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December 23, 2015

RCRA Docket  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, N.W.  
Washington, D.C. 20460

Attention: Docket ID No. EPA-HQ-RCRA-2007-0932

Dear Sir/Madam:

The Compliance Monitoring and Enforcement Task Force within the Hazardous Waste Subcommittee of the Association of State and Territorial Solid Waste Management Officials (ASTSWMO) appreciates the opportunity to provide comments on the proposed rule, Management Standards for Hazardous Waste Pharmaceuticals, published in the Federal Register on September 25, 2015 (80 FR 58013). These comments have not been reviewed or adopted by the ASTSWMO Board of Directors. In addition, individual State or Territorial hazardous waste programs may also provide comments based on their own State perspectives and experiences.

ASTSWMO is an association representing the waste management and remediation programs of the 50 States, five Territories and the District of Columbia (States). Our membership includes State waste program experts in the management and regulation of solid and hazardous waste.

The attached comments reflect the input of members of the Compliance Monitoring and Enforcement Task Force, as well as comments shared by State hazardous waste programs outside of the Task Force membership. The term "States" as used in these comments refers to the States that have provided input to the Task Force. Our submittal also presents the diversity of the State comments received, noting where States are in agreement, and where views may differ or were expressed by a certain number of States.

All of the States that provided comments on the proposed rule offered their general support. One State commented: "We are generally very pleased with this draft rule and commend EPA for how well it is drafted and the obvious thought and hard work that has gone into its preparation."

We appreciate the opportunity to provide comments on this important topic. If you have any questions about these comments, please contact Steve Simoes (VT), Vice-Chair of the Compliance Monitoring and Enforcement Task Force, at [steve.simoes@vermont.gov](mailto:steve.simoes@vermont.gov) or 802-522-0386, or Kerry Callahan, ASTSWMO staff, at [kerry@astswmo.org](mailto:kerry@astswmo.org) or 202-640-1062.

Sincerely,

Tammie J. Hynum (AR)  
Chair, ASTSWMO Hazardous Waste Subcommittee

## ATTACHMENT

### Specific Comments Submitted by the Compliance Monitoring and Enforcement Task Force of the ASTSWMO Hazardous Waste Subcommittee regarding the

#### Proposed Rule, Management Standards for Hazardous Waste Pharmaceuticals

80 FR 58013

September 25, 2015

Docket ID No. EPA-HQ-RCRA-2007-0932

#### Specific Comments on the Preamble to the Proposed Rule:

1. **Section IV.C.3. (Why is EPA not finalizing the 2008 Pharmaceutical Universal Waste proposal?), page 58020:**

One State commented: “EPA states in column 3 that ‘this new proposed rulemaking will pertain to those waste pharmaceuticals that meet the current definition of a RCRA hazardous waste and are generated by healthcare-related facilities *and managed by pharmaceutical reverse distributors*, as defined by this proposal.’ This preamble language suggests that in order for waste pharmaceuticals to qualify for management under Subpart P, they must be managed by a pharmaceutical reverse distributor. EPA should clarify this statement as the rule does not necessarily require waste pharmaceuticals to be managed by a pharmaceutical reverse distributor (i.e., non-creditable hazardous waste pharmaceuticals may be sent directly to a TSD [Treatment, Storage and Disposal Facility]).”

2. **Section V.A. (What terms are defined in this proposed rule?), pages 58021 – 58025:**

Multiple States commented that EPA should define the term “forward distributor,” a term that is used throughout the proposed rule.

3. **Section V.A.1. (What is the proposed definition of “pharmaceutical?”), pages 58021 - 58022:**

While most States that offered comments to ASTSWMO expressed general support for the proposed definition of “pharmaceutical,” the following suggestions were provided:

- One State commented that “‘Pharmaceutical’ is defined as any chemical or biological product that is intended for use in the diagnosis, cure, treatment, or prevention of a disease or injury of a human or other animal; or any chemical or biological product that is product that is intended to affect the structure or function of the body of a human or other animal. The proposed definition of pharmaceutical specifically covers disease and injury but does not include illness or sickness. The definition should be expanded to cover ‘illness and sickness’ to ensure that other products that are offered over the counter are captured by the definition.”
- All but one of the States that offered comments supported EPA’s proposal to include dietary supplements in the definition of “pharmaceutical.”

- Many of the States that offered comments on EPA’s proposal to include “...personal protective equipment [PPE] contaminated with residues of pharmaceuticals, and clean-up material from the spills of pharmaceuticals” in the definition of “pharmaceutical” expressed the following concerns with that proposal:
  - A number of States suggested that the definition be limited to what people normally think of as pharmaceuticals, implying that most people would not normally associate PPE with pharmaceuticals.
  - Two States expressed concern that spill clean-up material (especially if contaminated with a p-listed chemical) would not be counted toward a facility’s generator status and would not be subject to biennial reporting.
  - One State offered that including spill material under the definition of “pharmaceutical” broadens the definition too much and may lead to confusion, releases, and abuse.
  - One State suggested that EPA clarify when PPE would be subject to the definition, providing the examples of PPE that has come in direct contact with liquid or semi-liquid pharmaceuticals, and PPE that is visually contaminated with pharmaceuticals.
  - Another State recommended that EPA further clarify within its definition of this term in the final rule the distinction between PPE contaminated with trace amounts of pharmaceutical residues due to activities associated with patient care and pharmaceutical spill cleanup, which are considered pharmaceuticals under the proposal, and PPE contaminated with trace amounts of pharmaceutical residues due to activities associated with on-site formulation and patient delivery systems, which the State assumes would not be considered pharmaceuticals under the proposal.
- One State commented that “EPA is proposing to ‘take a broad view in delineating what items are included in the definition of pharmaceutical’, and in the preamble mentions IV bags, tubing and syringes containing pharmaceutical residuals as being applicable. While EPA notes that ‘sharps’ would not meet this definition because they are defined as a medical waste, IV bags, tubing and syringes can often also be defined as medical waste as these items can come in contact with blood, blood products or pathogens. It is not uncommon to have back flow of blood into IV tubing and syringes.” As such, the State believes that the definition should specifically state that items potentially having come in contact with blood, blood products or pathogens do not meet this definition, noting, “We don’t want potential biohazard wastes involved in this regulatory scheme.”

**4. Section V.A.2. (What is the proposed definition of a “hazardous waste pharmaceutical”?), pages 58022 - 58023:**

One State commented that it is unclear “why EPA is ‘recommending’ that pharmaceutical with hazardous waste like qualities be managed as hazardous waste and not required to manage them as hazardous waste. Please broaden the definition to include antineoplastic agents. Currently, only a handful of antineoplastic agents are listed because new drugs are constantly being developed and the ‘P’ and ‘U’ list of chemicals has not been updated in many years. These pharmaceuticals are similar in chemical structure, mode of action and toxicity and should be managed as hazardous waste.”

**5. Section V.A.3. (What is the proposed definition of “potentially creditable hazardous waste pharmaceutical”?), pages 58022 - 58023:**

- One State offered that “potentially creditable hazardous waste pharmaceutical” is defined to mean a hazardous waste pharmaceutical that has the potential to receive manufacturer’s credit and is (1) unused or un-administered; and (2) unexpired or less than one year past expiration date. The State recommends that the proposed definition include “unopened” in addition to unused or un-administered because the EPA specifically cites instances where it is “well known that a pharmaceutical will not be creditable”. One such example listed by the EPA is when pharmaceuticals have been removed from their original container and re-packaged for dispensing purposes. Unused or un-administered pharmaceuticals have the potential to have been removed from their original container and re-packaged for dispensing purposes. However, unopened pharmaceuticals do not have the potential to have been removed from their original container and re-packaged for dispensing purposes. The State comments that, therefore, “unopened” is clearer and would help healthcare facilities to make sound decisions on whether or not pharmaceuticals would be “potentially creditable pharmaceuticals.”
- One State commented that it has already taken the position that a medication that is no longer going to be used for its intended purpose is a solid waste subject to hazardous waste determination requirements. Therefore, the medication is a waste at the facility (e.g., hospital, long-term care facility). The State believes that EPA’s proposed definition and regulatory handling of potentially creditable pharmaceuticals should ensure that these hazardous wastes are managed and disposed of properly. Previously, the State was concerned that hazardous waste pharmaceuticals were being sent to reverse distributors as a way to avoid hazardous waste transportation and disposal requirements.
- Another State suggested that in order to effectively regulate waste pharmaceuticals, the words “reasonable expectation of credit” should be used in the definition, which would infer that the healthcare facility has reviewed their potentially creditable pharmaceutical(s) and will not send uncreditable pharmaceutical to a reverse distributor.

**6. Section V.A.4. (What is the proposed definition of “non-creditable hazardous waste pharmaceutical”?), page 58023:**

One State commented that, as EPA points out, there are instances when it is well known that credit will not be received for certain pharmaceuticals. In many healthcare settings, the State has observed that medication waste streams can be relatively constant from month to month. As a result, facilities become aware of which pharmaceuticals will and which will not be credited. The State agrees with the proposed definition.

