

December 24, 2015

RCRA Docket

Environmental Protection Agency

Submitted via the Federal Rulemaking Portal: <http://www.regulations.gov>

Docket No. EPA–HQ–RCRA–2007–0932.

Dear Sir or Madam:

The Connecticut Department of Energy and Environmental Protection (“CT DEEP”) has reviewed EPA’s September 25, 2015 Notice of Proposed Rulemaking entitled “Management Standards for Hazardous Waste Pharmaceuticals.” CT DEEP generally supports this proposed rule, appreciates EPA’s efforts to bring forth this proposal, and believes that it will improve both the effectiveness of the RCRA hazardous waste generator requirements and make them easier for generators to understand and to follow. However, CT DEEP has a number of comments on the proposed rule, which are detailed in the following numbered sections.

1. **Section III. Summary of the Proposed Rule**

In paragraph one, EPA states “If finalized, healthcare facilities that are currently small quantity generators (SQGs) or large quantity generators (LQGs) and all pharmaceutical reverse distributors, regardless of their RCRA generator category, will be required to manage their hazardous waste pharmaceuticals under subpart P of 40 CFR part 266, instead of 40 CFR part 262. That is, the proposed standards are not an optional alternative to managing hazardous waste pharmaceuticals under 40 CFR part 262; they are mandatory standards.”

EPA is proposing that the management standards be mandatory standards for healthcare facilities. Many healthcare facilities already have systems in place for the management of hazardous pharmaceutical waste that are compliant with full RCRA requirements. As a result, CT DEEP believes healthcare facilities should have the option to continue managing hazardous pharmaceutical waste in compliance with full RCRA or under new subpart P of 40 CFR part 266.

2. **Section IV.A.3. Are Pharmaceuticals Considered Hazardous Waste Under RCRA?**

As referenced in this section, EPA has issued several clarifications regarding the regulatory status of certain commercial chemical products on the P- and U-lists since the hazardous waste rules were initially promulgated. Such clarifications have affected the regulatory status of some active pharmaceutical ingredients including phentermine, epinephrine, and nitroglycerine.

In a February 12, 2012 memo to RCRA Division Directors from Betsy Devlin, Acting Director of EPA's Office of Resource Conservation and Recovery, Ms. Devlin clarified that phentermine hydrochloride and other phentermine salts are not included within the scope of the P046 (phentermine) listing.

CT DEEP disagrees with EPA and believes that EPA should revise the P046 definition to include phentermine salts.

### 3. **Section IV.D. EPA's Office of Inspector General Report**

EPA's Office of the Inspector General (OIG) reviewed EPA's process for identifying and listing pharmaceuticals as hazardous wastes. On May 25, 2012, the OIG issued the report, *EPA Inaction in Identifying Hazardous Waste Pharmaceuticals May Result in Unsafe Disposal* (Report No. 12-P-0508). As part of the report, the OIG provided the following recommendations to EPA's Assistant Administrator for the Office of Solid Waste and Emergency Response (OSWER):

- a) Identify and review existing pharmaceuticals to determine whether they qualify for regulation as hazardous waste.
- b) Establish a process to review new pharmaceuticals to determine whether they qualify for regulation as hazardous waste.
- c) Develop a nationally consistent outreach and compliance assistance plan to help states address challenges that healthcare facilities, and others as needed, have in complying with RCRA regulations for managing hazardous waste pharmaceuticals.

CT DEEP agrees with the three recommendations made in the OIG report and finds them to be appropriate.

OSWER stated in its response to the OIG that this proposed rule fulfilled the obligation with respect to the third recommendation noted above.

CT DEEP strongly encourages EPA to work with other state and federal agencies to identify and review existing pharmaceuticals to determine whether they qualify for regulation as hazardous waste, and establish a process to promptly review new pharmaceuticals as they are introduced to determine whether they qualify for regulation as hazardous waste.

### 4. **Section V.A. What Terms Are Defined in this Proposed Rule?**

- a. This proposed rule defines "pharmaceutical" as

"...any chemical or biological product that is intended for use in the diagnosis, cure, mitigation, care, treatment, or prevention of disease or injury of a human or other animal; or any chemical or biological product that is intended to affect the structure or function of the body of a human or other animal. This definition includes, but is not limited to: dietary supplements as defined by the Federal Food, Drug and

Cosmetic Act (FD&C Act), prescription drugs, over-the-counter drugs, residues of pharmaceuticals remaining in containers, personal protective equipment contaminated with residues of pharmaceuticals, and clean-up material from the spills of pharmaceuticals.”

