPA prefers to allow a performance-based standard that allows flexibility to verify the 180-day accumulation time rather than require dating on the container labels. Most of the commenters that requested accumulation start dates on labels were states. Although the requirement is not being finalized at the federal level, any authorized state has the ability to impose more stringent regulations. If a state chooses to require the accumulation start date on the container label, that would be considered more stringent and permissible under RCRA.

In terms of container management standards, the Agency is finalizing the proposed requirements that are similar to the container management standards for LQGs as well as the additional management requirements specific to evaluated hazardous waste pharmaceuticals. Specifically, only containers with evaluated hazardous waste pharmaceuticals that are liquids or gels must be kept closed during accumulation, although EPA expects that all containers of evaluated hazardous waste pharmaceuticals will be closed given that evaluated hazardous waste pharmaceuticals are in their original packaging. As with the proposal, if the original packaging for gels or liquids is intact and sealed or the pharmaceuticals have been repackaged (*e.g.,* for unit dosing) and the repackaged packaging for gels and liquids is intact and sealed, they are considered to meet the closed container standard.

EPA is also finalizing that containers of evaluated hazardous waste pharmaceuticals must be maintained in good condition to prevent leaks and the container material must be compatible with the hazardous waste pharmaceuticals placed in the container. In addition, a reverse distributor that manages any container of ignitable or reactive evaluated hazardous waste pharmaceuticals or any container of commingled incompatible evaluated hazardous waste pharmaceuticals must manage the container to prevent dangerous situations, such as fire, explosion, or release of toxic fumes. These regulations are consistent with the LQG container management regulations in part 262 and already apply to LQG reverse distributors accumulating hazardous waste on site. The Agency is also finalizing that reverse distributors that accumulate evaluated hazardous waste pharmaceuticals must segregate the pharmaceuticals that are prohibited from being combusted because of the dilution prohibition of § 268.3(c) and accumulate them in separate containers from other evaluated hazardous waste pharmaceuticals. The dilution prohibition of § 268.3(c) already prohibits the incineration of some hazardous waste pharmaceuticals. This new provision highlights this prohibition to the reverse distributors accumulating the hazardous waste pharmaceuticals prior to sending off site for treatment and disposal.

Comments and Responses. EPA is finalizing management standards only for containers used to accumulate evaluated hazardous waste pharmaceuticals because commenters

[448] See comment numbers EPA–HQ–RCRA–2007–0932–0211, EPA–HQ–RCRA–2007–0932–0235, EPA–HQ–RCRA–2007–0932–0341, and EPA–HQ–RCRA–2007–0932–0257 in the docket for this rulemaking.

[449] See comment number EPA–HQ–RCRA–2007–0932–0280 in the docket for this rulemaking.

[450] See comment number EPA–HQ–RCRA–2007–0932–0333 in the docket for this rulemaking.

[451] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[452] See comment number EPA–HQ–RCRA–2007–0932–0296 in the docket for this rulemaking.

confirmed that reverse distributors do not use other types of hazardous waste accumulation units, such as tanks, containment buildings, or drip pads.

In addition, the Agency is not requiring reverse distributors to meet the air emission standards found in 40 CFR part 265 subpart CC as required for LQGs in § 262.17(a)(1)(i) because the Agency anticipates that they will not be applicable. Specifically, § 265.1083(c) of subpart CC exempts tanks, surface impoundments, and containers from the organic air emission standards if the hazardous waste entering the accumulation unit has an average volatile organic concentration of less than 500 parts per million by weight, while § 265.1080(b)(2) of subpart CC exempts containers with a capacity of less than 0.1 m^3 (26 gallons) from the standards. EPA understands that the only evaluated hazardous waste pharmaceuticals that have the potential for air emissions are liquids and gels, but they generally do not contain volatile organics. Thus, they do not release organic air emissions, which is what the 40 CFR part 265 subpart CC air emission standards for tanks, surface impoundments, and containers were promulgated to control. Moreover, because evaluated hazardous waste pharmaceuticals are often in their original packaging, and EPA is requiring that liquid and gel evaluated hazardous waste pharmaceuticals must be in intact, sealed packaging or otherwise in closed containers, EPA believes that the container air emission standards are unnecessary. In addition, the Agency anticipates that the packaging and containers for hazardous waste pharmaceuticals will have a capacity of less than 0.1 m^3 (26 gallons) further limiting the applicability of the container air emission standards. Similarly, EPA does not anticipate that the 40 CFR part 265 subpart AA (air emissions standards for process vents) and subpart BB (air emission standards for equipment leaks) are applicable to the activities of a reverse distributor and its management of evaluated hazardous waste pharmaceuticals. Therefore, like 40 CFR part 265 subpart CC discussed previously, EPA is not requiring that 40 CFR part 265 subparts AA and BB apply to reverse distributors.

e. *Hazardous waste numbers (codes).*

Summary of Proposal. EPA proposed that RCRA hazardous waste numbers (commonly called "hazardous waste codes") must be marked on the container label in order to ensure that they are readily visible and cannot be separated from the hazardous waste. In the proposal, the Agency did not require that the reverse distributor be the party that adds the hazardous waste codes to the containers. The proposed regulations allowed a vendor to perform this duty on behalf of the reverse distributor.

Summary of Comments. Two states supported the requirement that hazardous waste codes be placed on containers of evaluated hazardous waste pharmaceuticals.[453] Waste Management National Services, Inc. argued that it is not practical to include all hazardous waste codes on each container label and instead suggested that codes be listed on the hazardous waste profile developed with the TSDF and on the manifest.[454]

Final Rule Provisions. Under the final rule, EPA is requiring that the containers of evaluated hazardous waste pharmaceuticals be marked with the applicable RCRA hazardous waste numbers (codes) at § 266.510(c)(5). The hazardous waste codes must be added prior to shipping evaluated hazardous waste pharmaceuticals off site, although they may be placed on the container label at any time during on-site accumulation. The hazardous waste numbers must be marked on the container label in order to ensure that it is readily visible and cannot be separated from the hazardous waste. It is necessary that the hazardous waste numbers are on the containers so that transporters, transfer facilities, and TSDFs know how to properly transport, consolidate, treat, store and dispose of the hazardous waste in compliance with the applicable RCRA regulations. In the final rule, the Agency is not requiring that the reverse distributor be the party that adds the hazardous waste numbers to the containers. The regulations allow a vendor to perform this duty on behalf of the reverse distributor. In practice, however, if a vendor is responsible for assigning hazardous waste numbers, personnel from the reverse distributor may need to assist in the process. To be consistent with the Hazardous Waste Generator Improvements final rule, we have added a sentence to § 266.510(c)(5) indicating that a nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the EPA Hazardous Waste number(s).

f. *Shipping evaluated hazardous waste pharmaceuticals.*

Summary of Proposal. Although it is already stated in § 266.508(a) under the section of the regulations that pertains to shipping standards, for clarity, EPA proposed to repeat in the § 266.510 the reverse distributor regulations that reverse distributors that ship evaluated hazardous waste pharmaceuticals off site must do so in accordance with the proposed shipping requirements in § 266.508(a). This includes the applicable DOT packaging, marking and labeling requirements, as well as the requirement to utilize the hazardous waste manifest when shipping the evaluated hazardous waste to a designated facility.

Summary of Comments. Two states generally supported the shipping requirements for evaluated hazardous waste pharmaceuticals.[455] One state supported that EPA repeat in § 266.510 the requirements pertaining to shipping standards although it is already stated in § 266.508(a).[456]

Final Rule Provisions. For clarity, the final reverse distributor regulations state that a reverse distributor must ship evaluated hazardous waste pharmaceuticals that are destined for a permitted or interim status treatment, storage or disposal facility in accordance with the applicable shipping standards in § 266.508(a) or (b). This includes the applicable DOT packaging, marking and labeling requirements, as well as the requirement to utilize the hazardous waste manifest when shipping the evaluated hazardous waste to a permitted or interim status TSDF.

g. *Procedures for managing rejected shipments.*

Summary of Proposal. The Agency proposed to require that reverse distributors meet the same procedures that LQGs must meet for rejected shipments in § 262.42(c). Specifically, if a designated permitted or interim status TSDF identified on the hazardous waste manifest cannot accept a shipment of evaluated hazardous waste pharmaceuticals from a reverse distributor and the TSDF returns the shipment to the reverse distributor, EPA proposed that the reverse distributor must sign either item 18c of the original manifest or item 20 of a new manifest. In addition, the proposal allowed the reverse distributor to consolidate the rejected hazardous waste pharmaceuticals on site for up to 90 days provided they were managed in the on-site accumulation area and in accordance with the reverse distributor standards for evaluated hazardous waste pharmaceuticals. EPA also proposed that reverse distributors send a copy of

[453] See comment numbers EPA–HQ–RCRA–2007–0932–0300 and EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[454] See comment number EPA–HQ–RCRA–2007–0932–0257 in the docket for this rulemaking.

[455] See comment numbers EPA–HQ–RCRA–2007–0932–0261 and EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[456] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

the manifest to the designated facility that returned the shipment to the reverse distributor within 30 days of delivery.

Summary of Comments. One state requested the EPA clarify that a reverse distributor that receives a rejected shipment does not have to transport it off site upon receipt by the reverse distributor.[457] One state argued that a reverse distributor does not need 90 days to accumulate rejected hazardous waste pharmaceuticals in the on-site accumulation area and argued that 30 days is sufficient.[458]

Final Rule Provisions. The Agency is finalizing in § 266.510(c)(7) that reverse distributors must meet the same procedures that LQGs must meet for rejected shipments in § 262.42(c). Under part 262, these rejected shipment procedures already apply to LQG reverse distributors. Furthermore, EPA anticipates that a rejected shipment is a relatively infrequent occurrence and therefore should not be a burden to reverse distributors. In addition, the final rule allows the reverse distributor to consolidate the rejected hazardous waste pharmaceuticals on site for up to 90 days provided they are managed in the on-site accumulation area and in accordance with the reverse distributor standards for evaluated hazardous waste pharmaceuticals. Although one state requested EPA only allow accumulation for 30 days, any authorized state has the ability to impose more stringent regulations. If a state chooses to shorten the accumulation time, that would be considered more stringent and permissible under RCRA.

h. *Land disposal restrictions.*

Summary of Proposal. EPA proposed that reverse distributors are subject to the same LDRs that apply to LQGs with respect to their evaluated hazardous waste pharmaceuticals. In addition, EPA proposed to amend the testing, tracking, and recordkeeping requirements for generators, treaters and disposal facilities at § 268.7 to add the words, "pharmaceutical reverse distributors" to the title of that section to make the applicability of the treatment standards clear.

Summary of Comments. EPA received multiple comments in support of the requirement that reverse distributors meet the same LDRs that apply to LQGs with respect to their evaluated hazardous waste pharmaceuticals, including two states.[459] The Oregon Association of Clean Water Agencies wrote that applying the LDRs will reduce mobility of pharmaceutical constituents in landfill leachate, which is frequently routed to POTWs in Oregon.[460]

Final Rule Provisions. As required by HSWA, EPA is finalizing that reverse distributors are subject to the same land disposal restrictions that apply to LQGs with respect to their evaluated hazardous waste pharmaceuticals. In addition, EPA is amending the titles at §§ 268.7 and 268.7(a) to add the words, "reverse distributors" to make the applicability of the land disposal restrictions clear. SQG and LQG reverse distributors are already subject to LDRs for their hazardous waste pharmaceuticals. Therefore, this provision does not impose additional burden on reverse distributors.

i. *Reporting.*

Summary of Proposal. EPA proposed that reverse distributors submit a biennial report (BR) for the evaluated hazardous waste pharmaceuticals that are transported to a TSDF in order for the Agency to have as complete a picture of the amount of hazardous waste generated, treated, stored, or disposed of annually. The Agency proposed that the BR should only include the evaluated hazardous waste pharmaceuticals, and not the potentially creditable hazardous waste pharmaceuticals that a reverse distributor sends to another reverse distributor. Specifically, EPA proposed that a reverse distributor comply with the LQG BR requirements in § 262.41, except for § 262.41(a)(7), which included the requirement to report changes in volume and toxicity of waste achieved during the year in comparison to previous years. The Agency did not propose that a reverse distributor provide such information because it does not have control of the volume or toxicity of the hazardous waste pharmaceuticals it receives from healthcare facilities, and thus has no ability to reduce the volume or toxicity of the hazardous waste pharmaceuticals.

EPA proposed that reverse distributors provide an exception report when a TSDF does not return the hazardous waste manifest to the reverse distributor for shipments of evaluated hazardous waste pharmaceuticals. Likewise, EPA proposed that reverse distributors meet LQG exception reporting when a shipment from a reverse distributor is rejected by the designated facility and forwarded onto an alternate facility. These proposed standards were adapted from the exception reporting for LQGs in § 262.42(a).