**7. Section V.A.9. (What is the proposed definition of “healthcare facility”?), page 58024:**

While most States that offered comments to ASTSWMO expressed general support for the proposed definition of “healthcare facility,” the following suggestions were also provided:

- With respect to the statement in the preamble that the “proposed definition of ‘healthcare facility’ does not apply to pharmaceutical manufacturers and their representatives, wholesalers, or any other entity that is involved in the manufacturing, processing or wholesale distribution of over-the-counter or prescription pharmaceuticals, unless they meet the definition of a ‘reverse distributor...’”:
  - One State commented that “EPA should include this language in the definition of ‘healthcare facility.’ Many definitions that currently exist under 40 CFR 260.10 contain language that specify what is not included in those definitions.”
  - Another State asked the following questions:
    - “Is it EPA’s intent to also exclude pharmaceutical development laboratories from this definition? What about development laboratories with associated animal testing facilities?”
    - “Is it EPA’s intent to include diagnostic and other laboratories located within a healthcare facility in the definition of ‘healthcare facility’? Example 1 – a small hospital may have one or two laboratories that are used to test body fluids, tissue, etc., that may also have pharmaceuticals used in some of their testing. Example 2 – a large research hospital with multiple research labs, clinical labs, and teaching laboratories. Would pharmaceuticals generated in these labs be managed under this proposed rule?”
    - “Is it EPA’s intent to include animal research facilities, kennels, and animal testing labs under the definition of ‘healthcare facility’? Animals are kept at these facilities long-term and pharmaceuticals associated with their care, along with pharmaceuticals potentially tested on them, may be generated in these facilities.”
- One State noted the EPA statement that it is seeking comment “on the proposed definition of ‘healthcare facility’, including whether it is appropriate to consider compounders as healthcare facilities within the scope of the proposed rule.” The State comments that compounders do perform functions associated with both pharmaceutical manufacturers and healthcare facilities as defined by the Agency’s proposed definition. However, compounders should be included in the definition of healthcare facility because they do not predictably generate a known range of hazardous wastes like a manufacturing facility would. Compounders would be compounding pharmaceuticals for a myriad of customer’s needs and thus would face problems similar to that of a healthcare facility. The State also supports the inclusion of locations that sell pharmaceuticals over the internet, through the mail, or through other distribution mechanisms the proposed definition of “healthcare facility”.
- One State simply offered that it agrees with the proposed definition.
- Another State specified that much of this proposal regarding potentially creditable pharmaceuticals and reverse distribution seems to be tailored to retail pharmacies, yet the logic

behind sector-specific regulatory relief refers mostly to facilities that actually provide care (e.g., hospitals, health clinics, and long-term care facilities). The State would feel more comfortable applying these provisions to a narrower range of healthcare facilities that did not include retail pharmacies or facilities that only “provide care” by providing pharmaceuticals. The State also offered that healthcare facility should be defined as “Any facility that...” rather than “Any person that...”, given the definitions and responsibilities of facilities and persons under the RCRA Subtitle C program.

- One State specified that further clarification regarding the applicability of the Part 266 standards to hospice and home health organizations is needed since these entities may generate hazardous waste pharmaceuticals as part of an in-home visit.
- One State suggested that the definition of healthcare facility could result in a significant expansion in the number of generators regulated, and that many of these healthcare facilities may have little or no familiarity with RCRA. This could present challenges with regard to implementation of and compliance with the proposed waste pharmaceutical management standards. Therefore, the State recommends that EPA consider releasing additional guidance and training materials that cater to different types of healthcare facilities concurrent with the final rule, for utilization by healthcare facilities and States during the six-month period between promulgation and when the final rule would become effective. The State also recommends that EPA establish national regulatory performance criteria to evaluate the ability of EPA’s proposed management standards to effectively track pharmaceutical hazardous waste.
- With respect to EPA’s request for comment on including coroners within the definition of healthcare facility:
  - One State commented that it believes the definition of “healthcare facility” should not include coroners and medical examiners, as the nature of what these entities do, and the vast majority of wastes that are generated (medical waste –due to contact with blood/pathogens), is inconsistent with the definition of a “pharmaceutical” and “healthcare facility”. However, if they remain included in the definition, the State comments that their applicability should be specifically limited to drugs taken from response sites, as noted in the preamble.
  - Two other States supported including coroners within the definition of a healthcare facility, with one State commenting “based on the chemicals and pharmaceuticals they use for the performance of testing and autopsies”, and the other State expressing support “since coroners handle and dispose of pharmaceuticals as part of their services and should be included in the regulatory framework to ensure proper disposal of their RCRA hazardous waste.”

**8. Section V.A.10. (What is the proposed definition of “long-term care facility”?), pages 58024 - 58025:**

Two States commented that they agreed with the proposed definition of “long-term care facility.”

One State suggested that EPA consider defining long-term care facilities by size, to exclude very small facilities (less than 10 beds or less than 20 beds). That State would also like EPA to consider

including an exemption in the definition of long-term care facilities, to exempt any facility that has less than 20 beds from the requirements of Subpart P (other than the sewer ban) by specifically allowing a facility of that size to utilize community collection programs for their pharmaceuticals.

9. **Section V.A.11. (What is the proposed definition of “pharmaceutical reverse distributor?”), page 58025:**

Two States commented that they agreed with the proposed definition of “pharmaceutical reverse distributor.”

10. **Section V.B.1.a. (What is the scope of this proposed rule? / Healthcare facilities), pages 58025 - 58026:**

In response to EPA’s proposal to make Subpart P mandatory for healthcare facilities that generate above Conditionally Exempt Small Quantity Generator [CESQG] monthly quantity limits:

- Two States commented that having one set of standards will be less confusing to the regulated community. Both States also encourage EPA to consider regulating all healthcare facilities (including CESQGs) that generate hazardous waste pharmaceuticals under the proposed regulations to minimize confusion and promote consistency across the entire spectrum of the healthcare industry settings.
- Another State specified that EPA should consider requiring all generator categories to comply with the proposed standards for management of hazardous waste pharmaceuticals generated at their facilities, including CESQGs.

11. **Section V.B.1.b. (What is the scope of this proposed rule? / Long-term care facilities subject to this rule), pages 58026 - 58027:**

In response to EPA’s proposal to change its current policy that hazardous waste pharmaceuticals generated on the premises of long-term care facilities, when under the control of a patient or resident, are subject to RCRA’s household hazardous waste exemption:

- Two States agreed that long-term care facilities should be considered healthcare facilities. One of these States specified that “only the facilities that allow patients to dispense and administer their own medications should be excluded as a household”. The other State offered that “today’s typical long-term care facility does not so much reflect a household as it does a hospital.”
- One State opposed removing long-term health care facilities (group homes) from the designation as households and offered that:
  - Group homes provide assistance in daily living activities such as housekeeping, eating, and grooming. Group home facilities are not required to have healthcare professionals (e.g., registered nurses) on staff. The facilities are prohibited from providing medical treatment with the exception of first-aid. If a resident requires medical treatment, the

resident is transported to a healthcare facility such as a hospital, doctor's office, dialysis facility, etc.

- Medications taken by residents in group homes are the same medications taken by individuals in households across the county. Medications are provided to the residents in a manner similar to when a legal guardian gives medication to their ward (e.g., parent to a child, or adult child to a dependent parent).
- Group homes are regulated by the State Health Division. Health Division regulatory oversight of group homes includes disposal of waste pharmaceuticals in an environmentally sound and responsible manner. Subjecting group homes to RCRA regulation is a duplicative and unnecessary allocation of limited State resources.

**12. Section V.B.1.c. (What is the scope of this proposed rule? / Conditionally Exempt Small Quantity Generators (CESQGs)), page 58027:**

In response to EPA's request for comment on whether the proposed healthcare facility standards, in addition to the sewer ban, should apply to CESQG healthcare facilities, two States commented that they would prefer to see all of the proposed standards, including the sewer ban, apply to CESQGs for the following reasons: 1) as EPA points out, healthcare professionals are not RCRA specialists and therefore the disposal regulations should be as consistent as possible across the spectrum; 2) healthcare professionals can be highly mobile, moving from State to State and industry to industry within the healthcare sector. Keeping the regulatory requirements as consistent as possible across the healthcare industry (to include CESQGs) will minimize non-compliance and reduce confusion; 3) the nature of pharmaceutical waste (toxicity, potency, persistence in the environment) and the existing and growing prevalence of all types of healthcare facilities to match the growing need for these services, warrants full inclusion of CESQGs to the proposed rule; and 4) as EPA points out, not all medications that might meet the definition of a RCRA hazardous waste have been identified, leaving the possibility that more RCRA hazardous waste is generated than is currently known.

With respect to EPA's proposal to allow CESQGs to continue to send their potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor, and EPA's request for comment on whether this change being proposed in Part 266 Subpart P should be made in § 261.5 instead, two States commented that they would prefer to see the change made in both places, and one State commented that the CESQG rules of § 261.5 should identify the options available to CESQG healthcare facilities, since "CESQGs all know their requirements are in § 261.5, that is where EPA should outline the options available."