Dietary Supplements. CT DEEP supports the inclusion of dietary supplements in the definition of pharmaceutical. CT DEEP has found that many dietary supplements contain chromium and/or selenium. Some dietary supplements contain enough chromium and/or selenium to require management as “toxic” hazardous waste(s) when disposed. Although not toxic to humans when such supplements are taken “as directed”, a full container of a dietary supplement or many containers of dietary supplements containing chromium and/or selenium disposed at once will often contain sufficient quantities of metals that meet or exceed the toxicity threshold(s) listed in 40 CFR 261.24.

This issue is especially important in Connecticut. The federal RCRA Subtitle C regulations and many states provide an exemption from hazardous waste requirements for wastes that contain primarily trivalent chromium. Trivalent chromium, rather than hexavalent chromium, is biologically active and is the form of chromium contained in dietary supplements. However, Connecticut has not adopted this exemption. Therefore, many dietary supplements that will be classified as a hazardous waste for chromium in Connecticut, will not be in other states.

Personal Protective Equipment. The above definition includes personal protective equipment (PPE) contaminated with residues of pharmaceuticals. CT DEEP would like EPA to explain the basis for inclusion of these materials within the scope of the proposed definition of “pharmaceutical”. CT DEEP can only conclude that EPA is implying that PPE contaminated with P and U-listed hazardous waste pharmaceuticals are commercial chemical products. CT DEEP does not agree with such implication, if true, and further recommends EPA delete the inclusion of PPE contaminated with residues of pharmaceuticals from the proposed definition of “pharmaceutical”. These materials are more appropriately covered under the proposed definitions of “non-pharmaceutical hazardous waste”.

Loose Tablets. The proposed definition of “pharmaceutical” also includes “clean-up material from the spills of pharmaceuticals”. EPA clarified in paragraph seven that “related spill clean-up materials (including loose tablets accumulated during pharmacy floor sweepings) meet the definition of “pharmaceutical”.

CT DEEP agrees that loose tablets meet the definition of “pharmaceutical” and believes that EPA is including clean-up materials under the definition of pharmaceutical so an exemption for such materials may be provided. Moreover, if the identity of the loose tablets are known (i.e., a hazardous pharmaceutical or a non-hazardous pharmaceutical), they should be managed as either a non-creditable hazardous waste pharmaceutical or a non-hazardous waste pharmaceutical, respectively. However, if the identity of the loose tablets are not known, they should be managed as a non-creditable hazardous waste pharmaceutical.

Antiseptics. EPA explains in the preamble that “pharmaceutical” is intended to include all dose forms, including, but not limited to, tablets, capsules, medicinal gums or lozenges, medicinal liquids, ointments and lotions, intravenous (IV) or other compounded solutions, chemotherapy pharmaceuticals, vaccines, allergenics, medicinal shampoos, antiseptics, and any delivery device, including medicinal dermal patches, with the primary purpose to deliver or dispense the pharmaceutical.

CT DEEP requests clarification as to what “antiseptics” are intended to cover. “Antiseptics”, as a group, can encompass a huge range of products, most of which do not seem appropriate within the proposed definition of “pharmaceutical” (e.g., from hand sanitizers to products used to disinfect hospital rooms).

Radioactive Component. Paragraph four under V.A.1. states that the proposed definition of “pharmaceutical” no longer excludes pharmaceuticals with a radioactive component. CT DEEP requests EPA clarify to what extent, if any, would the low-level mixed waste rule (LLMWR) apply to hazardous waste pharmaceuticals that contain a radioactive component. If the LLMWR does not apply, CT DEEP suggests EPA modify the LLMWR to note that hazardous waste pharmaceuticals containing a radioactive component are no longer regulated by such rule.

- b. The proposed rule defines “hazardous waste pharmaceutical” as

“...a pharmaceutical that is a solid waste, as defined in 40 CFR 261.2, and is listed in part 261, subpart D, or exhibits one or more characteristics identified in part 261, subpart C”.

EPA is soliciting information on whether any dietary supplements currently on the market meet or potentially could meet RCRA’s definition of a hazardous waste.

CT DEEP requests EPA to refer to CT DEEP’s comment number 4.a. above regarding the definition of “pharmaceutical”.

- c. EPA states in the first paragraph of Section V.A.3. that in order to distinguish between hazardous waste pharmaceuticals transported from a healthcare facility to RCRA treatment, storage and disposal facilities (TSDFs) from those hazardous waste pharmaceuticals being returned by a healthcare facility to a pharmaceutical reverse distributor for a determination or verification of manufacturer’s credit, they are proposing a definition for “potentially creditable hazardous waste pharmaceutical.”