Summary of Comments. One state supported both of the proposed reporting requirements for reverse distributors managing evaluated hazardous waste pharmaceuticals that are transported to a TSDF.[461] RILA argued that the requirement that reverse distributors submit a BR for the evaluated hazardous waste pharmaceuticals that are transported to a TSDF is effectively more stringent than current generator requirements that only require generators to submit a biennial report if they generate over 1000 kg of hazardous waste in a month.[462]

Final Rule Provisions. EPA is finalizing at § 266.510(c)(9)(i) that reverse distributors submit a BR for the evaluated hazardous waste pharmaceuticals that are transported to a TSDF in order for the Agency to have as complete a picture of the amount of hazardous waste generated, treated, stored, or disposed of annually. The BR should only include the evaluated hazardous waste pharmaceuticals, and not the potentially creditable hazardous waste pharmaceuticals that a reverse distributor sends to another reverse distributor. EPA does not expect that requiring reverse distributors to submit a BR for evaluated hazardous waste pharmaceuticals will be burdensome because most reverse distributors currently operate as LQGs and already submit a BR.[463] Specifically, under the final rule, reverse distributors must comply with the LQG BR requirements in § 262.41. EPA proposed that reverse distributors had to comply with the LQG BR requirements in § 262.41 except § 262.41(a)(7), which included the requirement to report changes in volume and toxicity of waste achieved during the year in comparison to previous years. However, since the proposed rulemaking, the 2016 Hazardous Waste Generator Improvement rule was finalized. As part of that final rule, § 262.41(a)(7) was removed from the generator requirements. Thus, the final rule only states that reverse distributors must

[457] See comment number EPA–HQ–RCRA–2007–0932–0231 in the docket for this rulemaking.

[458] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[459] See comment numbers EPA–HQ–RCRA–2007–0932–0315 and EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[460] See comment number EPA–HQ–RCRA–2007–0932–0288 in the docket for this rulemaking.

[461] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[462] See comment number EPA–HQ–RCRA–2007–0932–0295 in the docket for this rulemaking.

[463] See the Regulatory Impact Analysis in the docket for this rulemaking EPA–HQ–RCRA–2007–0932.

comply with the LQG BR requirements in § 262.41.

Consistent with the LQG regulations in part 262, EPA is finalizing at § 266.510(c)(9)(ii) that reverse distributors must provide an exception report when a TSDF does not return the signed hazardous waste manifest to the reverse distributor for shipments of hazardous waste pharmaceuticals to a designated facility within 45 days of shipment. Likewise, EPA is finalizing that reverse distributors must provide an exception report when a shipment from a reverse distributor is rejected by the designated facility and forwarded onto an alternate facility and the reverse distributor does not receive a copy of the manifest with the signature of the owner or operator of the alternate facility within 35 days. These standards were adapted from the exception reporting for LQGs in § 262.42(a), while the standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals were adapted from the exception reporting for SQGs § 262.42(b). EPA is finalizing that a reverse distributor that does not receive a copy of the manifest within 35 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter must contact the transporter or TSDF to determinate the status of the evaluated hazardous waste pharmaceuticals. EPA is also finalizing that a reverse distributor must submit a copy of an exception report if it has not received a copy of the manifest within 45 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter. The exception report must include a legible copy of the manifest for which the reverse distributor does not have confirmation of delivery and a cover letter explaining efforts taken to locate the evaluated hazardous waste pharmaceuticals.

j. *Recordkeeping.*

Summary of Proposal. In total, EPA proposed five recordkeeping requirements that pertain to evaluated hazardous waste pharmaceuticals at reverse distributors. First, EPA proposed that a reverse distributor keep a log (written or electronic) of its weekly inspections of the on-site accumulation area. The other four recordkeeping requirements that EPA proposed for reverse distributors are the same as the LQG recordkeeping requirements that appear in §§ 262.17(a)(7)(iv) and (v), 262.40, and 262.42; these include training documentation, hazardous waste manifest records, records of biennial reports, and exception reporting.

Summary of Comments. Hennepin County supported the requirement for reverse distributors to document training.[464]

Final Rule Provisions. Many of the final recordkeeping requirements that pertain to evaluated hazardous waste pharmaceuticals have been discussed in the sections previously, but for clarity, it is useful to restate them in this recordkeeping section, so that reverse distributors can refer to one section to determine their recordkeeping requirements related to evaluated hazardous waste pharmaceuticals. In total, EPA is finalizing five recordkeeping requirements that pertain to evaluated hazardous waste pharmaceuticals at reverse distributors that can be found listed at § 266.510(c)(10). First, EPA is requiring that a reverse distributor keep a log (written or electronic) of its inspections of the on-site accumulation area. The other four recordkeeping requirements that EPA is requiring under the final rule for reverse distributors are the same as the LQG recordkeeping requirements in part 262. These include hazardous waste manifest records, records of biennial reports, exception reporting and training documentation.

4. When a Reverse Distributor Must Have a RCRA Hazardous Waste Permit (§ 266.510(d))

a. *Summary of proposal.* In the proposed rulemaking, EPA did not require that a reverse distributor have a RCRA permit or interim status for accumulating potentially creditable and evaluated hazardous waste pharmaceuticals, provided that the reverse distributor follows all the conditions of the permitting exemption in § 266.510. However, EPA proposed that a reverse distributor must have a RCRA permit (or interim status) if it treats or disposes of hazardous waste on site or if it accepts manifested hazardous waste from off site.

b. *Summary of comments.* One state supported the proposed requirement that a reverse distributor must have a RCRA permit (or interim status) if it treats or disposes of hazardous waste on site or if it accepts manifested hazardous waste from off site.[465] Clean Harbors argued that EPA's rationale for not requiring a hazardous waste storage permit is flawed and argued that the requirement for obtaining a full RCRA permit be based on the amount of time a potentially creditable hazardous waste pharmaceutical is stored.[466] The Environmental Technology Council argued that reverse distributors should be required to obtain permits or interim status for storage.[467]

c. *Final rule provisions.* Under the final rule, EPA is not requiring that a reverse distributor have a RCRA permit or interim status for accumulating potentially creditable and evaluated hazardous waste pharmaceuticals, provided that the reverse distributor follows all the conditions of the permitting exemption in § 266.510. In other words, a reverse distributor will be subject to regulation as a TSDF and require a RCRA permit (or interim status) if it does not meet the conditions of § 266.510. In addition, EPA is finalizing that a reverse distributor must have a RCRA permit (or interim status) if it treats or disposes of hazardous waste on site or if it accepts manifested hazardous waste from off site. A reverse distributor is required to reject shipments of manifested hazardous waste that it may inadvertently receive from off site because a reverse distributor is not a designated facility and therefore is not eligible to receive hazardous waste shipped with a manifest. EPA believes that this approach to regulation of reverse distributors that accumulate potentially creditable and evaluated hazardous waste pharmaceuticals strikes an appropriate balance because it recognizes that reverse distributors are different from typical hazardous waste TSDFs for permitting purposes, while it still imposes certain conditions for exemption from permitting requirements that provide the necessary environmental protection.

XVIII. Amendments to the Part 268 Prohibitions on Storage

The Agency is finalizing conforming changes that we proposed to the prohibitions on storage of restricted waste in § 268.50. We are finalizing two new subparagraphs in § 268.50(a) to make it clear that the storage prohibitions apply to both healthcare facilities and reverse distributors operating under part 266 subpart P. Specifically, we are adding paragraph (4) for healthcare facilities and paragraph (5) for reverse distributors to extend the application of the existing storage prohibition to facilities operating under subpart P. Under the LDR storage prohibition the storage of restricted hazardous wastes is

[464] See comment number EPA–HQ–RCRA–2007–0932–0386 in the docket for this rulemaking.

[465] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[466] See comment number EPA–HQ–RCRA–2007–0932–0333 in the docket for this rulemaking.

[467] See comment number EPA–HQ–RCRA–2007–0932–0297 in the docket for this rulemaking.

prohibited unless certain conditions are met. Healthcare facilities must comply with the applicable requirements in §§ 266.502 and 266.503 and reverse distributors must comply with § 266.510 when accumulating hazardous waste pharmaceuticals on site.

XIX. Implementation and Enforcement

A. Healthcare Facilities

1. Determining Whether a Healthcare Facility Is Subject to Part 266 Subpart P

EPA is finalizing that healthcare facilities that are currently considered LQGs or SQGs are subject to the final 40 CFR part 266 subpart P requirements for the management of hazardous waste pharmaceuticals. Thus, a healthcare facility that generates more than 100 kg of hazardous waste per month, or more than 1 kg of acute hazardous waste per calendar month, or more than 100 kg of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute wastes listed in §§ 261.31, or 261.33(e), must manage its hazardous waste pharmaceuticals in compliance with the 40 CFR part 266 subpart P requirements. In addition, healthcare facilities that are VSQGs are subject to the prohibition on sewering hazardous waste pharmaceuticals in § 266.505, the empty container standards in § 266.507, and the optional standards of § 266.504.

To determine whether a healthcare facility is subject to 40 CFR part 266 subpart P or is a VSQG regulated under § 262.14, a healthcare facility must count all the hazardous waste—pharmaceutical and non-pharmaceutical—it generates in a calendar month. Note that in the final rule EPA has revised which pharmaceuticals are considered hazardous wastes. Specifically, EPA is finalizing that potentially creditable hazardous waste pharmaceuticals transported to a reverse distributor are considered a solid and hazardous waste from the point of generation at the healthcare facility and therefore must be counted when determining whether the healthcare facility is a VSQG regulated under § 262.14 or whether it is regulated under 40 CFR part 266 subpart P for its hazardous waste pharmaceuticals. This differs from previous healthcare facility practice of not counting the potentially creditable hazardous waste pharmaceuticals it sends to a reverse distributor towards its hazardous waste generator category. Therefore, although a healthcare facility may have been considered a VSQG under that previous practice, when it begins counting its potentially creditable hazardous waste pharmaceuticals, it may no longer be a VSQG. In that case, the healthcare facility would be subject to the 40 CFR part 266 subpart P requirements for its hazardous waste pharmaceuticals.

2. Healthcare Facilities Managing Hazardous Waste Pharmaceuticals Under Part 266 Subpart P

EPA is finalizing that all healthcare facilities operating Under part 266 subpart P will be subject to the same regulations for the management of their hazardous waste pharmaceuticals, regardless of the quantity of hazardous waste pharmaceuticals generated. A healthcare facility that generates both pharmaceutical and non-pharmaceutical hazardous waste must manage the non-pharmaceutical hazardous waste pursuant to part 262, but need not count its hazardous waste pharmaceuticals toward determining the facility's monthly hazardous waste generator category. Therefore, although a facility that previously may have been considered an LQG, once it no longer counts its hazardous waste pharmaceuticals towards its monthly hazardous waste generator category, it may no longer be an LQG. As a result, it is possible that the healthcare facility may not need to manage its non-pharmaceutical hazardous waste pursuant to the LQG regulations in § 262.17, but rather can operate under the reduced regulations for SQGs in § 262.16 or for VSQGs in § 262.14. In addition, if a healthcare facility that is a VSQG does not want to keep track of the amount of hazardous waste pharmaceuticals it generates to ensure it does not exceed the VSQG quantity limits, it can choose to operate under this final rule. If it chooses to operate under this final rule, however, a healthcare facility must comply with all the requirements of this subpart for the management of its hazardous waste pharmaceuticals.

Following publication of the final rule, EPA plans extensive outreach to educate healthcare facilities and reverse distributors on the provisions of this final rule.

B. Reverse Distributors and Reverse Logistics Centers

1. Prescription Pharmaceuticals Sent to Reverse Distributors Are Solid Wastes

EPA proposed to change how RCRA would apply to pharmaceuticals returned to reverse distributors to obtain manufacturers credit. EPA proposed that the decision by a healthcare facility to send a pharmaceutical to a reverse distributor is the decision to discard the pharmaceutical. Due to many comments on this proposed change, the Agency is now making a clear distinction in the final rule between reverse distribution, in the case of prescription pharmaceuticals, and reverse logistics in the case of all other pharmaceuticals—including over-the counter pharmaceuticals and dietary supplements, as well as other unsold consumer items (see section VI for a discussion of the comments). EPA is finalizing that the decision by a healthcare facility to send a prescription pharmaceutical to a reverse distributor is the decision to discard the prescription pharmaceutical. Therefore, under this final rule, once the healthcare facility makes the decision to send a prescription pharmaceutical to a reverse distributor for credit, it is a solid waste at the healthcare facility. A portion of the potentially creditable solid waste prescription pharmaceuticals at healthcare facilities that are destined for a reverse distributor will also meet the definition of hazardous waste and as a result, these potentially creditable hazardous waste prescription pharmaceuticals would need to be managed in accordance with the final 40 CFR part 266 subpart P requirements.

In addition, the Agency notes that the change in EPA's position concerning reverse distribution and the management standards discussed in this final rule pertain only to the reverse distribution of prescription hazardous waste pharmaceuticals and does not apply to the reverse logistics of other pharmaceuticals or to the reverse logistics systems that may exist for other unsold consumer items.