Two States responded to EPA's request for comment on providing a rebuttable presumption that long-term care facilities with fewer than 10 beds are assumed to be CESQGs as follows:

- One State commented that it agrees with this proposal assuming the limit is kept to 10. It has been the State's experience that it is not as much the bed count that impacts the amount of hazardous waste generated, but rather the focus of that particular healthcare facility and specific patient medical needs that drive the amount of waste generated. It has also been the

State's experience that all of its long-term care facilities are CESQGs, regardless of number of beds.

- The other State commented that it does not support the idea of a rebuttable presumption that a long-term care facility with less than 10 beds is a CESQG, indicating "we believe that all generators must be required to make a hazardous waste determination and count the HW [hazardous waste] they generate, because the generator category impacts what other regulations apply. The regulated entity will never be motivated to rebut the presumption that they are not subject to regulation, yet they are the party with information about their waste generation that could be used to rebut the presumption. It is a waste of resources for regulators to be charged with rebutting such a presumption by gathering information from the generator. Rebuttable presumptions that assume MORE regulation and can be rebutted by the regulated entity make better sense (for example, 40 CFR 279.10(b)(1)(ii))."

**13. Section V.C.1. (What are the proposed standards for healthcare facilities that manage non-creditable hazardous waste pharmaceuticals? / Notification Requirement), page 58031:**

The following comments were offered regarding the proposed notification requirement:

- Two States commented that a notification requirement is necessary for the identification of the healthcare universe and outreach to the healthcare community.
- One State recommended that the final rule provide a 60-day period for all healthcare facilities to notify or re-notify.
- While another State agreed with the 60-day notification requirement because it is consistent with its current requirement for hazardous waste generators, that State also offered that it will be "very confusing to count the hazardous waste pharmaceuticals to determine if a healthcare facility is a CESQG (presumably for the sewer ban element) [see part 266, Subpart P, page 08068, column 1], but not count the hazardous waste pharmaceuticals for their monthly generator status (CESQG, SQG [Small Quantity Generator], LQG [Large Quantity Generator]) [see part 266, Subpart P, page 08068, column 2]. To have a checkbox on the form for whether or not the healthcare facility has dropped below the CESQG status adds even more confusion to exactly what waste is being counted."
- One State offered that it believes all facilities subject to subpart P should notify within 60 days, and not have the option of waiting until the next biennial report cycle to notify. The State would like hazardous waste pharmaceuticals to be included in biennial reports for facilities required to submit those reports. The State suggests perhaps there could be a separate reporting form that is required of all facilities operating under subpart P, since there are many facilities that are currently LQGs that will drop down to SQG or CESQG status if pharmaceuticals are not counted toward their monthly generation status.
- One State commented that "for healthcare facilities and reverse distributors, their 'sub-generator' status (for lack of a better term - CESQG, SQG, LQG) specifically as it relates to pharmaceutical waste generation amounts, should also be included. This will assist States regarding inspection targeting. As it is proposed that pharmaceutical wastes will not be counted

towards standard generator status and since CESQGs have lower priority status from an inspection perspective, we could have CESQG facilities handling LQG levels of pharmaceuticals and may want to prioritize some of these inspections, especially with the ‘newness’ of the rule.”

- One State “strongly encourages that EPA consider requiring biennial reporting for healthcare facilities regardless of whether or not hazardous waste pharmaceuticals count towards generator status. Many States utilize federally required reporting as a basis for evaluating State fees due from generators. Without federally required reporting, States may be forced to establish additional reporting requirements at the State level.”

**14. Section V.C.2. (What are the proposed standards for healthcare facilities that manage non-creditable hazardous waste pharmaceuticals? / Personnel Training Requirements for Healthcare Facilities managing Non-Creditable Hazardous Waste Pharmaceuticals), page 58032:**

All States that provided comments generally support the proposed personnel training requirements. The following additional comments were also offered:

- One State commented that it “prefers that written training documentation be required particularly due to the turnover and shift work (most are 24/7 operations) that occur at these facilities. Many of these facilities already maintain training documentation.”
- One State offered that it is supportive of the training requirement but recommends that EPA establish clear minimum requirements for this training beyond those mentioned within the proposal.
- Two States specified “that tracking and documenting training is essential given that healthcare professionals are highly mobile within the healthcare industry. Without some sort of tracking mechanism in place that can be verified, the training aspect of these regulations will be difficult for regulators to assess and enforce.” Another State reiterated the concern about compliance monitoring by stating that if there is no documentation requirement, it will be impossible for inspectors to verify compliance with the training requirement.
- One State indicated that it supports a requirement to maintain records of the training, but also supports a requirement for annual training.

**15. Section V.C.3. (What are the proposed standards for healthcare facilities that manage non-creditable hazardous waste pharmaceuticals? / Making a Hazardous Waste Determination for Non-Creditable Hazardous Waste Pharmaceuticals), page 58032:**

In response to EPA’s statement that “...healthcare facilities may choose to manage all of their pharmaceutical waste as hazardous waste, and thus, if a healthcare facility chooses this approach, they would not need to make individual hazardous waste determinations, but would have made a generic decision that all of their waste pharmaceuticals are hazardous and managed them as hazardous waste pharmaceuticals in accordance with the proposed requirements of 40 CFR part 266, subpart P”, one State commented that it “applauds EPA for specifying this approach within the proposed rule. By having the option to not make hazardous waste determinations (a daunting task for facilities not well versed in RCRA) on waste pharmaceuticals, many healthcare facilities will likely

be encouraged to manage all of their pharmaceutical waste in an environmentally protective manner (i.e., as hazardous waste pharmaceuticals).”

**16. Section V.C.4. (What are the proposed standards for healthcare facilities that manage non-creditable hazardous waste pharmaceuticals? / No Central Accumulation Area and Satellite Accumulation Area Requirements for Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals), page 58033:**

- One State commented that while it agrees that the satellite accumulation area regulations are not necessarily appropriate for the management of non-creditable hazardous waste pharmaceuticals, the State believes that accumulated non-creditable hazardous waste pharmaceuticals should be transferred to/managed in a central accumulation area to help facilitate compliance monitoring by EPA and authorized State programs.
- One State specified that because facilities that may generate hazardous waste pharmaceuticals typically do so in small quantities at many locations within the facility, the preamble of the final rule should suggest (but not require) central accumulation areas for collection of waste pharmaceuticals to facilitate compliance.
- Two States agreed with the decision to not require specific central and satellite accumulation areas.

**17. Section V.C.5. (What are the proposed standards for healthcare facilities that manage non-creditable hazardous waste pharmaceuticals? / Container Standards for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals), pages 58033 - 58034:**

- Two States commented that they agree with the proposed container standards.
- With respect to the EPA statement that “...the Agency is proposing to require that incompatible wastes not be placed in the same container unless... [five specified conditions are met]”, one State commented that it “believes that the specified conditions are subjective (i.e., due to language like “extreme heat or pressure,” “uncontrolled toxic mists,” “uncontrollable flammable fumes or gases) and that incompatible wastes should not be placed in the same container under any circumstance.”

**18. Section V.C.6. (What are the proposed standards for healthcare facilities that manage non-creditable hazardous waste pharmaceuticals? / Labeling Standards on Containers for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals), page 58034:**

- Three States agreed with the proposed labeling requirement.
- Another State commented that EPA should be more flexible in its labeling requirement rather than prescribing precise text for the label. Many violations are cited for labels not having the exact text required by a rule even though the label clearly identifies what is in the container. The final rule should offer flexibility, by including language such as “mark each container with the phrase “Hazardous Waste Pharmaceuticals” or similar language that clearly identifies the contents of the container.”

**19. Section V.C.7. (What are the proposed standards for healthcare facilities that manage non-creditable hazardous waste pharmaceuticals? / Accumulation Time Limits for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals), page 58034:**

- Two States agreed with the proposed accumulation time limit of one year.
- One State commented that “the one-year waste accumulation timeframe seems to be at odds with the security issues (pilfering) identified in the proposal. Storing a year’s worth of waste pharmaceuticals in some back closet does not seem like a good idea, especially for high volume facilities.” The State recommends accumulation timeframes be established based on volumes generated.

**20. Section V.C.8. (What are the proposed standards for healthcare facilities that manage non-creditable hazardous waste pharmaceuticals? / Land Disposal Restrictions [LDR] for Non-Creditable Hazardous Waste Pharmaceuticals), pages 58034 - 58039:**

- One State commented that “Generated non-creditable wastes of LDR concern at healthcare facilities should be segregated and labeled separately and identified appropriately by waste code on the manifest. While this may present complexity to new entities (existing entities are required to do it now), it will ensure a clear path of generator regulatory responsibility/liability and provide the necessary information to the TSDFs to ensure proper treatment.
- Two States commented that it is necessary to include requirements to segregate and label hazardous waste pharmaceuticals that cannot be incinerated in the generator and reverse distributor management standards in subpart P.