The proposed rule defines “potentially creditable hazardous waste pharmaceutical” to mean “...a hazardous waste pharmaceutical that has the potential to receive manufacturer’s credit and is:

- i) Unused or un-administered; and
- ii) Unexpired or less than one year past expiration date”.

EPA states in paragraph three of this section that manufacturer’s credit is determined solely by a manufacturer’s return policy and that the return policies of manufacturers change regularly. As a result, healthcare facilities are not always aware if a particular pharmaceutical will be creditable at the time that it is removed from shelves.

Enforceability. CT DEEP views the proposed definition, especially the word “potentially”, to be overly broad and difficult to enforce. States may not have the necessary regulatory clarity or control over what generators believe are potentially creditable hazardous waste pharmaceuticals versus what a regulatory agency may believe are potentially creditable hazardous waste pharmaceuticals. Further, the lack of specificity in this definition will almost certainly lead generators to believe that some of their hazardous waste pharmaceuticals which require management as non-creditable hazardous waste pharmaceuticals can

be managed as potentially creditable hazardous waste pharmaceuticals. Lack of specificity will almost certainly impede enforcement efforts to uphold the purpose and integrity of the proposed rule and to ensure a level playing field for those facilities complying with the reduced management standards. Therefore, if EPA believes using the term “creditable” is prudent, CT DEEP strongly suggests EPA use the term “reasonably” instead of “potentially” in the definition (e.g., hazardous waste pharmaceutical having a reasonable expectation of credit). The word “potentially” is defined by *The American Heritage Dictionary of the English Language* as “Possibly but not yet realized; capability of being but not yet in existence”. Whereas the word “reasonable” is defined by *The American Heritage Dictionary of the English Language* as “Rational; Governed by or in accordance with reason or sound thinking”. Although EPA may argue that the word “reasonable” may also be open to interpretation, CT DEEP believes such a change in the definition would put regulators and the regulated community in a much better position to determine whether a particular “drug” can be sent to a reverse distributor versus must be managed as non-creditable.

In addition, CT DEEP requests EPA help state programs and all stakeholders further understand what pharmaceuticals are/may be and are not/may not be “potentially creditable”. Specifically, it would be helpful if EPA could provide guidance as to what RCRA inspectors should look for and ask to see when performing a compliance inspection and what information healthcare facilities must be able to produce at the time of the inspection to demonstrate that a hazardous waste pharmaceutical sent to a pharmaceutical reverse distributor was credited or not.

Generic Drugs. CT DEEP requests EPA to clarify that generic drugs have the “potential” to receive manufacturer’s credit or must be managed as non-creditable hazardous waste pharmaceuticals. It is CT DEEP’s understanding that manufacturer’s may give credit for generic drugs. If generic drugs are not potentially creditable, EPA should explicitly state as such in the final rule. CT DEEP believes generic drugs should be afforded the same regulatory relief as their name brand counterparts as this will simplify the regulatory construct, help ensure proper management, and improve the safe handling and disposal of all pharmaceuticals which have the identical environmental risk regardless of the manufacturer.

TSDFs. EPA also indicates that it is not their intent for reverse distributors to serve as TSDFs when it is well known that a manufacturer will not give credit for a specific hazardous waste pharmaceutical.

CT DEEP not only agrees with the above statement, but would like to see this situation eliminated. Again, if healthcare facilities, and/or their service companies do not have a clear understanding as to what pharmaceuticals should be returned for manufacturers’ credit, reverse distributors may continue to serve as TSDFs.

Expired Drugs. EPA specifically allows in the definition of potentially creditable hazardous waste pharmaceutical the return of hazardous waste pharmaceuticals that are less than one year past their expiration date.

It is CT DEEP’s understanding that expired drugs are not eligible for manufacturers’ credit. Therefore, CT DEEP requests EPA to clarify whether manufacturers ever offer credit for expired drugs or if manufacturers only provide credit up to a short period of time after the drug’s expiration date.

Partials. EPA contends in paragraph four under Section V.A.3. that pharmaceutical manufacturers' return policies often allow for crediting of partials (i.e., opened containers that have had some contents removed) and therefore, would consider partials to be potentially creditable hazardous waste pharmaceuticals.

CT DEEP seeks further clarification as to the quantity of a pharmaceutical that can be normally be returned to receive manufacturer's credit. For instance, must there be at least 25%, 50% or 75% of the tablets/capsules remaining in the container for a healthcare facility to receive manufacturer's credit?

- d. "Non-creditable hazardous waste pharmaceutical" is defined in the proposed rule as " a hazardous waste pharmaceutical that is not expected to be eligible for manufacturer's credit.