2. Nonprescription Pharmaceuticals Sent to Reverse Logistics Centers Are Not Solid Wastes

EPA proposed that the decision by a healthcare facility to send any pharmaceutical to a reverse distributor is the decision to discard the pharmaceutical, but is now making a clear distinction in the final rule between reverse distribution of prescription pharmaceuticals and reverse logistics of nonprescription pharmaceuticals and other unsold retail items. In response to comments, EPA is codifying our previous policy that the decision by a healthcare facility to send nonprescription pharmaceuticals to a reverse logistics center is not a decision to discard if the nonprescription pharmaceuticals have a reasonable expectation of being legitimately used/reused (*e.g.*, lawfully redistributed for their intended purpose) or reclaimed. In other words, EPA is finalizing that nonprescription pharmaceuticals are not

solid wastes, and therefore not hazardous waste pharmaceuticals if they have a reasonable expectation of being legitimately used/reused (*e.g.*, lawfully redistributed for their intended purpose) or reclaimed.

3. Reverse Distributors Managing Hazardous Waste Pharmaceuticals Under Part 266 Subpart P

EPA is finalizing that all reverse distributors are subject to 40 CFR part 266 subpart P and will be subject to the same standards with respect to their hazardous waste pharmaceuticals, regardless of the amount of hazardous waste pharmaceuticals they manage. Even reverse distributors that are currently VSQGs will be regulated under 40 CFR part 266 subpart P for the management of their hazardous waste pharmaceuticals. Therefore, a reverse distributor subject to 40 CFR part 266 subpart P will no longer have to keep track of the amount of hazardous waste pharmaceuticals that it generates on a monthly basis.

C. Healthcare Facilities and Reverse Distributors Managing Non-Pharmaceutical Hazardous Waste in Accordance With 40 CFR Part 262 or Part 273 (i.e., Complying With "More Than One RCRA")

Most, if not all, healthcare facilities and reverse distributors generate at least some hazardous wastes other than pharmaceuticals. These non-pharmaceutical hazardous wastes will continue to be regulated under 40 CFR part 262 (and other applicable Subtitle C regulations). The standards established by this rulemaking apply only to the management of hazardous waste pharmaceuticals at healthcare facilities and reverse distributors. Healthcare facilities and reverse distributors likely generate or manage other types of hazardous wastes. For example, hospitals may generate non-pharmaceutical hazardous wastes, such as solvents in their diagnostic laboratories; those hazardous wastes must still be managed in accordance with the part 262 generator regulations (such as the RCRA SAA regulations (§ 262.15)), or if it is a teaching hospital, the Academic Laboratories Rule (if it has opted into part 262 subpart K). Retail stores, including pharmacies and grocery stores, may have non-pharmaceutical hazardous wastes on-site as well, which must be managed in accordance with the 40 CFR part 262 regulations and all other applicable RCRA Subtitle C regulations. For example, fluorescent bulbs may be managed under the universal waste program (40 CFR part 273). For reverse distributors, this rule only applies to the management of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals. Some reverse distributors may generate other non-pharmaceutical hazardous wastes from activities, such as cleaning and maintenance; other RCRA Subtitle C regulations will apply to those non-pharmaceutical hazardous wastes.

D. State Enforcement Activities and Interpretations

States have taken a variety of approaches regarding hazardous waste pharmaceuticals. One major goal of this final rule is to provide clarity on this topic, and thereby promote national consistency, which should promote better compliance among healthcare facilities, including pharmacies.

In 2012, Connecticut's Department of Energy and Environmental Protection (DEEP) took enforcement actions at seven CVS stores for violations of the RCRA hazardous waste regulations. Consent orders from CT DEEP direct CVS stores in the state to follow a set of best management practices.[468] A number of the practices developed in these consent orders mirror some of the practices EPA is finalizing in this rule, particularly with regard to pharmaceuticals destined for a reverse distributor. CT DEEP asserts RCRA jurisdiction over the pharmaceuticals destined for reverse distributors by applying specific management practices. For example, CVS must maintain records of each shipment of non-dispensable pharmaceuticals to a reverse distributor, including confirmation of receipt of the non-dispensable pharmaceuticals from the receiving reverse distributor. The best practices also include procedures for addressing situations when CVS does not receive delivery confirmation of shipment to a reverse distributor. Further, the consent order sets out separate, more comprehensive practices for the non-dispensable pharmaceuticals that are not suitable for reverse distribution.

Aside from best management practices developed by Connecticut as part of a consent order, at least two other states have developed guidance documents that apply conditions to the management of hazardous wastes pharmaceuticals in exchange for enforcement discretion. In particular, in 2008, the Washington State Department of Ecology issued guidance titled, Interim Enforcement Policy: Pharmaceutical Waste in Healthcare.[469] This interim enforcement discretion policy had some elements in common with this final rule for hazardous waste pharmaceuticals. For instance, a healthcare facility was required to notify the Department of Ecology that it was operating under the policy and had to train its staff involved in pharmaceutical waste management. Only a time limit, rather than a quantity limit, applied to the accumulation of the hazardous waste pharmaceuticals on site. Of particular note is that Washington State prohibited disposing of most hazardous waste pharmaceuticals down the toilet or drain. In anticipation of this final rule, Washington State updated the interim policy in June 2017 to provide regulated facilities with the opportunity to use some of the provisions outlined in the proposed rulemaking, such as allowing facilities to send creditable pharmaceuticals to a reverse distributor for evaluation without providing hazardous waste codes.[470]

In 2011, Minnesota's Pollution Control Agency (MPCA) issued a fact sheet titled Reverse Distribution of Pharmaceuticals: Guidance for Minnesota Healthcare Providers.[471] In this guidance, Minnesota states, "Whether a pharmaceutical is eligible for return credit does not affect its product or waste status. In Minnesota, if a pharmaceutical is not used or reused for its intended purpose, it is a waste. The MPCA considers health care practitioners and pharmacies to be generators of these pharmaceutical wastes. Nevertheless, the MPCA believes that the established reverse distribution system provides an environmentally protective method for handling waste pharmaceuticals. Therefore, it will allow Minnesota health care practitioners and pharmacies to manage certain pharmaceuticals through reverse distribution, subject to additional requirements discussed in this fact sheet." This is similar to the approach that EPA is finalizing for potentially creditable hazardous waste pharmaceuticals. For example, like EPA's final rule, MPCA does not require hazardous waste pharmaceuticals destined for a reverse distributor to be

[468] See the docket for this rulemaking EPA–HQ–RCRA–2007–0932–0173.

[469] See the 2008 interim enforcement policy in the docket for this rulemaking EPA–HQ–RCRA–2007–0932–0181.

[470] See the 2017 interim enforcement policy at *https://fortress.wa.gov/ecy/publications/documents/0704024.pdf* or in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[471] See the guidance document in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932–0178).

counted toward determining a healthcare facility's generator category. In addition, MPCA does not require hazardous waste pharmaceuticals to be accompanied by a hazardous waste manifest when shipped to a reverse distributor. By finalizing a rule that is consistent with state approaches, EPA is bringing national consistency to the management of hazardous waste pharmaceuticals, while avoiding disruption to practices already in place.

E. Intersection of Part 266 Subpart P With the Hazardous Waste Generator Improvements Rule

The Hazardous Waste Generator Improvements rule was finalized on November 28, 2016.[472] This rule finalized a much-needed update to the hazardous waste generator regulations in part 262 to make the rules easier to understand, facilitate better compliance, provide greater flexibility in how hazardous waste is managed and close important gaps in the regulations. This section of preamble discusses three portions of the Hazardous Waste Generator Improvements final rule that might impact healthcare facilities and reverse distributors that are subject to part 266 subpart P.

1. Episodic Generation

One of the key provisions with which EPA added regulatory flexibility allows a hazardous waste generator to avoid increased burden of a higher generator category when generating episodic waste provided the episodic waste is properly managed in accordance with part 262 subpart L. Healthcare facilities and reverse distributors will be able to take advantage of this added regulatory flexibility (assuming their state has adopted this provision).

A healthcare facility that is a VSQG for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste can use the episodic generation provision of part 262 subpart L for all of its hazardous waste, including its hazardous waste pharmaceuticals. If a healthcare facility is generally operating under § 262.14 as a VSQG, but has an episodic event, it would be far less burdensome to comply with part 262 subpart L than to come into compliance with all the provisions of part 266 subpart P for the short duration of the episodic event. For example, if a VSQG healthcare facility is directed to dispose of recalled pharmaceuticals, it could use the episodic generator provisions of part 262 subpart L to avoid an increase in hazardous waste generator category. However, if a healthcare facility that is a VSQG generates hazardous waste in excess of the allowable amounts as a VSQG,[473] and it chooses not to use the episodic generator provisions in part 262 subpart L, it would become subject to part 266 subpart P for its hazardous waste pharmaceuticals.

As discussed previously, healthcare facilities and reverse distributors that are subject to part 266 subpart P for their hazardous waste pharmaceuticals may still be subject to part 262 for the management of their non-pharmaceutical hazardous waste. A healthcare facility or reverse distributor operating under part 266 subpart P for its hazardous waste pharmaceuticals may not use the episodic generator standards of part 262 subpart L with respect to its hazardous waste pharmaceuticals. Under part 266 subpart P, all healthcare facilities are regulated the same regardless of amounts of hazardous waste pharmaceuticals generated and all reverse distributors are regulated the same, regardless of amounts of hazardous waste pharmaceuticals managed, making the need for episodic generation provisions unnecessary. On the other hand, if a healthcare facility or reverse distributor is generally operating as a VSQG or SQG for its non-pharmaceutical hazardous waste, but has an episodic event, the healthcare facility may use the provisions in part 262 subpart L for its non-pharmaceutical hazardous waste.

2. Small Quantity Generator Re-Notification

The 2016 Hazardous Waste Generator Improvements final rule added a new requirement for periodic re-notification by SQGs.[474] Under this new provision, SQGs must re-notify EPA starting in 2021 and every four years thereafter using EPA Form 8700–12. This re-notification must be submitted by September 1st of each year in which re-notifications are required.[475] Healthcare facilities and reverse distributors operating under part 266 subpart P may also be subject to part 262 for the management of its non-pharmaceutical hazardous waste. If a healthcare facility or reverse distributor is an SQG for its non-pharmaceutical hazardous waste, then it will be subject to this re-notification requirement under part 262. Therefore, in order to avoid duplicative notification requirements, under part 266 subpart P, EPA is not requiring re-notification by healthcare facilities and reverse distributors.

3. Very Small Quantity Generators That Accumulate More Than 1 Kg of Acute Hazardous Waste

The 2016 Hazardous Waste Generator Improvements final rule clarified in § 262.14(a)(3) that if a VSQG accumulates at any time greater than 1 kg of acute hazardous waste,[476] all quantities of that acute hazardous waste are subject to the additional conditions for exemption for LQGs. More specifically, the acute hazardous waste must be held on site for no more than 90 days beginning on the date when more than 1 kg is exceeded, and the acute hazardous waste is subject to the LQG conditions for exemption in § 262.17(a) through (g). In other words, while the acute hazardous waste becomes subject to the stricter standards for LQGs when the accumulation limits are exceeded, the generator continues to be considered a VSQG, provided the generator continues to generate within the VSQG thresholds identified in the definition of VSQG in § 260.10.

If a healthcare facility that is a VSQG accumulates more than 1 kg of acute hazardous waste,[477] then it will remain subject to § 262.14(a)(3); the healthcare facility will not become subject to part 262 subpart P.

XX. State Authorization

A. Applicability of Rules in Authorized States

Under section 3006 of RCRA, EPA may authorize states to administer the RCRA Subtitle C hazardous waste program. Following authorization, the authorized state program operates in lieu of the federal regulations. EPA retains authority to enforce the authorized state Subtitle C program, although authorized states have primary enforcement authority. EPA also retains its authority under RCRA sections 3007, 3008, 3013, and 7003. The standards and requirements for state authorization are found at 40 CFR part 271.

Prior to enactment of the Hazardous and Solid Waste Amendments of 1984 (HSWA), a state with final RCRA authorization administered its hazardous waste program entirely in

[472] See November 28, 2016; 81 FR 85732.

[473] See the definition of very small quantity generator in 40 CFR 2601.10.

[474] See 40 CFR 262.18(d)(1).

[475] See 81 FR 85777–8; November 28, 2016 for the preamble discussion explaining the need for re-notification.

[476] Or more than 100 kg of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous waste listed in § 261.31 or 261.33(e).

[477] Or more than 100 kg of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous waste listed in § 261.31 or 261.33(e).

lieu of EPA administering the federal program in that state. EPA did not issue permits for any facilities in that state, since the state was now authorized to issue RCRA permits. When new, more stringent federal requirements were promulgated, the state was obligated to enact equivalent authorities within specified time frames. However, the new requirements did not take effect in an authorized state until the state adopted the equivalent state requirements.

In contrast, under RCRA section 3006(g) (42 U.S.C. 6926(g)), which was added by HSWA, new requirements and prohibitions imposed under HSWA authority take effect in authorized states at the same time that they take effect in unauthorized states. While states must still adopt HSWA-related provisions as state law to retain authorization, EPA implements the HSWA provisions in authorized states, including the issuance of any permits pertaining to HSWA requirements, until the state is granted authorization to do so.

Authorized states are required to modify their programs only when EPA promulgates federal requirements that are more stringent or broader in scope than existing federal requirements.[478] RCRA section 3009 allows the states to impose standards more stringent than those in the federal program (see 40 CFR 271.1). Therefore, authorized states may, but are not required to, adopt federal regulations, both HSWA and non-HSWA, that are considered less stringent than previous federal regulations.