**21. Section V.C.9. (What are the proposed standards for healthcare facilities that manage non-creditable hazardous waste pharmaceuticals? / Shipments of Non-Creditable Hazardous Waste Pharmaceuticals Off-site from Healthcare Facilities), page 58039:**

- In response to the EPA statement that “...the Agency is proposing that for hazardous waste pharmaceuticals shipped by healthcare facilities, the RCRA hazardous waste codes do not need to be listed on the manifest”, one State suggested that “EPA create a single hazardous waste code for ‘non-creditable hazardous waste pharmaceuticals’ that may be used by healthcare facilities when shipping such wastes off-site. It should be noted that the absence of a hazardous waste code on manifests may create problems for State hazardous waste manifest tracking and tax assessment systems. Also, will manifest section 13 (i.e., Waste Codes) be a required field on the proposed e-manifest?”
- Another State commented that it agreed with the “suggestion to create a single hazardous waste code for ‘non-creditable hazardous waste pharmaceuticals.’ Treatment limits (LDR) could be created that include all of the potential constituents to aid transporters and TSDFs, and to make it easier and more cost effective for States and TSDFs to incorporate and adjust to the new rule.”

- One State commented that the preamble states that “the fact that EPA is proposing to not require hazardous waste codes for shipping hazardous waste pharmaceuticals is not intended to alter or impact any Department of Transportation [DOT] requirements for the shipment of these hazardous wastes”. The State asked, “Don’t DOT requirements include use of the [uniform hazardous waste] manifest and require that the manifest be completely filled out, including waste codes? The State suggests that if EPA defines pharmaceutical waste as a listed category of hazardous waste [see section VII of the proposed rule], then a single waste code can be used on the manifest form that applies to pharmaceutical waste in general, which would solve this problem.
- One State recommends that, if a specific waste code for hazardous waste pharmaceuticals (which is preferable) is not created, including the term “hazardous waste pharmaceuticals” in Box 14 (the special handling instructions and additional information) of EPA Form 8700-22 (manifest form) for both healthcare facilities and reverse distributors (even though the reverse distributors have to include the waste codes). The State comments, “With the soon to be implementation of the national e-manifest system, the consistent use of this term, in this consistent location (obviously a standard waste code would be better here), will provide easy and comprehensive reporting capability on the volumes of these wastes across both the healthcare and reverse distributor universe and not just rely on the reverse distributor [biennial] report which will not provide the full volumes of generated pharmaceutical wastes.”

**22. Section V.C.12. (What are the proposed standards for healthcare facilities that manage non-creditable hazardous waste pharmaceuticals? / Recordkeeping Requirements for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals), pages 58040 - 58041:**

- Three States agreed with the proposed recordkeeping requirements.
- One State commented that under the proposed generator improvement rule [80 FR 57918], the documentation generators are required to retain to support a waste determination is spelled out in greater detail than it is in the current regulations. The State provided these additional comments: “If the generator improvement rule is finalized as proposed, will these documentation requirements apply to generators of hazardous waste pharmaceuticals even if they manage pharmaceutical waste under subpart P? If so, this could be a helpful and important component of how the rules ‘encourage’ over-management [see section VII of the proposed rule]. In order to determine their generator status and whether they are subject to subpart P, generators would need to make a waste determination on their pharmaceutical waste, but it appears to the State that if they are required or opt to manage under subpart P, the proposed requirement to document waste determination would probably not apply to their pharmaceutical waste.”

**23. Section V.C.13. (What are the proposed standards for healthcare facilities that manage non-creditable hazardous waste pharmaceuticals? / Response to Releases by Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals), page 58041:**

- Three States agreed with the proposed standards for response to releases of non-creditable hazardous waste pharmaceuticals.
- One of these three States added that a release of potentially creditable hazardous waste pharmaceuticals should also be subject to these containment and cleanup requirements, unless the rule is intended to imply that all releases of potentially creditable hazardous waste pharmaceuticals render them non-creditable. Some potentially creditable hazardous waste pharmaceuticals (e.g., tablets or capsules) may remain potentially creditable after they have been cleaned up while others (e.g., liquids or gels), would likely be non-creditable after a release. This State indicated that to rectify this concern, the final rule should require any release of hazardous waste pharmaceuticals to be cleaned up, any potentially creditable hazardous waste pharmaceuticals that were released and then cleaned up, must be evaluated to determine whether or not they remain creditable and the healthcare facility must handle them accordingly.

**24. Section V.C.14. (What are the proposed standards for healthcare facilities that manage non-creditable hazardous waste pharmaceuticals? / Long-Term Care Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals), page 58041:**

- One State commented that “this part of the proposed rule will be very difficult to enforce. In order to verify that pharmaceuticals are being properly managed throughout a facility, inspectors would have to enter private residences (i.e., apartments). This is not authorized in State statutes or regulations and is also not a safe practice. Additional verification might also require searching through garbage in dumpsters at these facilities to ensure that pharmaceuticals are not (being) illegally disposed in the trash. Searching through garbage in dumpsters is also very unsafe and not a good use of agency resources.”
- In response to EPA’s request for comment on the requirement that long-term care facilities keep an inventory of the pharmaceuticals that individuals self-administer so as to facilitate the collection of hazardous waste pharmaceuticals for proper disposal, two States agreed that there should be a requirement that long-term care facilities keep an inventory of self-administered pharmaceuticals. However, those States do not believe that the regulations should be overly prescriptive on how this inventory is to be kept, noting long-term care facilities are best able to develop their own processes for meeting this requirement.
- In response to EPA’s request for comment on the requirement that long-term care facilities collect and manage self-administered hazardous waste pharmaceuticals generated at their facility, two States agreed that long-term care facilities should be required to collect and manage self-administered hazardous waste pharmaceuticals generated at their facilities, but do not think that the regulations should be overly prescriptive on how this is to be accomplished.

Rather, the regulations should simply require that this happen and leave individual facilities to develop processes tailored to their individual facilities.

**25. Section V.C.15. (What are the proposed standards for healthcare facilities that manage non-creditable hazardous waste pharmaceuticals? / Healthcare Facilities that Accept Hazardous Waste Pharmaceuticals from Off-Site Conditionally Exempt Small Quantity Generators [CESQGs]), pages 58041 - 58042:**

- In response to EPA’s statement that “EPA is proposing to allow healthcare facilities that are CESQGs operating under this subpart to send their hazardous waste pharmaceuticals to an off-site healthcare facility, without a hazardous waste manifest, provided four conditions are met. First, the receiving healthcare facility must be *contracted* (emphasis added) to supply pharmaceutical products to the CESQG... and the receiving healthcare facility must both be under the control of the same person...”, one State commented that while it agrees that it is important that both the sending CESQG and receiving healthcare facility be under the control of the same person, the State does “not understand the logic of requiring the receiving healthcare facility be ‘contracted’ to supply pharmaceutical products to the CESQG.”
- Two States commented that they agree with EPA’s proposal to allow CESQGs to send their hazardous waste pharmaceuticals to an off-site healthcare facility provided certain conditions are met. One of those States added that currently in that State “there are CESQG long-term care facilities that send their waste pharmaceuticals back to their pharmacist who then determines what can be sent for credit, what can be restocked, and the remaining medications are then sent for hazardous waste incineration.” The State indicates it has been evaluating these situations on a case-by-case basis. The State commented that in addition, this process is essential for smaller health care facilities to work with some reverse distributors since, in several cases, the reverse distributors will not work directly with the long-term care facility, but only through their pharmacist. Regardless, the State requires that the generator ensure proper disposal (tracking and confirmation) whether they ship it directly to a TSD or to a pharmacist who then ships the waste medications off for proper disposal after separating out re-usable or creditable medications.
- One State commented that it fully supports each of the three options for hazardous waste pharmaceutical management by CESQG healthcare facilities; however, the State notes that nothing in the proposed rule requires a method for these facilities to ensure their hazardous waste pharmaceuticals are received at a designated facility.
- In response to EPA’s request for comment on whether to allow facilities to accept hazardous waste from off-site CESQGs:
  - Four States supported the proposal, and one of those States commented that it believes that this should be allowed because rural areas in particular could utilize a local hospital as a collection point for their CESQG hazardous waste. The State noted that this would result in a significant cost reduction (in the form of less travel/transportation costs) since the transporter would only have to visit one location at one time, instead of multiple locations at potentially different time intervals.

- One State commented that it believes that any facility allowed to receive hazardous waste from off-site should be subject to a high safety standard for accumulation. The State indicated it opposed this proposed provision unless the receiving facility is required to be a “LQG/subject to all LQG requirements...If a military medical logistics facility is...[a] LQG..., and subject to the management standards of one of those categories, we would approve of that facility consolidating CESQG pharmaceutical waste under the same provisions as a healthcare facility.” The State noted that it would prefer that this provision not be finalized and that the proposed generator improvement rule provision for CESQG waste to be consolidated at an LQG under the control of the same person be finalized and utilized by healthcare facilities. If healthcare facilities are allowed to receive hazardous waste pharmaceuticals from off-site, the State believes the receiving facility should notify the regulatory agency, similar to the notification requirement for consolidation of CESQG waste at LQGs in EPA’s generator improvements proposal, and also send a copy of the notification to regulatory agencies in States where sending CESQGs are located.