B. Effect on State Authorization

This action adds a new subpart P to 40 CFR part 266, and it is being finalized in part under the authority of HSWA and in part under non-HSWA authority. The bulk of 40 CFR part 266 subpart P is being finalized under non-HSWA authority. Thus, the amendments promulgated under non-HSWA authority are applicable on the effective date only in those states that do not have final authorization of their base RCRA programs. Only the prohibition of sewering hazardous waste pharmaceuticals (§ 266.504) is being finalized under HSWA authority in section 3018 of RCRA. The amendments promulgated under the authority of HSWA (*i.e.*, the prohibition on sewering hazardous waste pharmaceuticals) are applicable on the effective date of the final rule in all states. Moreover, authorized states are required to modify their programs only when EPA promulgates federal regulations that are more stringent or broader in scope than the authorized state regulations. For those changes that are less stringent, states are not required to modify their programs.

While some provisions of part 266 subpart P are considered less stringent than the current federal standards, other provisions of the final rule are considered more stringent than the current federal standards. Taken as a whole, we consider the entire new subpart P under 40 CFR part 266 entitled "Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities" (sections VIII–XVII of this preamble) to be more stringent than the current federal standards. Therefore, authorized states will be required to modify their programs to adopt these revisions. When a state adopts this new subpart, if elements of the 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.

On the other hand, one final revision is less stringent than the current hazardous waste regulations. The amendment to exempt from the P075 listing the nicotine patches, gums and lozenges that are FDA-approved OTC nicotine replacement therapies is less stringent that the current hazardous waste regulations (section V of this preamble). Thus, authorized states may, but are not required to, adopt the change to the P075 listing.

C. Effect on State Authorization in States That Have Added Pharmaceuticals to the Universal Waste Program

The Universal Waste program allows states to add waste streams to their own state program, even when the waste stream has not been added to the federal Universal Waste program, provided the state has adopted and been authorized for the petition process in §§ 260.20 and 260.23. Two states have added hazardous waste pharmaceuticals to their Universal Waste programs: Florida and Michigan. Because the added subpart P under CFR part 266 is considered more stringent than either the "traditional RCRA" standards or the Universal Waste program, both Florida and Michigan will be required to modify their programs to adopt an approach at least as stringent as the amendments. Furthermore, because the Agency has determined that it is not appropriate to add hazardous waste pharmaceuticals to the Universal Waste program, both Florida and Michigan must remove hazardous waste pharmaceuticals from their Universal Waste program when they adopt this new subpart, although they may continue to regulate non-hazardous waste pharmaceuticals under the Universal Waste program, to the extent allowed under state law. In addition, states may choose to add non-hazardous waste pharmaceuticals to their Universal Waste program or may regulate them more stringently as part of their hazardous waste program but states may not add hazardous waste pharmaceuticals to their Universal Waste program in the future. Accordingly, we have amended the regulations in § 273.80(a) and added § 273.80(d) to reflect this decision that states may not add hazardous waste pharmaceuticals to their Universal Waste program.

XXI. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. Pursuant to the terms of Executive Order 12866, as affirmed in Executive Order 13563, the Agency has determined that this rule is a significant regulatory action because it contains novel policy issues, as defined under section 3(f)(4) of the Order. Any changes made in response to OMB recommendations have been documented in the docket.

As discussed in section I above, EPA prepared an economic analysis of the potential costs and benefits associated with this action. This analysis, *Regulatory Impact Analysis for EPA's Final Regulations for the Management of Hazardous Waste Pharmaceuticals,* indicates that the rule is projected to result in net annual cost savings of approximately $12.99 million to $14.96 million based on a discount rate of 7 percent or $12.98 to $14.95 million based on a discount rate of 3 percent. The full analysis is available in the docket for this rule.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is considered an Executive Order 13771 deregulatory

[478] EPA notes that decisions regarding whether a state rule is more stringent or broader in scope than the federal program are made when the Agency authorizes a state program for a particular rule.

action. Details on the estimated cost savings of this final rule can be found in EPA's analysis of the potential costs and benefits associated with this action.

C. Paperwork Reduction Act

The information collection activities in this rule have been submitted for approval to the Office of Management and Budget (OMB) under the PRA. The Information Collection Request (ICR) document that EPA prepared has been assigned EPA ICR number 2486.02, OMB control number 0250–0212. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

EPA is finalizing in this rule, under a new subpart P to 40 CFR part 266, new and revised reporting and recordkeeping requirements for healthcare facilities and reverse distributors. These requirements, which are also identified in the ICR supporting this action, will enable EPA and state regulatory agencies to identify the universe of healthcare facilities managing hazardous waste pharmaceuticals. In addition, the requirements include provisions for tracking of hazardous waste pharmaceuticals that are sent to reverse distributors.

EPA will use the collected information to ensure that hazardous waste pharmaceuticals are being managed in a protective manner. The tracking requirements ensure that these wastes arrive at their intended destinations rather than diverted for illicit purposes or managed at facilities not equipped to manage these wastes. These tracking requirements will also help facilities identify shipments that do not arrive at their destination as planned, allowing generators to take corrective action that will ensure that future shipments are transported to the appropriate location. Information marked on containers of hazardous waste pharmaceuticals will assist handlers and transporters in ensuring proper management during storage and shipment.

Respondents/affected entities: Drug wholesalers, supermarkets and other grocery stores, pharmacies and drug stores, warehouse clubs and supercenters, veterinary clinics, physicians' offices, dentists' offices, other health practitioners, outpatient care centers, other ambulatory health care services, hospitals, nursing care facilities, continuing care retirement communities, and reverse distributors.

Respondent's obligation to respond: The recordkeeping and notification requirements are mandatory and are being promulgated under section 3001 of RCRA.

Estimated number of respondents: 13,373.

Frequency of response: The frequency of response varies.

Total estimated burden: EPA estimated the total annual burden to respondents to be approximately 43,577 hours. Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: EPA estimated the total estimated annual cost of this paperwork burden to respondents to be approximately $2,543,409.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

D. Regulatory Flexibility Act

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden or otherwise has a positive economic effect on the small entities subject to the rule. As documented in the Regulatory Impact Analysis found in the docket for this proposal, EPA does not expect the rule to result in an adverse impact to a significant number of small entities. EPA estimates that there are at least 10,481 to 15,114 small entities that will be impacted by this rule. However, small entities are expected to experience a net cost savings under the final rule, and for the small entities that are expected to experience a net cost under the final rule, the RIA estimates the costs, at most, to represent 0.013 percent of annual revenues for small entities. We have therefore concluded that this action will either relieve regulatory burden or have no net regulatory burden for all directly regulated small entities.

E. Unfunded Mandates Reform Act

As documented in the Regulatory Impact Analysis found in the docket for this rule, this action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. As indicated previously, the annual net cost savings is estimated to be between approximately $13 million and $15 million (based on a discount rate of 7%). Thus, this rule is not subject to the requirements of sections 202 or 205 of UMRA.

This rule is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments. While some hospitals are publicly owned, the requirements affecting those facilities are not unique in that they are the same as those affecting all facilities in the proposed rulemaking. Also, using data on revenues of hospitals owned by state and local governments, EPA estimated that the costs of the rule borne by state and local governments represent less than 0.001% of their revenues. Therefore, the costs incurred by small governments are not expected to be significant.

F. Executive Order 13132: Federalism

As documented in the Regulatory Impact Analysis found in the docket for this rule, this action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation With Tribal Governments

This action may have tribal implications as specified in Executive Order 13175. The final rule will neither impose substantial direct compliance costs on tribal government, not preempt tribal law. Under the RCRA statute, the federal government implements hazardous waste regulations directly in Indian Country. Thus, the final rule would not impose any direct costs on tribal governments.

To assess the potential tribal implications of the action, EPA compiled data on the number of tribally run healthcare facilities in the U.S. and estimated the costs of this action for these facilities. As documented in the Regulatory Impact Analysis in the docket for this rule, the rule is not expected to impose a substantial burden on tribal governments.

EPA consulted with tribal officials under the EPA Policy on Consultation and Coordination with Indian Tribes early in the process of developing this regulation to permit them to have meaningful and timely input into its

development. A summary of that consultation is provided in the docket for this rule (see EPA–HQ–RCRA–2008–0932).

As required by section 7(a), the EPA's Tribal Consultation Official has certified that the requirements of the executive order have been met in a meaningful and timely manner. A copy of the certification is included in the docket for this action.

H. Executive Order 13045: Children's Health

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866 and because the EPA does not believe the environmental health or safety risks addressed by this proposed action present a disproportionate risk to children. This action's health and risk assessments are contained in the *Regulatory Impact Analysis for EPA's Final Regulations for the Management of Hazardous Waste Pharmaceuticals,* found in the docket for this action.

I. Executive Order 13211: Energy Supply

This action is not a "significant energy action" because it is not likely to have a significant adverse effect on the supply, distribution or use of energy. The final rule does not directly regulate energy production or consumption. Changes in the management of hazardous waste pharmaceuticals stipulated in this action are not expected to impact energy production or distribution and will have minimal impact on energy consumptions.

J. National Technology Transfer and Advancement Act

This final rulemaking does not involve technical standards.

K. Executive Order 12898: Environmental Justice

EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The documentation for this decision is contained in the Regulatory Impact Analysis, which can be found at regulations.gov under docket number EPA–HQ–RCRA–2007–0932.

To meet the requirements of Executive Order 12898, EPA analyzed potential environmental justice impacts associated with the diversion of hazardous waste pharmaceuticals from sewer disposal to hazardous waste combustion facilities. Populations living near and downstream from wastewater treatment plants may also benefit from the elimination of sewering of hazardous waste pharmaceuticals. To the extent that minority and/or low-income populations near or downstream from wastewater treatment plants make up a disproportionately high portion of the overall population, this final action may result in positive environmental justice impacts.

Overall, EPA expects that this action may positively affect U.S. environmental justice populations, although the size of the impact will vary by wastewater treatment plant. A reduction in sewering expected under the final rule may benefit relatively large minority and low-income populations in close proximity to or downstream from wastewater treatment plants. The diversion of hazardous waste pharmaceuticals from wastewater treatment plants to combustion facilities, however, may increase the environmental burden borne by environmental justice populations near these combustion facilities. Although these effects offset each other to a certain degree, the number of minority and low-income individuals near wastewater treatment facilities exceeds the number near hazardous waste combustion facilities. This suggests that, on the whole, the final action may benefit environmental justice populations.

L. Congressional Review Act

EPA will submit a report containing this rule and other information required by the Congressional Review Act (5 U.S.C. 801 *et seq.*) to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication in the **Federal Register**. A major rule cannot take effect until sixty (60) days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2). This final authorization will be effective August 22, 2019.

List of Subjects

40 CFR Part 261

Environmental protection, Hazardous waste, Recycling, Reporting and recordkeeping requirements.

40 CFR Part 262

Environmental protection, Exports, Hazardous materials transportation, Hazardous waste, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

40 CFR Part 264

Environmental protection, Air pollution control, Hazardous waste, Insurance, Packaging and containers, Reporting and recordkeeping requirements, Security measures, Surety bonds.

40 CFR Part 265

Environmental protection, Air pollution control, Hazardous waste, Insurance, Packaging and containers, Reporting and recordkeeping requirements, Security measures, Surety bonds, Water supply.

40 CFR Part 266

Environmental protection, Energy, Hazardous waste, Recycling, Reporting and recordkeeping requirements.

40 CFR Part 268

Environmental protection, Hazardous waste, Reporting and recordkeeping requirements.

40 CFR Part 270

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous materials transportation, Hazardous waste, Reporting and recordkeeping requirements, Water pollution control, Water supply.

40 CFR Part 273

Environmental protection, Hazardous materials transportation, Hazardous waste.

Dated: December 11, 2018.

Andrew R. Wheeler,

Acting Administrator.

For the reasons stated in the preamble, Title 40, chapter I, of the Code of Federal Regulations is amended as follows:

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

■ 1. The authority citation for part 261 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, 6922, 6924(y) and 6938.

■ 2. Section 261.4 is amended by revising paragraph (a)(1)(ii) to read as follows:

§ 261.4 Exclusions.

(a) * * *

(1) * * *

(ii) Any mixture of domestic sewage and other wastes that passes through a sewer system to a publicly-owned treatment works for treatment, except as prohibited by § 266.505 and Clean Water Act requirements at 40 CFR 403.5(b). "Domestic sewage" means

untreated sanitary wastes that pass through a sewer system.

* * * * *

■ 3. Section 261.7 is amended by adding paragraph (c) to read as follows:

§ 261.7 Residues of hazardous waste in empty containers.

* * * * *

(c) Containers of hazardous waste pharmaceuticals are subject to § 266.507 for determining when they are considered empty, in lieu of this section, except as provided by § 266.507(c) and (d).

■ 4. Section 261.33 is amended by:

■ a. Revising paragraph (c); and

■ b. Revising the four entries for "P075" in the table in paragraph (e).

The revisions read as follows:

§ 261.33 Discarded commercial chemical products, off-specification species, container residues, and spill residues thereof.

* * * * *

(c) Any residue remaining in a container or in an inner liner removed from a container that has held any commercial chemical product or manufacturing chemical intermediate having the generic name listed in paragraphs (e) or (f) of this section, unless the container is empty as defined in § 261.7(b) or § 266.507 of this chapter.

[*Comment:* Unless the residue is being beneficially used or reused, or legitimately recycled or reclaimed; or being accumulated, stored, transported or treated prior to such use, re-use, recycling or reclamation, EPA considers the residue to be intended for discard, and thus, a hazardous waste. An example of a legitimate re-use of the residue would be where the residue remains in the container and the container is used to hold the same commercial chemical product or manufacturing chemical intermediate it previously held. An example of the discard of the residue would be where the drum is sent to a drum reconditioner who reconditions the drum but discards the residue.]

* * * * *

(e) * * *

Hazardous waste No.	Chemical abstracts No.	Substance
*	*	* * * * * *
P075	[1] 54–11–5	Nicotine, & salts (this listing does not include patches, gums and lozenges that are FDA-approved over-the-counter nicotine replacement therapies).
*	*	* * * * * *
P075	[1] 54–11–5	Pyridine, 3-(1-methyl-2-pyrrolidinyl)-, (S)-, & salts (this listing does not include patches, gums and lozenges that are FDA-approved over-the-counter nicotine replacement therapies).
*	*	* * * * * *
P075	[1] 54–11–5	Nicotine, & salts (this listing does not include patches, gums and lozenges that are FDA-approved over-the-counter nicotine replacement therapies).
*	*	* * * * * *
P075	[1] 54–11–5	Pyridine, 3-(1-methyl-2-pyrrolidinyl)-, (S)-, & salts (this listing does not include patches, gums and lozenges that are FDA-approved over-the-counter nicotine replacement therapies).
*	*	* * * * * *

* * * * *

PART 262—STANDARDS APPLICABLE TO GENERATORS OF HAZARDOUS WASTE

■ 5. The authority citation for part 262 continues to read as follows:

Authority: 42 U.S.C. 6906, 6912, 6922–6925, 6937, 6938, and 6939g.

■ 6. Section 262.10 is amended by adding paragraphs (m) and (n) to read as follows:

§ 262.10 Purpose, scope and applicability.

* * * * *

(m) All reverse distributors (as defined in § 266.500) are subject to 40 CFR part 266 subpart P for the management of hazardous waste pharmaceuticals in lieu of this part.

(n) Each healthcare facility (as defined in § 266.500) must determine whether it is subject to 40 CFR part 266 subpart P for the management of hazardous waste pharmaceuticals, based on the total hazardous waste it generates per calendar month (including both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste). A healthcare facility that generates more than 100 kg (220 pounds) of hazardous waste per calendar month, or more than 1 kg (2.2 pounds) of acute hazardous waste per calendar month, or more than 100 kg (220 pounds) per calendar month of any residue or contaminated soil, water, or other debris, resulting from the clean-up of a spill, into or on any land or water, of any acute hazardous wastes listed in § 261.31 or § 261.33(e), is subject to 40 CFR part 266 subpart P for the management of hazardous waste pharmaceuticals in lieu of this part. A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, remains subject to § 262.14 and is not subject to part 266 subpart P, except for §§ 266.505 and 266.507 and the optional provisions of § 266.504.

■ 7. Section 262.13 is amended by adding paragraph (c)(9) to read as follows:

[1] CAS Number given for parent compound only.

§ 262.13 Generator category determination.

* * * * *

(c) * * *

(9) Is a hazardous waste pharmaceutical, as defined in § 266.500, that is subject to or managed in accordance with 40 CFR part 266 subpart P or is a hazardous waste pharmaceutical that is also a Drug Enforcement Administration controlled substance and is conditionally exempt under § 266.506.

* * * * *

■ 8. Section 262.14 is amended by adding paragraphs (a)(5)(ix) and (x) to read as follows:

§ 262.14 Conditions for exemption for a very small quantity generator.

(a) * * *

(5) * * *

(ix) A reverse distributor (as defined in § 266.500), if the hazardous waste pharmaceutical is a potentially creditable hazardous waste pharmaceutical generated by a healthcare facility (as defined in § 266.500).

(x) A healthcare facility (as defined in § 266.500) that meets the conditions in §§ 266.502(l) and 266.503(b), as applicable, to accept non-creditable hazardous waste pharmaceuticals and potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator.

* * * * *

PART 264—STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

■ 9. The authority citation for part 264 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6924, 6925, and 6939g.

■ 10. Section 264.1 is amended by adding paragraph (g)(13) to read as follows:

§ 264.1 Purpose, scope and applicability.

* * * * *

(g) * * *

(13) Reverse distributors accumulating potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals, as defined in § 266.500. Reverse distributors are subject to regulation under 40 CFR part 266 subpart P in lieu of this part for the accumulation of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

* * * * *

PART 265—INTERIM STATUS STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

■ 11. The authority citation for part 265 continues to read as follows:

Authority: 42 U.S.C. 6905, 6906, 6912, 6922, 6923, 6924, 6925, 6935, 6936, 6937, and 6939g.

■ 12. Section 265.1 is amended by adding paragraph (c)(16) to read as follows:

§ 265.1 Purpose, scope, and applicability.

* * * * *

(c) * * *

(16) Reverse distributors accumulating potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals, as defined in § 266.500. Reverse distributors are subject to regulation under 40 CFR part 266 subpart P in lieu of this part for the accumulation of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

* * * * *

PART 266—STANDARDS FOR THE MANAGEMENT OF SPECIFIC HAZARDOUS WASTES AND SPECIFIC TYPES OF HAZARDOUS WASTE MANAGEMENT FACILITIES

■ 13. The authority citation for part 266 continues to read as follows:

Authority: 42 U.S.C. 1006, 2002(a), 3001–3009, 3014, 3017, 6905, 6906, 6912, 6921, 6922, 6924–6927, 6934, and 6937.

Subpart O—[Reserved]

■ 14. Add reserved subpart O.

■ 15. Add subpart P, consisting of §§ 266.500 through 266.510, to read as follows:

Subpart P—Hazardous Waste Pharmaceuticals

Sec.

Subpart P—Hazardous Waste Pharmaceuticals

§ 266.500 Definitions for this subpart.

The following definitions apply to this subpart:

Evaluated hazardous waste pharmaceutical means a prescription hazardous waste pharmaceutical that has been evaluated by a reverse distributor in accordance with § 266.510(a)(3) and will not be sent to another reverse distributor for further evaluation or verification of manufacture credit.

Hazardous waste pharmaceutical means a pharmaceutical that is a solid waste, as defined in § 261.2, and exhibits one or more characteristics identified in part 261 subpart C or is listed in part 261 subpart D. A pharmaceutical is not a solid waste, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical, if it is legitimately used/reused (*e.g.,* lawfully donated for its intended purpose) or reclaimed. An over-the-counter pharmaceutical, dietary supplement, or homeopathic drug is not a solid waste, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical, if it has a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for its intended purpose) 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 over-the-counter 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 surgical 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 means a pharmaceutical that is a solid waste, as defined in § 261.2, but is excluded from being a hazardous waste under § 261.4(b)(1).

Long-term care facility means 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 facilities, nursing facilities, 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 hazardous waste pharmaceutical means a prescription hazardous waste pharmaceutical that does not have a reasonable expectation to be eligible for manufacturer credit or a nonprescription hazardous waste pharmaceutical that does not have a reasonable expectation to be legitimately used/reused or reclaimed. 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 the spills of pharmaceuticals.

Non-hazardous waste pharmaceutical means a pharmaceutical that is a solid waste, as defined in § 261.2, and is not listed in 40 CFR part 261 subpart D, and does not exhibit a characteristic identified in 40 CFR part 261 subpart C.

Non-pharmaceutical hazardous waste means a solid waste, as defined in § 261.2, that is listed in 40 CFR part 261 subpart D, or exhibits one or more characteristics identified in 40 CFR part 261 subpart C, but is not a pharmaceutical, as defined in this section.

Pharmaceutical means 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); over-the-counter 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 hazardous waste pharmaceutical means a prescription hazardous waste pharmaceutical 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 hazardous waste pharmaceuticals or nonprescription pharmaceuticals including, but not limited to, over-the-counter drugs, homeopathic drugs, and dietary supplements.

Reverse distributor means any person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals 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.

§ 266.501 Applicability.

(a) A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, remains subject to § 262.14 and is *not* subject to this subpart, except for §§ 266.505 and 266.507 and the optional provisions of § 266.504.

(b) A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, has the option of complying with § 266.501(d) for the management of its hazardous waste pharmaceuticals as an alternative to complying with § 262.14 and the optional provisions of § 266.504.

(c) A healthcare facility or reverse distributor remains subject to all applicable hazardous waste regulations with respect to the management of its non-pharmaceutical hazardous waste.

(d) With the exception of healthcare facilities identified in paragraph (a) of this section, a healthcare facility is subject to the following in lieu of parts 262 through 265:

(1) Sections 266.502 and 266.505 through 266.508 of this subpart with respect to the management of:

(i) Non-creditable hazardous waste pharmaceuticals, and

(ii) Potentially creditable hazardous waste pharmaceuticals if they are not destined for a reverse distributor.

(2) Sections 262.502(a), 266.503, 266.505 through 266.507, and 266.509 of this subpart with respect to the management of potentially creditable hazardous waste pharmaceuticals that are prescription pharmaceuticals and are destined for a reverse distributor.

(e) A reverse distributor is subject to §§ 266.505 through 266.510 of this subpart in lieu of parts 262 through 265 with respect to the management of hazardous waste pharmaceuticals.

(f) Hazardous waste pharmaceuticals generated or managed by entities other than healthcare facilities and reverse distributors (*e.g.,* pharmaceutical manufacturers and reverse logistics centers) are not subject to this subpart. Other generators are subject to 40 CFR part 262 for the generation and accumulation of hazardous wastes, including hazardous waste pharmaceuticals.

(g) The following are not subject to 40 CFR parts 260 through 273, except as specified:

(1) Pharmaceuticals that are not solid waste, as defined by § 261.2, because they are legitimately used/reused (*e.g.,* lawfully donated for their intended purpose) or reclaimed.

(2) Over-the-counter pharmaceuticals, dietary supplements, or homeopathic drugs that are not solid wastes, as

defined by § 261.2, because they have a reasonable expectation of being legitimately used/reused (*e.g.*, lawfully redistributed for their intended purpose) or reclaimed.

(3) Pharmaceuticals being managed in accordance with a recall strategy that has been approved by the Food and Drug Administration in accordance with 21 CFR part 7 subpart C. This subpart does apply to the management of the recalled hazardous waste pharmaceuticals after the Food and Drug Administration approves the destruction of the recalled items.

(4) Pharmaceuticals being managed in accordance with a recall corrective action plan that has been accepted by the Consumer Product Safety Commission in accordance with 16 CFR part 1115. This subpart does apply to the management of the recalled hazardous waste pharmaceuticals after the Consumer Product Safety Commission approves the destruction of the recalled items.

(5) Pharmaceuticals stored according to a preservation order, or during an investigation or judicial proceeding until after the preservation order, investigation, or judicial proceeding has concluded and/or a decision is made to discard the pharmaceuticals.

(6) Investigational new drugs for which an investigational new drug application is in effect in accordance with the Food and Drug Administration's regulations in 21 CFR part 312. This subpart does apply to the management of the investigational new drug after the decision is made to discard the investigational new drug or the Food and Drug Administration approves the destruction of the investigational new drug, if the investigational new drug is a hazardous waste.

(7) Household waste pharmaceuticals, including those that have been collected by an authorized collector (as defined by the Drug Enforcement Administration), provided the authorized collector complies with the conditional exemption in §§ 266.506(a)(2) and 266.506(b).

§ 266.502 Standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals.

(a) *Notification and withdrawal from this subpart for healthcare facilities managing hazardous waste pharmaceuticals*—(1) *Notification.* A healthcare facility must notify the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700–12), that it is a healthcare facility operating under this subpart. A healthcare facility is not required to fill out Box 10.B. (Waste Codes for Federally Regulated Hazardous Waste) of the Site Identification Form with respect to its hazardous waste pharmaceuticals. A healthcare facility must submit a separate notification (Site Identification Form) for each site or EPA identification number.

(i) A healthcare facility that already has an EPA identification number must notify the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700–12), that it is a healthcare facility as part of its next Biennial Report, if it is required to submit one; or if not required to submit a Biennial Report, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(ii) A healthcare facility that does not have an EPA identification number must obtain one by notifying the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700–12), that it is a healthcare facility as part of its next Biennial Report, if it is required to submit one; or if not required to submit a Biennial Report, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(iii) A healthcare facility must keep a copy of its notification on file for as long as the healthcare facility is subject to this subpart.

(2) *Withdrawal.* A healthcare facility that operated under this subpart but is no longer subject to this subpart, because it is a very small quantity generator under § 262.14, and elects to withdraw from this subpart, must notify the appropriate EPA Regional Administrator using the Site Identification Form (EPA Form 8700–12) that it is no longer operating under this subpart. A healthcare facility is not required to fill out Box 10.B. (Waste Codes for Federally Regulated Hazardous Waste) of the Site Identification Form with respect to its hazardous waste pharmaceuticals. A healthcare facility must submit a separate notification (Site Identification Form) for each EPA identification number.