**26. Section V.D.3. (How does this proposed rule address healthcare facilities that accumulate potentially creditable hazardous waste pharmaceuticals prior to shipment to pharmaceutical reverse distributors? / Accumulation Time, Container Management, and Labeling for Potentially Creditable Hazardous Waste Pharmaceuticals at Healthcare Facilities), page 58044:**

- In response to EPA’s request for comment on whether healthcare facilities promptly remove waste pharmaceuticals from their shelves for shipment to reverse distributors, one State commented that it has been its experience that healthcare facilities do promptly remove their potentially creditable hazardous waste pharmaceuticals from their shelves for shipment to reverse distributors.
- In response to EPA’s request for comment on its proposal to not require specific labeling or container management standards for potentially creditable hazardous waste pharmaceuticals due to concerns of diversion:
  - Two States recommended that the final rule require labeling language that accurately reflect what is in each container. One of those States added that the potential confusion generated by not accurately labeling each container could result in inaccurate waste determinations and ultimate disposal problems. In that State’s opinion, facility security and processes that minimize the potential for diversion are better options.
  - One State commented that it believes that the same accumulation requirements should be applied to potentially creditable hazardous waste pharmaceuticals as are applied to non-creditable hazardous waste pharmaceutical (closed container, containers in good condition, secure storage, label, one-year limit). The State further commented that although generators should have a financial incentive to manage potentially creditable pharmaceuticals properly, this is not a logical argument against imposing management standards such as a one-year accumulation limit.
  - One State commented that it strongly recommends that storage and labeling requirements be established for potentially creditable hazardous waste

pharmaceuticals. “From an inspection perspective, it will be difficult to discern whether these waste are truly potentially creditable or non-creditable or even considered product. Leaving it up to the individual facility is not practical from an inspection perspective. The tried and true inspection philosophy will emerge -- if it looks like waste and the facility is treating it like waste (no indication of value), we will assume it is waste until the facility can prove otherwise. This scenario can be avoided simply by establishing storage and labeling requirements for these potentially creditable wastes.”

- One State commented that to help facilitate compliance monitoring by EPA and authorized State programs, it “believes that potentially creditable hazardous waste pharmaceuticals (as well as potentially creditable hazardous waste pharmaceuticals that are co-mingled with potentially creditable non-hazardous waste pharmaceuticals) should be accumulated in a designated location and that either the designated location be identified with signage or the containers holding potentially creditable hazardous waste pharmaceuticals be marked/labeled.”
- One State commented that it is not supportive of an unlimited accumulation time or EPA’s decision to not propose labeling requirements for any type of waste material as this is not adequately protective of human health and the environment. The State recommends that labeling as potentially creditable hazardous waste pharmaceuticals with applicable hazardous waste codes and a one-year accumulation time limit should also be required for potentially creditable hazardous waste pharmaceuticals.

**27. Section V.E.1. (What are the proposed novel prohibitions, exemptions and other unique management requirements for hazardous waste pharmaceuticals? / Sewer Disposal Prohibition), pages 58044 - 58047:**

The seven States that offered comments regarding EPA’s proposal “to impose a sewer ban on all hazardous waste pharmaceuticals managed by healthcare facilities and pharmaceutical reverse distributors that are subject to [the proposed] rule” and apply the ban “to healthcare facilities that are CESQGs,” all supported the proposal with the following additional comments:

- One State commented that the proposed rule “has two flaws. First, there is no prohibition from disposal of hazardous waste pharmaceuticals into septic systems. We believe this prohibition should be included because septic system disposal results in an almost-immediate release to the environment through the lateral line field with little to no treatment.” Secondly, the State believes the second sentence [of the proposed ban] could be interpreted to mean that EPA is exerting RCRA authority over domestic sewage if it contains hazardous waste pharmaceuticals.
- With respect to EPA’s request for comment on its proposal to incorporate a cross-reference to the Clean Water Act (CWA) regulations prohibiting the sewerage of liquid ignitable waste, three States agreed with the proposal, and one of those States added that it “believes it would be helpful to include a reference to the CWA ban on sewerage of ignitable waste in 40 CFR 261.4(a)(1)(ii). A reference to the new ban on sewerage hazardous waste pharmaceuticals would also be appropriate here; the sewer ban should apply to all generators, whether or not

they are 'healthcare facilities'. If the sewer ban applies to all generators, it is possible that coroners need not be included in the definition of healthcare facility."

- One State commented that the "concerns noted by EPA can and should be managed by training, proper security and other management processes to eliminate diversion."
- One State commented that this is another area where creating a categorical definition of pharmaceuticals as hazardous waste would provide stronger protection to human health and the environment, because the ban would apply to all pharmaceutical waste rather than applying to a subset of pharmaceutical waste and encouraging over-management (because it may be easier than identifying that subset)."
- With respect to EPA's preamble statement that "finally, we would note that although the sewer ban is limited 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), except when sewerage is specifically directed by FDA [Food and Drug Administration] guidance", one State commented that it "would like to point out that by specifying an approach that allows healthcare facilities to manage all of their non-creditable pharmaceutical waste as hazardous waste (i.e., both hazardous and non-hazardous pharmaceuticals) and to not require healthcare facilities to make individual hazardous waste determinations if they choose this approach, it is likely that those facilities will not be inclined to sewer their non-hazardous pharmaceuticals. If EPA eventually chooses to regulate all pharmaceutical waste as a category (as recommended in NEWMOA's February 21, 2012, letter to EPA's Office of Resource Conservation and Recovery, and ASTSWMO's April 2013 position paper, *A New Regulatory Approach to Pharmaceutical Waste Management*), EPA could then ban the sewerage of all pharmaceutical wastes."
- One State commented that it is concerned that the proposed ban fails to neither clarify expectations for State enforcement nor address significant challenges States may face with regard to its enforcement. It notes that State RCRA programs are not responsible for pretreatment standards or sewer ordinances. Therefore, coordination with publicly-owned treatment works [POTWs] to ensure they have been notified of the sewer ban will be imperative. The State recommends that EPA's Office of Resource Conservation and Recovery and Office of Water collaborate to ensure federal and State programs are adequately informed of any regulatory changes. The State also recommends that EPA provide additional, specific explanation with regard to any expectations it has for State RCRA and/or Water programs to enforce this ban.

**28. Section V.E.2. (What are the proposed novel prohibitions, exemptions and other unique management requirements for hazardous waste pharmaceuticals? / Conditional Exemption for Hazardous Waste Pharmaceuticals That Are Also Controlled Substances), pages 58047 - 58049:**

With respect to EPA's request for comment on its proposal whether to allow sewerage of the five controlled substances that are also RCRA hazardous waste:

- One State commented that it does not agree with the proposal to allow sewerage of the five controlled substances, and believes the proposal would introduce unnecessary complexity and

invite accidental sewerage of pharmaceuticals where sewerage was not intended. In addition, the State notes these proposed regulations are striving for consistency and ease of use. "Allowing healthcare facilities to sewer some medications but not others is sending a mixed signal about environmental protection and pharmaceutical waste management."

- One State commented that it "agrees with EPA's assumption that this [proposal to allow sewerage of the five controlled substances] would be too confusing for healthcare facilities, and healthcare facilities would likely not keep track of which hazardous waste pharmaceuticals are allowed to be sewered and which are not. Therefore, the EPA should not allow healthcare facilities to sewer the five (5) hazardous wastes that are also controlled substances."
- Another State commented, in principle, "we support EPA deferring to the Drug Enforcement Administration's [DEA] destruction and disposal requirements for hazardous waste pharmaceuticals that are also controlled substances to avoid dual regulatory requirements; however, we question EPA's authority to do so." The State notes that RCRA explicitly requires hazardous wastes to be disposed at facilities with RCRA permits. If a DEA-approved incinerator does not have a RCRA permit, it is clear under RCRA the incinerator cannot accept hazardous wastes, including hazardous waste pharmaceuticals.

**29. Section V.E.2.b. (What are the proposed novel prohibitions, exemptions and other unique management requirements for hazardous waste pharmaceuticals? / Conditional Exemption for Hazardous Waste Pharmaceuticals That Are Also Controlled Substances / Household hazardous waste collected in DEA authorized collection receptacles), pages 58050 - 58051:**

- With respect to EPA's proposal "...that pharmaceuticals that are household hazardous waste (i.e., 'household waste pharmaceuticals') and are collected in DEA authorized collection receptacles where they may be co-mingled with controlled substances continue to be excluded from RCRA regulation, provided they are: (1) Combusted in a municipal solid waste or hazardous waste combustor, and (2) managed in accordance with all applicable DEA regulations...", one State commented that while it "agrees with the goal of ensuring that household waste pharmaceuticals collected in DEA authorized collection receptacles are sent for combustion, it is not clear under what authority EPA can require this. If this proposal is finalized, will the household exclusion be revised to specify that household waste pharmaceuticals are not excluded unless they are managed in DEA authorized receptacles, combusted and managed in accordance with all applicable DEA regulations?"
- Another State commented that it "agrees with EPA's proposal that pharmaceuticals that are household hazardous waste and are collected in DEA authorized collection receptacles be excluded from RCRA regulations, provided they are combusted at a municipal solid waste or hazardous waste combustor, and managed in accordance with all applicable DEA regulations."