(i) A healthcare facility must submit the Site Identification Form notifying that it is withdrawing from this subpart before it begins operating under the conditional exemption of § 262.14.

(ii) A healthcare facility must keep a copy of its withdrawal on file for three years from the date of signature on the notification of its withdrawal.

(b) *Training of personnel managing non-creditable hazardous waste pharmaceuticals at healthcare facilities.* A healthcare facility must ensure that all personnel that manage non-creditable hazardous waste pharmaceuticals are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies.

(c) *Hazardous waste determination for non-creditable pharmaceuticals.* A healthcare facility that generates a solid waste that is a non-creditable pharmaceutical must determine whether that pharmaceutical is a hazardous waste pharmaceutical (*i.e.*, it exhibits a characteristic identified in 40 CFR part 261 subpart C or is listed in 40 CFR part 261 subpart D) in order to determine whether the waste is subject to this subpart. A healthcare facility may choose to manage its non-hazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals under this subpart.

(d) *Standards for containers used to accumulate non-creditable hazardous waste pharmaceuticals at healthcare facilities.* (1) A healthcare facility must place non-creditable hazardous waste pharmaceuticals in a container that is structurally sound, compatible with its contents, and that lacks evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions.

(2) A healthcare facility that manages ignitable or reactive non-creditable hazardous waste pharmaceuticals, or that mixes or commingles incompatible non-creditable hazardous waste pharmaceuticals must manage the container so that it does not have the potential to:

(i) Generate extreme heat or pressure, fire or explosion, or violent reaction;

(ii) Produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;

(iii) Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;

(iv) Damage the structural integrity of the container of non-creditable hazardous waste pharmaceuticals; or

(v) Through other like means threaten human health or the environment.

(3) A healthcare facility must keep containers of non-creditable hazardous waste pharmaceuticals closed and secured in a manner that prevents unauthorized access to its contents.

(4) A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals and non-hazardous non-creditable waste pharmaceuticals in the same container, except that non-creditable hazardous waste pharmaceuticals prohibited from being combusted because of the dilution prohibition of § 268.3(c) must be accumulated in separate containers and

labeled with all applicable hazardous waste numbers (*i.e.*, hazardous waste codes).

(e) *Labeling containers used to accumulate non-creditable hazardous waste pharmaceuticals at healthcare facilities.* A healthcare facility must label or clearly mark each container of non-creditable hazardous waste pharmaceuticals with the phrase "Hazardous Waste Pharmaceuticals."

(f) *Maximum accumulation time for non-creditable hazardous waste pharmaceuticals at healthcare facilities.* (1) A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals on site for one year or less without a permit or having interim status.

(2) A healthcare facility that accumulates non-creditable hazardous waste pharmaceuticals on-site must demonstrate the length of time that the non-creditable hazardous waste pharmaceuticals have been accumulating, starting from the date it first becomes a waste. A healthcare facility may make this demonstration by any of the following methods:

(i) Marking or labeling the container of non-creditable hazardous waste pharmaceuticals with the date that the non-creditable hazardous waste pharmaceuticals became a waste;

(ii) Maintaining an inventory system that identifies the date the non-creditable hazardous waste pharmaceuticals being accumulated first became a waste;

(iii) Placing the non-creditable hazardous waste pharmaceuticals in a specific area and identifying the earliest date that any of the non-creditable hazardous waste pharmaceuticals in the area became a waste.

(g) *Land disposal restrictions for non-creditable hazardous waste pharmaceuticals.* The non-creditable hazardous waste pharmaceuticals generated by a healthcare facility are subject to the land disposal restrictions of 40 CFR part 268. A healthcare facility that generates non-creditable hazardous waste pharmaceuticals must comply with the land disposal restrictions in accordance with § 268.7(a) requirements, except that it is not required to identify the hazardous waste numbers (*i.e.*, hazardous waste codes) on the land disposal restrictions notification.

(h) *Procedures for healthcare facilities for managing rejected shipments of non-creditable hazardous waste pharmaceuticals.* A healthcare facility that sends a shipment of non-creditable hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of § 264.72 or § 265.72 of this chapter may accumulate the returned non-creditable hazardous waste pharmaceuticals on site for up to an additional 90 days provided the rejected or returned shipment is managed in accordance with paragraphs (d) and (e) of this section. Upon receipt of the returned shipment, the healthcare facility must:

(1) Sign either:

(i) Item 18c of the original manifest, if the original manifest was used for the returned shipment; or

(ii) Item 20 of the new manifest, if a new manifest was used for the returned shipment;

(2) Provide the transporter a copy of the manifest;

(3) Within 30 days of receipt of the rejected shipment, send a copy of the manifest to the designated facility that returned the shipment to the healthcare facility; and

(4) Within 90 days of receipt of the rejected shipment, transport or offer for transport the returned shipment in accordance with the shipping standards of § 266.508(a).

(i) *Reporting by healthcare facilities for non-creditable hazardous waste pharmaceuticals*—(1) *Biennial reporting by healthcare facilities.* Healthcare facilities are not subject to biennial reporting requirements under § 262.41, with respect to non-creditable hazardous waste pharmaceuticals managed under this subpart.

(2) *Exception reporting by healthcare facilities for a missing copy of the manifest*—(i) *For shipments from a healthcare facility to a designated facility.* (A) If a healthcare facility does not receive a copy of the manifest with the signature of the owner or operator of the designated facility within 60 days of the date the non-creditable hazardous waste pharmaceuticals were accepted by the initial transporter, the healthcare facility must submit:

(*1*) A legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the EPA Regional Administrator for the Region in which the healthcare facility is located; and

(*2*) A handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

(B) [Reserved]

(ii) *For shipments rejected by the designated facility and shipped to an alternate facility.* (A) If a healthcare facility does not receive a copy of the manifest for a rejected shipment of the non-creditable hazardous waste pharmaceuticals that is forwarded by the designated facility to an alternate facility (using appropriate manifest procedures), with the signature of the owner or operator of the alternate facility, within 60 days of the date the non-creditable hazardous waste was accepted by the initial transporter forwarding the shipment of non-creditable hazardous waste pharmaceuticals from the designated facility to the alternate facility, the healthcare facility must submit:

(*1*) A legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the EPA Regional Administrator for the Region in which the healthcare facility is located; and

(*2*) A handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

(B) [Reserved]

(3) *Additional reports.* The EPA Regional Administrator may require healthcare facilities to furnish additional reports concerning the quantities and disposition of non-creditable hazardous waste pharmaceuticals.

(j) *Recordkeeping by healthcare facilities for non-creditable hazardous waste pharmaceuticals.* (1) A healthcare facility must keep a copy of each manifest signed in accordance with § 262.23(a) for three years or until it receives a signed copy from the designated facility which received the non-creditable hazardous waste pharmaceuticals. This signed copy must be retained as a record for at least three years from the date the waste was accepted by the initial transporter.

(2) A healthcare facility must keep a copy of each exception report for a period of at least three years from the date of the report.

(3) A healthcare facility must keep records of any test results, waste analyses, or other determinations made to support its hazardous waste determination(s) consistent with § 262.11(f), for at least three years from the date the waste was last sent to on-site or off-site treatment, storage or disposal. A healthcare facility that manages all of its non-creditable non-hazardous waste pharmaceuticals as

non-creditable hazardous waste pharmaceuticals is not required to keep documentation of hazardous waste determinations.

(4) The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

(5) All records must be readily available upon request by an inspector.

(k) *Response to spills of non-creditable hazardous waste pharmaceuticals at healthcare facilities.* A healthcare facility must immediately contain all spills of non-creditable hazardous waste pharmaceuticals and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals in accordance with the requirements of this subpart.

(l) *Accepting non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator.* A healthcare facility may accept non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator under § 262.14, without a permit or without having interim status, provided the receiving healthcare facility:

(1) Is under the control of the same person (as defined in § 260.10) as the very small quantity generator healthcare facility that is sending the non-creditable hazardous waste pharmaceuticals off-site ("control," for the purposes of this section, means the power to direct the policies of the healthcare facility, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate healthcare facilities on behalf of a different person as defined in § 260.10 of this chapter shall not be deemed to "control" such healthcare facilities) or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the very small quantity generator healthcare facility;

(2) Is operating under this subpart for the management of its non-creditable hazardous waste pharmaceuticals;

(3) Manages the non-creditable hazardous waste pharmaceuticals that it receives from off site in compliance with this subpart; and

(4) Keeps records of the non-creditable hazardous waste pharmaceuticals shipments it receives from off site for three years from the date that the shipment is received.

§ 266.503 Standards for healthcare facilities managing potentially creditable hazardous waste pharmaceuticals.

(a) *Hazardous waste determination for potentially creditable pharmaceuticals.* A healthcare facility that generates a solid waste that is a potentially creditable pharmaceutical must determine whether the potentially creditable pharmaceutical is a potentially creditable hazardous waste pharmaceutical (*i.e.,* it is listed in 40 CFR part 261 subpart D or exhibits a characteristic identified in 40 CFR part 261 subpart C). A healthcare facility may choose to manage its potentially creditable non-hazardous waste pharmaceuticals as potentially creditable hazardous waste pharmaceuticals under this subpart.

(b) *Accepting potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator.* A healthcare facility may accept potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator under § 262.14, without a permit or without having interim status, provided the receiving healthcare facility:

(1) Is under the control of the same person, as defined in § 260.10, as the very small quantity generator healthcare facility that is sending the potentially creditable hazardous waste pharmaceuticals off site, or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the very small quantity generator healthcare facility;

(2) Is operating under this subpart for the management of its potentially creditable hazardous waste pharmaceuticals;

(3) Manages the potentially creditable hazardous waste pharmaceuticals that it receives from off site in compliance with this subpart; and

(4) Keeps records of the potentially creditable hazardous waste pharmaceuticals shipments it receives from off site for three years from the date that the shipment is received.

(c) *Prohibition.* Healthcare facilities are prohibited from sending hazardous wastes other than potentially creditable hazardous waste pharmaceuticals to a reverse distributor.

(d) *Biennial Reporting by healthcare facilities.* Healthcare facilities are not subject to biennial reporting requirements under § 262.41 with respect to potentially creditable hazardous waste pharmaceuticals managed under this subpart.

(e) *Recordkeeping by healthcare facilities.* (1) A healthcare facility that initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor must keep the following records (paper or electronic) for each shipment of potentially creditable hazardous waste pharmaceuticals for three years from the date of shipment:

(i) The confirmation of delivery; and

(ii) The shipping papers prepared in accordance with 49 CFR part 172 subpart C, if applicable.

(2) The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

(3) All records must be readily available upon request by an inspector.

(f) *Response to spills of potentially creditable hazardous waste pharmaceuticals at healthcare facilities.* A healthcare facility must immediately contain all spills of potentially creditable hazardous waste pharmaceuticals and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals in accordance with this subpart.

§ 266.504 Healthcare facilities that are very small quantity generators for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste.

(a) *Potentially creditable hazardous waste pharmaceuticals.* A healthcare facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may send its potentially creditable hazardous waste pharmaceuticals to a reverse distributor.

(b) *Off-site collection of hazardous waste pharmaceuticals generated by a healthcare facility that is a very small quantity generator.* A healthcare facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may send its hazardous waste pharmaceuticals off-site to another healthcare facility, provided:

(1) The receiving healthcare facility meets the conditions in § 266.502(l) of this subpart and § 266.503(b), as applicable; or

(2) The very small quantity generator healthcare facility meets the conditions in § 262.14(a)(5)(viii) and the receiving large quantity generator meets the conditions in § 262.17(f).

(c) *Long-term care facilities that are very small quantity generators.* A long-

term care facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may dispose of its hazardous waste pharmaceuticals (excluding contaminated personal protective equipment or clean-up materials) in an on-site collection receptacle of an authorized collector (as defined by the Drug Enforcement Administration) that is registered with the Drug Enforcement Administration provided the contents are collected, stored, transported, destroyed and disposed of in compliance with all applicable Drug Enforcement Administration regulations for controlled substances.

(d) *Long-term care facilities with 20 beds or fewer.* A long-term care facility with 20 beds or fewer is presumed to be a very small quantity generator subject to § 262.14 for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste and *not* subject to this subpart, except for §§ 266.505 and 266.507 and the other optional provisions of this section. The EPA Regional Administrator has the responsibility to demonstrate that a long-term care facility with 20 beds or fewer generates quantities of hazardous waste that are in excess of the very small quantity generator limits as defined in § 260.10. A long-term care facility with more than 20 beds that operates as a very small quantity generator under § 262.14 must demonstrate that it generates quantities of hazardous waste that are within the very small quantity generator limits as defined by § 260.10.

§ 266.505 Prohibition of sewering hazardous waste pharmaceuticals.

All healthcare facilities—including very small quantity generators operating under § 262.14 in lieu of this subpart—and reverse distributors are prohibited from discharging hazardous waste pharmaceuticals to a sewer system that passes through to a publicly-owned treatment works. Healthcare facilities and reverse distributors remain subject to the prohibitions in 40 CFR 403.5(b)(1).