**30. Section V.E.3. (What are the proposed novel prohibitions, exemptions and other unique management requirements for hazardous waste pharmaceuticals? / Management of Residues in Pharmaceutical Containers), pages 58052 - 58056:**

- One State commented that it “supports EPA’s proposed changes, as they will address a significant area of current confusion within the healthcare regulated community while ensuring continued protection of human health and the environment.”

**31. Section V.E.3.b. (What are the proposed novel prohibitions, exemptions and other unique management requirements for hazardous waste pharmaceuticals? / Management of Residues in Pharmaceutical Containers / Unit-dose containers), pages 58052 - 58055:**

With respect to EPA’s request for comment on whether “RCRA empty” pharmaceutical containers that are original pharmaceutical packages should be destroyed prior to placing them into the trash:

- One State commented that it does not agree that “RCRA empty” containers should be destroyed prior to placing them into the trash, indicating this would be a cumbersome requirement for healthcare facilities to comply with since healthcare facilities would be required to do more than just defacing the label.
- One State commented that it has not experienced any concerning issues as described in this section. State inspectors have seen dumpsters broken into for waste medications, but there has been no evidence to date suggesting that anyone is attempting to obtain empty bottles to use for illicit purposes such as packaging for counterfeit pharmaceuticals. The State cautions against EPA requiring shredding or crushing of containers that once contained pharmaceuticals due to the potential for residual pharmaceuticals becoming airborne.
- One State commented that “we believe that defacing the container label prior to disposal of an empty pharmaceutical container is sufficient to minimize the potential for diversion. We do not believe that the destruction of empty containers is necessary and are concerned about the burden this would impose on generators.”
- One State commented that it supports a requirement that these containers be crushed or shredded and suggests that an additional requirement be put in place to ban the recycling of these containers unless such recycling can be done without a rinsing step that could potentially release residual pharmaceuticals to the environment.
- One State commented that “EPA provides no information regarding subsequent recycling of the destroyed plastic unit dose containers, dispensing bottles, etc. that held hazardous waste pharmaceuticals. Many of these containers have recycling codes making them eligible for MSW recycling. Does EPA have a position on this?”

**32. Section V.E.3.c. (What are the proposed novel prohibitions, exemptions and other unique management requirements for hazardous waste pharmaceuticals? / Management of Residues in Pharmaceutical Containers / Dispensed syringes), pages 58055 - 58056:**

With respect to EPA's request for comment on the practice of squirting residues remaining in dispensed syringes onto gauze pads and then placing the syringe in an appropriate container, one State commented that it has been advocating this method for several years and has not received any negative feedback. The State comments that if this is not allowed to occur, the liquid will either go down the drain or remain in the sharps and be disposed of in the regular trash.

**33. Section V.E.3.d. (What are the proposed novel prohibitions, exemptions and other unique management requirements for hazardous waste pharmaceuticals? / Management of Residues in Pharmaceutical Containers / Other containers, including delivery devices), page 58056:**

In response to EPA's proposal that the residues remaining in unused or used containers including delivery devices (such as IV bags and tubing, inhalers, aerosols, nebulizers, tubes of ointment, gels, or creams) would be regulated as hazardous waste if the material is listed or characteristic RCRA hazardous waste, one State commented that it agrees with this proposal.

**34. Section V.F.1.a. (What are the proposed standards for shipping hazardous waste pharmaceuticals? / Shipping Standards for Non-Creditable Hazardous Waste Pharmaceuticals and Evaluated Hazardous Waste Pharmaceuticals to Treatment, Storage, and Disposal Facilities / Shipping Standards for Non-Creditable Hazardous Waste Pharmaceuticals from Healthcare Facilities to TSDFs), page 58056:**

In response to EPA's request for comment on its proposed approach for manifesting non-creditable hazardous waste pharmaceuticals from healthcare facilities (i.e., in lieu of hazardous waste codes), EPA is proposing that the words "hazardous waste pharmaceuticals" be entered in the "special handling and additional information" box on the manifest:

- Two States commented that they agree with the proposal, while one of those States also suggested that, as suggested under section V.C.9., EPA develop a single code "for the category of 'pharmaceutical waste' that could be used by healthcare facilities when shipping such wastes (i.e., either 'hazardous waste pharmaceuticals' or combined hazardous/non-hazardous waste pharmaceuticals) off-site. It should be noted that the absence of a hazardous waste code on manifests may create problems for State hazardous waste manifest tracking and tax assessment systems. Also, will manifest section 13 (i.e., Waste Codes) be a required field on the proposed e-manifest?"
- One State commented that it believes it is important for waste codes to be included on the manifest. The State also refers to section V.C.9 in the proposed rule regarding shipping and section VII regarding a possible solution of creating a general listing for pharmaceutical wastes as a category.

- One State commented that since the healthcare facility must determine if the pharmaceuticals are listed and/or characteristic hazardous wastes prior to shipment, providing the applicable hazardous waste codes on shipment manifests would not be a “burden” to the facility. The State notes that the hazardous waste codes will be known when making waste determinations and should be included on the manifest.

**35. Section V.F.1.b. (What are the proposed standards for shipping hazardous waste pharmaceuticals? / Shipping Standards for Non-Creditable Hazardous Waste Pharmaceuticals and Evaluated Hazardous Waste Pharmaceuticals to Treatment, Storage, and Disposal Facilities / Shipping Standards for Evaluated Hazardous Waste Pharmaceuticals from Pharmaceutical Reverse Distributors to TSDFs), pages 58056 - 58057:**

- One State commented that it agrees with “the proposed pre-transport, shipping and manifest requirements for evaluated hazardous waste pharmaceuticals from reverse distributors.”
- Another State commented that it “agrees with the proposal to require reverse distributors to include the appropriate hazardous waste codes on the manifest when shipping to a TSDF.”

**36. Section V.F.2. (What are the proposed standards for shipping hazardous waste pharmaceuticals? / Shipping Standards for Potentially Creditable Hazardous Waste Pharmaceuticals), pages 58057 - 58059:**

- One State commented that while it “supports the proposed tracking system, it is not clear how an authorized State compliance monitoring program could determine if a shipment of potentially creditable hazardous waste pharmaceuticals reached its final destination (i.e., a TSDF) if the shipment is sent to an out-of-State reverse distributor (or second reverse distributor).”
- Two States commented that they agree with the proposed tracking system and controls for shipping potentially creditable hazardous waste pharmaceuticals to reverse distributors and between reverse distributors and that the proposed tracking systems and controls are sufficient to protect human health and environment.
- One State commented that it “agrees that the proposed provisions for tracking shipments are sufficient. We believe that healthcare facilities and reverse distributors should be required to report unreceived shipments if they are unable to ‘determine the status and whereabouts’ of the shipment and if the shipment has not been delivered to its intended destination within a specified time frame (35 days?). Documentation of efforts to locate the shipment should be required as part of this report.”
- Another State recommends that if a shipment of potentially creditable hazardous waste pharmaceuticals, shipped from a healthcare or reverse distribution facility, is not received by the receiving facility that the implementing agency be notified via email, phone or fax. The State comments that this will allow the agency to initiate an investigation if warranted.
- In response to EPA’s request for comment on whether any additional requirements, such as reporting to the implementing agency, are necessary in cases where the healthcare facility or reverse distributor does not get confirmation of delivery, one State commented that it “believes

that the proposed tracking and record keeping requirements are sufficient and does not believe that additional notification requirements are necessary. Since all records will be kept for three years, any potential issues will be evident during a site inspection.”

- In response to EPA’s request for comment on whether additional recordkeeping is necessary to document the cases when the pharmaceutical reverse distributor does not receive a shipment of potentially creditable pharmaceuticals within seven calendar days and the steps that must be taken to locate the shipment, one State commented that it “believes that such records must be maintained in order for EPA and authorized State programs to adequately evaluate compliance with the proposed shipping standards.”
- One State commented that the final rule should include both a provision requiring some form of shipping paper to document that potentially creditable hazardous waste pharmaceuticals were received at the reverse distribution facility, and an exception reporting requirement if the healthcare facility has not received a signed copy of that shipping paper within the seven days discussed in § 266.509(c).

**37. Section V.G.2. (What are the proposed standards for pharmaceutical reverse distributors? / EPA’s Rationale for Proposing New RCRA Management Standards for Pharmaceutical Reverse Distributors), pages 58060 - 58061:**

In response to EPA’s request for comment as to whether the regulatory standards for reverse distributors should be included directly in Subpart P, instead of providing a cross-reference to the standard in 40 CFR part 265:

- Two States commented that EPA should include the regulatory standards directly in 40 CFR Part 266, Subpart P instead of providing a cross-reference to the standards in 40 CFR Part 265.
- Another State commented that “EPA has explained that the health care industry is not as familiar with hazardous waste requirements; therefore, for the clarity of the operator of a Reverse Distributor, it is recommended that EPA include it in the 40 CFR part 266.”

**38. Section V.G.3.a.ii. (What are the proposed standards for pharmaceutical reverse distributors? / Detailed Discussion of Proposed Pharmaceutical Reverse Distributor Standards / Standards for Pharmaceutical Reverse Distributors / Inventory), pages 58061 - 58062:**

One State suggested that, in addition to including the identity (e.g., name or national drug code [NDC]) and quantity of each potentially creditable hazardous waste pharmaceutical and evaluated hazardous waste pharmaceuticals, the name of the originating healthcare facility also be included. In making this recommendation, that State noted that in the event of a problem, it will be much easier to discern the originating source.

**39. Section V.G.3.a.iv. (What are the proposed standards for pharmaceutical reverse distributors? / Detailed Discussion of Proposed Pharmaceutical Reverse Distributor Standards / Standards for Pharmaceutical Reverse Distributors / Maximum 90 days for on-site accumulation and petition for an extension of accumulation time), pages 58062 - 58063:**

- One State recommends that the LQG accumulation standards pertaining to reverse distribution facilities be included directly in 40 CFR part 266, subpart P to make the rules easier to follow.
- One State commented that it agrees with the proposal to limit the accumulation of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals on-site for up to 90 calendar days.
- In response to EPA's statement that "...because of the value of the potentially creditable hazardous waste pharmaceuticals, and the low risk these materials present, the Agency has decided not to propose specific container management standards", one State recommended that at a minimum the final rule specify that containers are in good condition.

**40. Section V.G.3.a.v. (What are the proposed standards for pharmaceutical reverse distributors? / Detailed Discussion of Proposed Pharmaceutical Reverse Distributor Standards / Standards for Pharmaceutical Reverse Distributors / Contingency plan and emergency procedures), page 58063:**

One State recommends EPA establish, for reverse distributors, a similar requirement to 40 CFR 264.31 [Failure of facility owner or operator to maintain or operate facility to minimize possibilities of fire, explosion or releases of hazardous waste or hazardous waste constituents] as these facilities will be storing and handling potentially large amounts of hazardous wastes.

**41. Section V.G.3.a.ix. (What are the proposed standards for pharmaceutical reverse distributors? / Detailed Discussion of Proposed Pharmaceutical Reverse Distributor Standards / Standards for Pharmaceutical Reverse Distributors / Evaluating potentially creditable hazardous waste pharmaceuticals within 21 days), page 58064:**

In response to EPA's proposal for a 21-day evaluation timeframe for reverse distributors to make an evaluation as to the creditability of received potentially creditable hazardous waste pharmaceuticals, one State commented that "while not requiring any specific reporting standards, proving compliance with this particular requirement to State or Federal inspection agencies will most likely require the facilities develop enhanced inventory programs and sophisticated reporting routines. It should be emphasized to the industry that this is an area of potential data development and also that this information needs to be readily available for inspection. Alternatively, as wastes have to be removed off site in 90 days anyway, is it so critical that a sub-timeframe needs to be established as opposed to just ensuring the wastes are evaluated?"

**42. Section V.G.3.b.i. (What are the proposed standards for pharmaceutical reverse distributors? / Additional Standards for Pharmaceutical Reverse Distributors Managing Potentially Creditable Hazardous Waste Pharmaceuticals Destined for Another Pharmaceutical Reverse Distributor / Where potentially creditable hazardous waste pharmaceuticals can be sent), pages 58064 – 58065:**

In response to the EPA statement that “...the Agency believes a reasonable limit is three transfers of potentially creditable hazardous waste pharmaceuticals before the pharmaceutical hazardous waste is ultimately transported to a TSDF”:

- One State commented that “three transfers does seem reasonable” but then asked, “How would EPA or an authorized State program evaluate/enforce this requirement if the various (potentially four) facilities are each located in different States?”
- One State commented that it is not supportive of this requirement and recommends that EPA consider a maximum of two transfers for evaluation prior to initiating disposal. “This would ensure that the final rule provides for effective disposal rather than promotion of storage opportunities.”
- In response to EPA’s request for comment on whether CESQG healthcare facilities would benefit from being able to consolidate potentially creditable hazardous waste pharmaceuticals off-site, one State commented that it has experienced numerous situations where CESQG healthcare facilities are utilizing their pharmacists (contract based, as pharmacists servicing CESQGs are typically not employees of the healthcare facility) to send back their medications. Once received by their pharmacists, it is the pharmacist who determines which medications can be sent for credit, which ones can be restocked, and which ones require disposal. The outcome of this process is then reported back to the healthcare facility for their records, including details regarding where the wastes have been shipped (including weights) and the final destination.

**43. Section V.G.3.c.iii. (What are the proposed standards for pharmaceutical reverse distributors? / Additional Standards for Pharmaceutical Reverse Distributors Managing Evaluated Hazardous Waste Pharmaceuticals / Personnel Training), page 58065:**

One State commented that it agrees pharmaceutical reverse distributors should meet the same federal classroom or on-the-job training requirements that LQGs must meet.

**44. Section V.G.3.c.iv. (What are the proposed standards for pharmaceutical reverse distributors? / Additional Standards for Pharmaceutical Reverse Distributors Managing Evaluated Hazardous Waste Pharmaceuticals / Labeling and management of containers in on-site accumulation area), pages 58065 - 58066:**

Two States commented that they support the requirement to mark containers with the words, ‘Hazardous Waste Pharmaceuticals.’ One of those States added it also highly recommended that an accumulation start date be included on the label. “While a reverse distributor’s inventory management data system could potentially be used to verify the accumulation start date, it may be

designed to key on individual pharmaceuticals within the accumulation container. From an inspection perspective, we would not rummage through the container to verify it matches the inventory report, thus a simple start accumulation date on the container is simpler and safer to confirm compliance.”

**45. Section VI.A. 1. (Implementation and Enforcement / Healthcare Facilities / Determining Whether a Healthcare Facility is Subject to Part 266, Subpart P), pages 58067 - 58068:**

One State commented that it agrees with the proposed change to allow potentially creditable hazardous waste pharmaceuticals to be excluded from a healthcare facility’s hazardous waste monthly generation count in order to determine generator status.

**46. Section VI.A. 2. (Implementation and Enforcement / Healthcare Facilities / Healthcare Facilities Managing Hazardous Waste Pharmaceuticals under Part 266, Subpart P), page 58068:**

In response to the EPA statement “if a healthcare facility does not want to keep track of the amount of hazardous waste it generates to ensure it does not exceed the CESQG quantity limits, it could choose to operate under this proposed rule”, one State commented that the statement is potentially confusing. The State requests that if this rule is finalized, EPA clarify in the preamble to the final rule that a CESQG healthcare facility would still need to keep track of the amount of its non-pharmaceutical hazardous waste generation to ensure CESQG status, even if it chooses to operate under subpart P.

**47. Section VI.B. 1. (Implementation and Enforcement / Pharmaceutical Reverse Distributors / Pharmaceuticals Sent to Pharmaceutical Reverse Distributors are Solid Wastes), page 58068:**

In response to EPA’s proposal to change its existing position on how RCRA would apply to pharmaceuticals returned to a reverse distributor by clarifying that a decision by a healthcare facility to send a pharmaceutical to a reverse distributor is a decision to discard the pharmaceutical, one State commented that it agrees with the proposed change.

**48. Section VII. (Request for Comment on EPA’s Efforts to Identify Additional Pharmaceutical Wastes), pages 58070 – 58071:**

In response to EPA’s question: “For example, should EPA develop and promulgate new criteria specific to discarded pharmaceuticals that would allow it to establish a single hazardous waste listing for all discarded pharmaceuticals that meet the new criteria?”:

- Three States agreed with the EPA proposal that it develop a single hazardous waste listing for all discarded pharmaceuticals and pointed out that that approach was recommended in NEWMOA’s February 21, 2012, letter to EPA’s Office of Resource Conservation and Recovery and ASTSWMO’s April 2013 position paper.
- One State commented that it does not believe it is realistic for EPA to update hazardous waste listings of pharmaceuticals regularly. The State also commented that it “...believes that the most

sensible alternative approach for identifying and listing pharmaceutical wastes is some type of broad, categorical listing.” The State “strongly endorses the suggestion that EPA ‘develop and promulgate new criteria specific to discarded pharmaceuticals that would allow it to establish a single hazardous waste listing for all discarded pharmaceuticals that meet the new criteria’”.

**49. Section VIII.D. and E. (Request for Comment on EPA’s Efforts to Amend the Acute Hazardous Waste Listing for Nicotine Salts (Hazardous Waste No. P075) / Two Possible Approaches for Amending the P075 Listing), pages 58072 – 58073:**

- One State commented that it supports Option 1 [Exemption from P075 Listing for FDA-Approved Over-the-Counter Nicotine-Containing Smoking Cessation Products].
- One State commented that it does not believe that e-cigarettes and nicotine-containing e-liquids fit the definition of pharmaceutical.
- One State commented that it believes that smoking cessation products such as nicotine patches, gums, lozenges, inhalers, nasal sprays, e-cigarettes, e-liquids, etc. should not be regulated as acutely hazardous wastes when discarded. The State also commented that EPA should revise the P075 listing to clarify EPA's original intent – that it applies only to nicotine when used as a pesticide.