§ 266.506 Conditional exemptions for hazardous waste pharmaceuticals that are also controlled substances and household waste pharmaceuticals collected in a take-back event or program.

(a) *Conditional exemptions.* Provided the conditions of paragraph (b) of this section are met, the following are exempt from 40 CFR parts 262 through 273:

(1) Hazardous waste pharmaceuticals that are also listed on a schedule of controlled substances by the Drug Enforcement Administration in 21 CFR part 1308, and

(2) Household waste pharmaceuticals that are collected in a take-back event or program, including those that are collected by an authorized collector (as defined by the Drug Enforcement Administration) registered with the Drug Enforcement Administration that commingles the household waste pharmaceuticals with controlled substances from an ultimate user (as defined by the Drug Enforcement Administration).

(b) *Conditions for exemption.* The hazardous waste pharmaceuticals must be:

(1) Managed in compliance with the sewer prohibition of § 266.505; and

(2) Collected, stored, transported, and disposed of in compliance with all applicable Drug Enforcement Administration regulations for controlled substances; and

(3) Destroyed by a method that Drug Enforcement Administration has publicly deemed in writing to meet their non-retrievable standard of destruction or combusted at one of the following:

(i) A permitted large municipal waste combustor, subject to 40 CFR part 62 subpart FFF or applicable state plan for existing large municipal waste combustors, or 40 CFR part 60 subparts Eb for new large municipal waste combustors; or

(ii) A permitted small municipal waste combustor, subject to 40 CFR part 62 subpart JJJ or applicable state plan for existing small municipal waste combustors, or 40 CFR part 60 subparts AAAA for new small municipal waste combustors; or

(iii) A permitted hospital, medical and infectious waste incinerator, subject to 40 CFR part 62 subpart HHH or applicable state plan for existing hospital, medical and infectious waste incinerators, or 40 CFR part 60 subpart Ec for new hospital, medical and infectious waste incinerators.

(iv) A permitted commercial and industrial solid waste incinerator, subject to 40 CFR part 62 subpart III or applicable state plan for existing commercial and industrial solid waste incinerators, or 40 CFR part 60 subpart CCCC for new commercial and industrial solid waste incinerators.

(v) A permitted hazardous waste combustor subject to 40 CFR part 63 subpart EEE.

§ 266.507 Residues of hazardous waste pharmaceuticals in empty containers.

(a) *Stock, dispensing and unit-dose containers.* A stock bottle, dispensing bottle, vial, or ampule (not to exceed 1 liter or 10,000 pills); or a unit-dose container (*e.g.,* a unit-dose packet, cup, wrapper, blister pack, or delivery device) is considered empty and the residues are not regulated as hazardous waste provided the pharmaceuticals have been removed from the stock bottle, dispensing bottle, vial, ampule, or the unit-dose container using the practices commonly employed to remove materials from that type of container.

(b) *Syringes.* A syringe is considered empty and the residues are not regulated as hazardous waste under this subpart provided the contents have been removed by fully depressing the plunger of the syringe. If a syringe is not empty, the syringe must be placed with its remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non-creditable hazardous waste pharmaceutical under this subpart and any applicable federal, state, and local requirements for sharps containers and medical waste.

(c) *Intravenous (IV) bags.* An IV bag is considered empty and the residues are not regulated as hazardous waste provided the pharmaceuticals in the IV bag have been fully administered to a patient. If an IV bag is not empty, the IV bag must be placed with its remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non-creditable hazardous waste pharmaceutical under this subpart, unless the IV bag held non-acute hazardous waste pharmaceuticals and is empty as defined in § 261.7(b)(1).

(d) *Other containers, including delivery devices.* Hazardous waste pharmaceuticals remaining in all other types of unused, partially administered, or fully administered containers must be managed as non-creditable hazardous waste pharmaceuticals under this subpart, unless the container held non-acute hazardous waste pharmaceuticals and is empty as defined in § 261.7(b)(1) or (2). This includes, but is not limited to, residues in inhalers, aerosol cans, nebulizers, tubes of ointments, gels, or creams.

§ 266.508 Shipping non-creditable hazardous waste pharmaceuticals from a healthcare facility or evaluated hazardous waste pharmaceuticals from a reverse distributor.

(a) *Shipping non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals.* A healthcare facility must ship non-creditable hazardous waste pharmaceuticals and a reverse distributor must ship evaluated hazardous waste pharmaceuticals off-

site to a designated facility (such as a permitted or interim status treatment, storage, or disposal facility) in compliance with:

(1) The following pre-transport requirements, before transporting or offering for transport off-site:

(i) *Packaging.* Package the waste in accordance with the applicable Department of Transportation regulations on hazardous materials under 49 CFR parts 173, 178, and 180.

(ii) *Labeling.* Label each package in accordance with the applicable Department of Transportation regulations on hazardous materials under 49 CFR part 172 subpart E.

(iii) *Marking.* (A) Mark each package of hazardous waste pharmaceuticals in accordance with the applicable Department of Transportation (DOT) regulations on hazardous materials under 49 CFR part 172 subpart D;

(B) Mark each container of 119 gallons or less used in such transportation with the following words and information in accordance with the requirements of 49 CFR 172.304:

HAZARDOUS WASTE—Federal Law Prohibits Improper Disposal. If found, contact the nearest police or public safety authority or the U.S. Environmental Protection Agency.

Healthcare Facility's or Reverse distributor's Name and Address

Healthcare Facility's or Reverse distributor's EPA Identification Number

Manifest Tracking Number

(C) Lab packs that will be incinerated in compliance with § 268.42(c) are not required to be marked with EPA Hazardous Waste Number(s), except D004, D005, D006, D007, D008, D010, and D011, where applicable. A nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the EPA Hazardous Waste Number(s).

(iv) *Placarding.* Placard or offer the initial transporter the appropriate placards according to Department of Transportation regulations for hazardous materials under 49 CFR part 172 subpart F.

(2) The manifest requirements of 40 CFR part 262 subpart B, except that:

(i) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals is not required to list all applicable hazardous waste numbers (*i.e.,* hazardous waste codes) in Item 13 of EPA Form 8700–22.

(ii) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals must write the word "PHARMS" in Item 13 of EPA Form 8700–22.

(b) *Exporting non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals.* A healthcare facility or reverse distributor that exports non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals is subject to 40 CFR part 262 subpart H.

(c) *Importing non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals.* Any person that imports non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals is subject to 40 CFR part 262 subpart H. A healthcare facility or reverse distributor may not accept imported non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals unless they have a permit or interim status that allows them to accept hazardous waste from off site.

§ 266.509 Shipping potentially creditable hazardous waste pharmaceuticals from a healthcare facility or a reverse distributor to a reverse distributor.

(a) *Shipping potentially creditable hazardous waste pharmaceuticals.* A healthcare facility or a reverse distributor who transports or offers for transport potentially creditable hazardous waste pharmaceuticals off-site to a reverse distributor must comply with all applicable U.S. Department of Transportation regulations in 49 CFR part 171 through 180 for any potentially creditable hazardous waste pharmaceutical that meets the definition of hazardous material in 49 CFR 171.8. For purposes of the Department of Transportation regulations, a material is considered a hazardous waste if it is subject to the Hazardous Waste Manifest Requirements of the U.S. Environmental Protection Agency specified in 40 CFR part 262. Because a potentially creditable hazardous waste pharmaceutical does not require a manifest, it is not considered hazardous waste under the Department of Transportation regulations.

(b) *Delivery confirmation.* Upon receipt of each shipment of potentially creditable hazardous waste pharmaceuticals, the receiving reverse distributor must provide confirmation (paper or electronic) to the healthcare facility or reverse distributor that initiated the shipment that the shipment of potentially creditable hazardous waste pharmaceuticals has arrived at its destination and is under the custody and control of the reverse distributor.

(c) *Procedures for when delivery confirmation is not received within 35 calendar days.* If a healthcare facility or reverse distributor initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor and does not receive delivery confirmation within 35 calendar days from the date that the shipment of potentially creditable hazardous waste pharmaceuticals was sent, the healthcare facility or reverse distributor that initiated the shipment must contact the carrier and the intended recipient (*i.e.,* the reverse distributor) promptly to report that the delivery confirmation was not received and to determine the status of the potentially creditable hazardous waste pharmaceuticals.

(d) *Exporting potentially creditable hazardous waste pharmaceuticals.* A healthcare facility or reverse distributor that sends potentially creditable hazardous waste pharmaceuticals to a foreign destination must comply with the applicable sections of 40 CFR part 262 subpart H, except the manifesting requirement of § 262.83(c), in addition to paragraphs (a) through (c) of this section.

(e) *Importing potentially creditable hazardous waste pharmaceuticals.* Any person that imports potentially creditable hazardous waste pharmaceuticals into the United States is subject to paragraphs (a) through (c) of this section in lieu of 40 CFR part 262 subpart H. Immediately after the potentially creditable hazardous waste pharmaceuticals enter the United States, they are subject to all applicable requirements of this subpart.

§ 266.510 Standards for the management of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals at reverse distributors.

A reverse distributor may accept potentially creditable hazardous waste pharmaceuticals from off site and accumulate potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals on site without a hazardous waste permit or without having interim status, provided that it complies with the following conditions:

(a) *Standards for reverse distributors managing potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals*—(1) *Notification.* A reverse distributor must notify the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700–12), that it is a reverse distributor operating under this subpart.

(i) A reverse distributor that already has an EPA identification number must notify the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700–12), that it is a reverse

distributor, as defined in § 266.500, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(ii) A reverse distributor that does not have an EPA identification number must obtain one by notifying the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700–12), that it is a reverse distributor, as defined in § 266.500, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(2) *Inventory by the reverse distributor.* A reverse distributor must maintain a current inventory of all the potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that are accumulated on site.

(i) A reverse distributor must inventory each potentially creditable hazardous waste pharmaceutical within 30 calendar days of each waste arriving at the reverse distributor.

(ii) The inventory must include the identity (*e.g.,* name or national drug code) and quantity of each potentially creditable hazardous waste pharmaceutical and evaluated hazardous waste pharmaceutical.

(iii) If the reverse distributor already meets the inventory requirements of this paragraph because of other regulatory requirements, such as State Board of Pharmacy regulations, the facility is not required to provide a separate inventory pursuant to this section.

(3) *Evaluation by a reverse distributor that is not a manufacturer.* A reverse distributor that is not a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste pharmaceutical within 30 calendar days of the waste arriving at the reverse distributor to establish whether it is destined for another reverse distributor for further evaluation or verification of manufacturer credit or for a permitted or interim status treatment, storage, or disposal facility.

(i) A potentially creditable hazardous waste pharmaceutical that is destined for another reverse distributor is still considered a "potentially creditable hazardous waste pharmaceutical" and must be managed in accordance with paragraph (b) of this section.

(ii) A potentially creditable hazardous waste pharmaceutical that is destined for a permitted or interim status treatment, storage or disposal facility is considered an "evaluated hazardous waste pharmaceutical" and must be managed in accordance with paragraph (c) of this section.

(4) *Evaluation by a reverse distributor that is a manufacturer.* A reverse distributor that is a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste pharmaceutical to verify manufacturer credit within 30 calendar days of the waste arriving at the facility and following the evaluation must manage the evaluated hazardous waste pharmaceuticals in accordance with paragraph (c) of this section.

(5) *Maximum accumulation time for hazardous waste pharmaceuticals at a reverse distributor.* (i) A reverse distributor may accumulate potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals on site for 180 calendar days or less. The 180 days start after the potentially creditable hazardous waste pharmaceutical has been evaluated and applies to all hazardous waste pharmaceuticals accumulated on site, regardless of whether they are destined for another reverse distributor (*i.e.,* potentially creditable hazardous waste pharmaceuticals) or a permitted or interim status treatment, storage, or disposal facility (*i.e.,* evaluated hazardous waste pharmaceuticals).

(ii) *Aging pharmaceuticals.* Unexpired pharmaceuticals that are otherwise creditable but are awaiting their expiration date (*i.e.,* aging in a holding morgue) can be accumulated for up to 180 days after the expiration date, provided that the unexpired pharmaceuticals are managed in accordance with paragraph (a) of this section and the container labeling and management standards in 266.510(c)(4)(i) through (vi).

(6) *Security at the reverse distributor facility.* A reverse distributor must prevent unknowing entry and minimize the possibility for the unauthorized entry into the portion of the facility where potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals are kept.

(i) Examples of methods that may be used to prevent unknowing entry and minimize the possibility for unauthorized entry include, but are not limited to:

(A) A 24-hour continuous monitoring surveillance system;

(B) An artificial barrier such as a fence; or

(C) A means to control entry, such as keycard access.

(ii) If the reverse distributor already meets the security requirements of this paragraph because of other regulatory requirements, such as Drug Enforcement Administration or State Board of Pharmacy regulations, the facility is not required to provide separate security measures pursuant to this section.

(7) *Contingency plan and emergency procedures at a reverse distributor.* A reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off site must prepare a contingency plan and comply with the other requirements of 40 CFR part 262 subpart M.

(8) *Closure of a reverse distributor.* When closing an area where a reverse distributor accumulates potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals, the reverse distributor must comply with § 262.17(a)(8)(ii) and (iii).