**50. Section IX.B.(State Authorization / Effect on State Authorization), pages 58073 – 58074:**

One State commented that “the sewerage prohibition is being proposed under HSWA [Hazardous and Solid Waste Amendments] authority and therefore, if/when the rule is finalized, this prohibition would be applicable on the effective date of the final rule.” As such, it may be necessary to specify a later alternative compliance date for this provision in order to allow healthcare facilities time to implement the process changes necessary to meet this requirement.

**Specific Comments on the Proposed Rule:**

**51. Section 262.10(n), 266.501:** One State commented that the term “conditionally exempt small quantity generator” does not actually have a definition; this language (proposed in § 266.501) should only be used after the Generator Improvement Proposed Rule is finalized. The State also commented that both § 262.10(n) and § 266.501 (“or, preferably, § 262.13 under the new Generator Improvement Proposal reorganization of part 262”) need to include a detailed discussion of generator category determination for healthcare facilities. The State notes this is confusing (and important) because a healthcare facility that generates some non-pharmaceutical hazardous waste and would be a LQG if pharmaceutical hazardous waste were counted toward its generator status (as instructed in § 262.10(n)) may be notifying under § 262.502(a)(1) as both a healthcare facility and a CESQG. “Thus, to say that a healthcare facility ‘is’ a conditionally exempt small quantity generator (in § 266.501(a) and (b)), is not clear. Clarifying instructions for generator status determination and what generator status (including or not including count of pharmaceutical hazardous waste) is referred to will make clear which facilities are subject to subpart P.”

52. **Section 266.502:** One State commented that “we believe that some parts of this section should apply to facilities managing hazardous waste pharmaceuticals, whether or not they are potentially creditable, such as § 266.502(a) and (k). Please consider whether there is a better way to organize §§ 266.502-266.504 and §§ 266.506-266.509, perhaps more like § 266.510 is organized.”
53. **Sections 266.502 and 266.510:** One State commented that “in order for the Standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals and Standards for evaluated hazardous waste pharmaceutical to be perfectly clear, a subpart needs to be added to each section to specifically direct the disposal of these wastes. Although the preamble states, ‘Accordingly, each off-site shipment of hazardous waste pharmaceuticals must be transported to an interim status or permitted TSDF via a hazardous waste transporter’”, the State “could not find the regulation that requires the healthcare facility to send their non-creditable hazardous waste pharmaceutical or evaluated hazardous waste pharmaceutical to a permitted TSDF or facility that has notified to transport hazardous waste. The rule has requirements for exception reporting and recordkeeping retention but does not clearly require that healthcare facilities or reverse distributors to use a uniform hazardous waste manifest for non-creditable hazardous waste pharmaceutical.”
54. **Section 266.502(b):** One State commented that although it agrees that LQG training requirements are excessive, the rule should require documentation of the training.
55. **Section 266.502(c):** One State commented that the proposed rule states “a healthcare facility that generates a solid waste that is a pharmaceutical must determine whether the solid waste pharmaceutical is a hazardous waste pharmaceutical...in order to determine whether the waste is subject to this subpart. A healthcare facility may choose to manage its solid waste pharmaceuticals as hazardous waste pharmaceuticals under this subpart even if the solid waste pharmaceuticals do not exhibit a characteristic identified in ...”. The State suggests that this section be modified to require either a hazardous waste determination, or a determination that all non-creditable pharmaceuticals will be managed as hazardous waste. The State notes that would create less burden on healthcare facilities. The State suggests that if this change is made, a change to the recordkeeping requirement should also be made to require either waste determination documentation or a statement that all non-creditable pharmaceuticals will be managed as hazardous waste pharmaceuticals.
56. **Section 266.502(f)(2)(iv):** One State commented that “the proposed rule option allowing ‘any other method that clearly demonstrates the length of time’ [that non-creditable hazardous waste pharmaceuticals have been accumulating on-site at a healthcare facility] is too ambiguous. Facility personnel could state that the accumulation start date is in their head. Remove this option since there are three other very good options.”
57. **Section 266.502(g):** One State commented that the rule specifically states that waste codes are not required; however, treatment standards are different depending on the pharmaceutical, i.e. arsenic trioxide, mercury. The State commented that by not requiring waste codes to be included on

containers, “health care facilities and regulators will not be able to ensure that pharmaceuticals will be treated correctly. Healthcare facilities are required to make waste determinations, so it seems logical they include waste codes on labels and manifests. It is unclear why healthcare facilities are not required to include waste codes on their non-creditable hazardous waste pharmaceutical but pharmaceutical reverse distributors are required to include waste codes. Both generators should be required to include waste codes.”

58. **Section 266.502(h)(4):** One State commented that based on the construction and text of paragraphs (h)(1) through (h)(4), it believes (h)(4) could be interpreted in a way that negates the 90-day period a healthcare facility is authorized to retain a returned shipment of hazardous waste pharmaceuticals.
59. **Section 266.502(k)(2):** One State commented that it disagrees with including PPE and spill clean-up materials as a non-creditable hazardous waste pharmaceutical, suggesting these items should be managed as a hazardous waste in order to ensure proper disposal. Spill clean-up materials and PPE in all other releases of hazardous waste are managed as hazardous waste. The State commented, “There is the very good possibility that this will be abused and all hazardous waste spills will be placed in the same pharmaceutical container.”
60. **Section 266.506:** One State commented that “EPA proposes the requirement that household waste pharmaceuticals collected by DEA-authorized collectors be incinerated—preferably at a permitted hazardous waste incinerator, but when that is not feasible, at a large or small municipal waste combustor—a requirement for collected household waste pharmaceuticals in § 266.506. However, the proposed § 266.506(a) exemption addresses hazardous waste pharmaceuticals listed on a schedule of controlled substances by the DEA in 21 CFR part 1308 *co-mingled* with hazardous waste pharmaceuticals that are exempt as a household waste under § 261.4(b)(1). Therefore, if household waste pharmaceuticals are *not co-mingled* with a hazardous waste pharmaceutical being listed on a schedule of controlled substances by the DEA in 21 CFR part 1308, then it appears that the conditions of the proposed § 266.506(b), i.e., combustion, would not apply.” The State “recommends EPA provide clarity as to whether its intent is to require all household waste pharmaceuticals from collection programs to be incinerated; as currently written this does not appear to be a requirement of the proposed regulations. It is also recommended that EPA thoroughly consider the costs associated with requiring combustion of household waste pharmaceuticals from collection programs and incorporate this analysis into its final rule.” Additionally, the State “recommends adding a fourth option for combustion in § 266.506(b) due to the limited number of existing facilities in § 266.506(b)(1) through (3) that would allow for combustion at an equivalent industrial or power generation boiler or industrial furnace equivalent in performance to the above devices that is registered with, and approved by, both the DEA and an equivalent State level law enforcement agency, to manage these materials per the DEA’s prescribed procedures.”

61. **Section 266.507(b):** One State commented that this section states residues remaining in a syringe are not regulated as hazardous waste provided: (1) The syringe has been used to administer the pharmaceutical to a patient, and (2) The syringe is placed in a sharps in a sharps container that is managed in accordance with all applicable federal, State, and local medical waste requirements. The State comments that the concern with this section is that in some cases, syringes are used – and the pharmaceutical contents dispensed – when preparing pharmaceuticals for administering them to patients; in those cases, the syringes never actually come in contact with patients. This should be considered when finalizing the rule to account for these situations.
62. **Section 266.508(a):** One State commented that although Part 266.508(a) states, “A healthcare facility or pharmaceutical reverse distributor that ships either non-creditable hazardous waste pharmaceutical or evaluated hazardous waste pharmaceutical, respectively, offsite to a designated facility....”, this sentence does not convey that it is a requirement to ship non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals to a designated facility, it gives the impression that it is optional.
63. **Section 266.509(c):** One State commented that this regulation specifies that if a confirmation of delivery has not been received within seven calendar days from the date of the shipment, the healthcare facility or pharmaceutical reverse distributor must “promptly” report that a confirmation of delivery has not been received. The State requests that EPA specify a report time period, e.g., “within 5 days”, commenting that the use of the word “promptly” is too vague.
64. **Section 262.510:**
- One State recommended that EPA include “text referenced from other 40 CFR Parts directly in subpart P for reverse distributors as much as possible, to improve readability and usability of rules, consistent with the Generator Improvement Proposal reorganization of part 262. For example, reference to 40 CFR part 265, subpart D in § 262.510(a)(6) and reference to § 265.16 in § 262.510(c)(3) could be eliminated and the referenced text could be included. (Or, if the generator proposal is finalized, change the reference to 40 CFR part 265, subpart D to a reference to 40 CFR part 262, subpart M since reverse distributors are likely to need to refer to part 262 as generators anyway.)”
  - Another State commented that based on the construction and text of paragraphs (c)(7)(i) through (iv), it believes (c)(7) could be interpreted in a way that negates the 90-day period a reverse distributor is authorized to retain a returned shipment of evaluated hazardous waste pharmaceuticals.