(9) *Reporting by a reverse distributor*—(i) *Unauthorized waste report.* A reverse distributor must submit an unauthorized waste report if the reverse distributor receives waste from off site that it is not authorized to receive (*e.g.,* non-pharmaceutical hazardous waste, regulated medical waste). The reverse distributor must prepare and submit an unauthorized waste report to the EPA Regional Administrator within 45 calendar days after the unauthorized waste arrives at the reverse distributor and must send a copy of the unauthorized waste report to the healthcare facility (or other entity) that sent the unauthorized waste. The reverse distributor must manage the unauthorized waste in accordance with all applicable regulations. The unauthorized waste report must be signed by the owner or operator of the reverse distributor, or its authorized representative, and contain the following information:

(A) The EPA identification number, name and address of the reverse distributor;

(B) The date the reverse distributor received the unauthorized waste;

(C) The EPA identification number, name, and address of the healthcare facility that shipped the unauthorized waste, if available;

(D) A description and the quantity of each unauthorized waste the reverse distributor received;

(E) The method of treatment, storage, or disposal for each unauthorized waste; and

(F) A brief explanation of why the waste was unauthorized, if known.

(ii) *Additional reports.* The EPA Regional Administrator may require reverse distributors to furnish additional reports concerning the quantities and disposition of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

(10) *Recordkeeping by reverse distributors.* A reverse distributor must keep the following records (paper or electronic) readily available upon request by an inspector. The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

(i) A copy of its notification on file for as long as the facility is subject to this subpart;

(ii) A copy of the delivery confirmation and the shipping papers for each shipment of potentially creditable hazardous waste pharmaceuticals that it receives, and a copy of each unauthorized waste report, for at least three years from the date the shipment arrives at the reverse distributor;

(iii) A copy of its current inventory for as long as the facility is subject to this subpart.

(b) *Additional standards for reverse distributors managing potentially creditable hazardous waste pharmaceuticals destined for another reverse distributor.* A reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements in paragraph (a) of this section, for the management of potentially creditable hazardous waste pharmaceuticals that are destined for another reverse distributor for further evaluation or verification of manufacturer credit:

(1) A reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from a healthcare facility must send those potentially creditable hazardous waste pharmaceuticals to another reverse distributor within 180 days after the potentially creditable hazardous waste pharmaceuticals have been evaluated or follow paragraph (c) of this section for evaluated hazardous waste pharmaceuticals.

(2) A reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from another reverse distributor must send those potentially creditable hazardous waste pharmaceuticals to a reverse distributor that is a pharmaceutical manufacturer within 180 days after the potentially creditable hazardous waste pharmaceuticals have been evaluated or follow paragraph (c) of this section for evaluated hazardous waste pharmaceuticals.

(3) A reverse distributor must ship potentially creditable hazardous waste pharmaceuticals destined for another reverse distributor in accordance with § 266.509.

(4) *Recordkeeping by reverse distributors.* A reverse distributor must keep the following records (paper or electronic) readily available upon request by an inspector for each shipment of potentially creditable hazardous waste pharmaceuticals that it initiates to another reverse distributor, for at least three years from the date of shipment. The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

(i) The confirmation of delivery; and

(ii) The DOT shipping papers prepared in accordance with 49 CFR part 172 subpart C, if applicable

(c) *Additional standards for reverse distributors managing evaluated hazardous waste pharmaceuticals.* A reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements of paragraph (a) of this section, for the management of evaluated hazardous waste pharmaceuticals:

(1) *Accumulation area at the reverse distributor.* A reverse distributor must designate an on-site accumulation area where it will accumulate evaluated hazardous waste pharmaceuticals.

(2) *Inspections of on-site accumulation area.* A reverse distributor must inspect its on-site accumulation area at least once every seven days, looking at containers for leaks and for deterioration caused by corrosion or other factors, as well as for signs of diversion.

(3) *Personnel training at a reverse distributor.* Personnel at a reverse distributor that handle evaluated hazardous waste pharmaceuticals are subject to the training requirements of § 262.17(a)(7).

(4) *Labeling and management of containers at on-site accumulation areas.* A reverse distributor accumulating evaluated hazardous waste pharmaceuticals in containers in an on-site accumulation area must:

(i) Label the containers with the words, "hazardous waste pharmaceuticals";

(ii) Ensure the containers are in good condition and managed to prevent leaks;

(iii) Use containers that are made of or lined with materials which will not react with, and are otherwise compatible with, the evaluated hazardous waste pharmaceuticals, so that the ability of the container to contain the waste is not impaired;

(iv) Keep containers closed, if holding liquid or gel evaluated hazardous waste pharmaceuticals. If the liquid or gel evaluated hazardous waste pharmaceuticals are in their original, intact, sealed packaging; or repackaged, intact, sealed packaging, they are considered to meet the closed container standard;

(v) Manage any container of ignitable or reactive evaluated hazardous waste pharmaceuticals, or any container of commingled incompatible evaluated hazardous waste pharmaceuticals so that the container does not have the potential to:

(A) Generate extreme heat or pressure, fire or explosion, or violent reaction;

(B) Produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;

(C) Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;

(D) Damage the structural integrity of the container of hazardous waste pharmaceuticals; or

(E) Through other like means threaten human health or the environment; and

(vi) Accumulate evaluated hazardous waste pharmaceuticals that are prohibited from being combusted because of the dilution prohibition of § 268.3(c) (*e.g.,* arsenic trioxide (P012)) in separate containers from other evaluated hazardous waste pharmaceuticals at the reverse distributor.

(5) *Hazardous waste numbers.* Prior to shipping evaluated hazardous waste pharmaceuticals off site, all containers must be marked with the applicable hazardous waste numbers (*i.e.,* hazardous waste codes). A nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the EPA Hazardous Waste Number(s).

(6) *Shipments.* A reverse distributor must ship evaluated hazardous waste pharmaceuticals that are destined for a permitted or interim status treatment, storage or disposal facility in accordance with the applicable shipping standards in § 266.508(a) or (b).

(7) *Procedures for a reverse distributor for managing rejected shipments.* A reverse distributor that sends a shipment of evaluated hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of § 264.72 or § 265.72 of this chapter, may accumulate the returned evaluated hazardous waste pharmaceuticals on

site for up to an additional 90 days in the on-site accumulation area provided the rejected or returned shipment is managed in accordance with § 266.510(a) and (c). Upon receipt of the returned shipment, the reverse distributor must:

(i) Sign either:

(A) Item 18c of the original manifest, if the original manifest was used for the returned shipment; or

(B) Item 20 of the new manifest, if a new manifest was used for the returned shipment;

(ii) Provide the transporter a copy of the manifest;

(iii) Within 30 days of receipt of the rejected shipment of the evaluated hazardous waste pharmaceuticals, send a copy of the manifest to the designated facility that returned the shipment to the reverse distributor; and

(iv) Within 90 days of receipt of the rejected shipment, transport or offer for transport the returned shipment of evaluated hazardous waste pharmaceuticals in accordance with the applicable shipping standards of § 266.508(a) or (b).

(8) *Land disposal restrictions.* Evaluated hazardous waste pharmaceuticals are subject to the land disposal restrictions of 40 CFR part 268. A reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off site must comply with the land disposal restrictions in accordance with § 268.7(a) requirements.

(9) *Reporting by a reverse distributor for evaluated hazardous waste pharmaceuticals*—(i) *Biennial reporting by a reverse distributor.* A reverse distributor that ships evaluated hazardous waste pharmaceuticals off-site must prepare and submit a single copy of a biennial report to the EPA Regional Administrator by March 1 of each even numbered year in accordance with § 262.41.

(ii) *Exception reporting by a reverse distributor for a missing copy of the manifest.*

(A) *For shipments from a reverse distributor to a designated facility.* (*1*) If a reverse distributor does not receive a copy of the manifest with the signature of the owner or operator of the designated facility within 35 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter, the reverse distributor must contact the transporter or the owner or operator of the designated facility to determine the status of the evaluated hazardous waste pharmaceuticals.

(*2*) A reverse distributor must submit an exception report to the EPA Regional Administrator for the Region in which the reverse distributor is located if it has not received a copy of the manifest with the signature of the owner or operator of the designated facility within 45 days of the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter. The exception report must include:

(*i*) A legible copy of the manifest for which the reverse distributor does not have confirmation of delivery; and

(*ii*) A cover letter signed by the reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated hazardous waste pharmaceuticals and the results of those efforts.

(B) *For shipments rejected by the designated facility and shipped to an alternate facility.* (*1*) A reverse distributor that does not receive a copy of the manifest with the signature of the owner or operator of the alternate facility within 35 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter must contact the transporter or the owner or operator of the alternate facility to determine the status of the hazardous waste. The 35-day time frame begins the date the evaluated hazardous waste pharmaceuticals are accepted by the transporter forwarding the hazardous waste shipment from the designated facility to the alternate facility.

(*2*) A reverse distributor must submit an Exception Report to the EPA Regional Administrator for the Region in which the reverse distributor is located if it has not received a copy of the manifest with the signature of the owner or operator of the alternate facility within 45 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter. The 45-day timeframe begins the date the evaluated hazardous waste pharmaceuticals are accepted by the transporter forwarding the hazardous waste pharmaceutical shipment from the designated facility to the alternate facility. The Exception Report must include:

(*i*) A legible copy of the manifest for which the generator does not have confirmation of delivery; and

(*ii*) A cover letter signed by the reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated hazardous waste pharmaceuticals and the results of those efforts.

(10) *Recordkeeping by a reverse distributor for evaluated hazardous waste pharmaceuticals.* (i) A reverse distributor must keep a log (written or electronic) of the inspections of the on-site accumulation area, required by paragraph (c)(2) of this section. This log must be retained as a record for at least three years from the date of the inspection.

(ii) A reverse distributor must keep a copy of each manifest signed in accordance with § 262.23(a) for three years or until it receives a signed copy from the designated facility that received the evaluated hazardous waste pharmaceutical. This signed copy must be retained as a record for at least three years from the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter.

(iii) A reverse distributor must keep a copy of each biennial report for at least three years from the due date of the report.

(iv) A reverse distributor must keep a copy of each exception report for at least three years from the submission of the report.

(v) A reverse distributor must keep records to document personnel training, in accordance with § 262.17(a)(7)(iv).

(vi) All records must be readily available upon request by an inspector. The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

(d) *When a reverse distributor must have a permit.* A reverse distributor is an operator of a hazardous waste treatment, storage, or disposal facility and is subject to the requirements of 40 CFR parts 264, 265, and 267 and the permit requirements of 40 CFR part 270, if the reverse distributor:

(1) Does not meet the conditions of this section;

(2) Accepts manifested hazardous waste from off site; or

(3) Treats or disposes of hazardous waste pharmaceuticals on site.

PART 268—LAND DISPOSAL RESTRICTIONS

■ 16. The authority citation for part 268 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, and 6924.

■ 17. Section 268.7 is amended by revising the section heading and the paragraph (a) subject heading to read as follows:

§ 268.7 Testing, tracking, and recordkeeping requirements for generators, reverse distributors, treaters, and disposal facilities.

(a) *Requirements for generators and reverse distributors.* * * *

* * * * *

■ 18. Section 268.50 is amended by adding paragraphs (a)(4) and (5) to read as follows:

§ 268.50 Prohibitions on storage of restricted wastes.

(a) * * *

(4) A healthcare facility accumulates such wastes in containers on site solely for the purpose of the accumulation of such quantities of hazardous waste pharmaceuticals as necessary to facilitate proper recovery, treatment, or disposal and the healthcare facility complies with the applicable requirements in §§ 266.502 and 266.503 of this chapter.

(5) A reverse distributor accumulates such wastes in containers on site solely for the purpose of the accumulation of such quantities of hazardous waste pharmaceuticals as necessary to facilitate proper recovery, treatment, or disposal and the reverse distributor complies with § 266.510 of this chapter.

* * * * *

PART 270—EPA ADMINISTERED PERMIT PROGRAMS: THE HAZARDOUS WASTE PERMIT PROGRAM

■ 19. The authority citation for part 270 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912, 6924, 6925, 6927, 6939, and 6974.

■ 20. Section 270.1 is amended by adding paragraph (c)(2)(x) to read as follows:

§ 270.1 Purpose and scope of these regulations.

* * * * *

(c) * * *

(2) * * *

(x) Reverse distributors accumulating potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals, as defined in § 266.500. Reverse distributors are subject to regulation under 40 CFR part 266 subpart P for the accumulation of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

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PART 273—STANDARDS FOR UNIVERSAL WASTE MANAGEMENT

■ 21. The authority citation for part 273 continues to read as follows:

Authority: 42 U.S.C. 6922, 6923, 6924, 6925, 6930, and 6937.

■ 22. Section 273.80 is amended by revising paragraph (a) and adding paragraph (d) to read as follows:

§ 273.80 General.

(a) Except as provided in paragraph (d) of this section, any person seeking to add a hazardous waste or category of hazardous waste to this part may petition for a regulatory amendment under this subpart and 40 CFR 260.20 and 260.23.

* * * * *

(d) Hazardous waste pharmaceuticals are regulated by 40 CFR part 266 subpart P and may not be added as a category of hazardous waste for management under this part.

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