Please refer back to CT DEEP's comments in number 4.a. above concerning loose tablets and number 4.c. above discussing a "reasonable" expectation of credit, generics, and partials.

- e. EPA's proposes to define the term "household waste pharmaceutical" as

"...a solid waste, as defined in 40 CFR 261.2, that also meets the definition of pharmaceutical, as defined in this proposed rule, but is not a hazardous waste because it is exempt from RCRA Subtitle C regulation by the household waste exclusion in 40 CFR 261.4(b)(1)."

EPA notes that they are proposing this term to distinguish the type of waste pharmaceuticals from the hazardous waste pharmaceuticals that are to be regulated under this proposal. EPA also states "This proposed rule does not apply to pharmaceutical waste that is exempt due to the household waste exclusion."

CT DEEP requests that EPA clarify whether pharmaceutical wastes generated in schools are covered under this exclusion, and if not, is any relief provided for schools under this proposed rule such as inclusion as a "healthcare facility".

- f. "Healthcare facility" is being defined as

"...any person that (1) provides preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or (2) sells or dispenses over-the-counter or prescription pharmaceuticals. This definition includes, but is not limited to, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians' offices, optical and dental providers, chiropractors, long-term care facilities, ambulance services, coroners and medical examiners, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of over-the-counter medications; and veterinary clinics and hospitals. Thus, these proposed regulations will be applicable to any healthcare facility for human or animal which generates hazardous waste pharmaceuticals on its premises."

CT DEEP supports the inclusion of coroners and medical examiners because we agree that coroners and/or medical examiners will often inventory, and then dispose of, any pharmaceuticals that have been found at the scene of a death. We do not want those pharmaceuticals flushed down the drain or otherwise mismanaged.

CT DEEP supports the proposed definition of “healthcare facility”. CT DEEP believes the definition should include school nurse’s offices and infirmaries if such facilities are not covered by the household waste exclusion in 40 CFR 261.4(b)(1). See CT DEEP’s comment under number 4.e. above. CT DEEP also feels that research facilities (i.e., clinics and/or hospitals) that are prescribing drugs in finished dosage form during drug trials should be included in the definition of a healthcare facility.

The third paragraph of Section V.A.9. states “The proposed definition of a ‘healthcare facility’ also applies to entities that engage in drug compounding.” CT DEEP supports the inclusion of compounders within the definition of a “healthcare facility” as described by EPA in the proposed rule.

- g. The term “long-term care facility” (LTCF) is defined as

“...a licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. This definition includes, but is not limited to, assisted living, hospices, nursing homes, skilled nursing facilities, and the assisted living and skilled nursing care portions of continuing care retirement communities. Not included within the scope of this definition are group homes, independent living communities, and the independent living portions of continuing care retirement communities.”

CT DEEP supports the proposed definition of “long-term care facility” and agree with the inclusion of assisted living facilities, skilled nursing facilities and other LTCFs that administer their residents’ pharmaceuticals as an integral part of their services.

- h. EPA is proposing to define a “pharmaceutical reverse distributor” as

“...any person that receives and accumulates potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer’s credit. Any person, including forward distributors and pharmaceutical manufacturers, that processes pharmaceuticals for the facilitation or verification of manufacturer’s credit is considered a pharmaceutical reverse distributor.”

CT DEEP requests EPA to clarify what is meant by the term “facilitating” within the framework of the proposed rule and recommends this term be eliminated as it may encourage sham enterprises. If EPA intended multiple handling points from generator to disposal, the Universal Waste listing would have addressed this need.

CT DEEP requests EPA to explain where facilities that receive waste pharmaceuticals for the sole purpose of sorting and shipping such pharmaceuticals to a reverse distributor fit within the scope of the proposed rule. In particular, would such a facility be considered to be "facilitating manufacturer's credit?" What about a facility that merely receives and stores/aggregates potentially creditable pharmaceuticals? Would that kind of a facility be regarded as facilitating manufacturer's credit? If so, would that facility count as one of the maximum three facilities which potentially creditable hazardous waste pharmaceuticals may be sent to?

- i. The terms “wholesaler” and “forward distributor” are frequently used throughout the proposed rule. CT DEEP requests EPA to provide definitions for such terms. Further, as part of the definition EPA should explain whether these entities would be considered either a “healthcare facility” or “reverse distributor” in the case of a pharmaceutical recall or damaged pharmaceuticals.

5. **Section V.B.1. What Facilities Are Subject to this Rulemaking?**

- a. Subparagraph b. of this section discusses long-term care facilities that are subject to this proposed rule. The purpose of such section is for EPA to explain its proposal to change its policy regarding the management of hazardous waste and hazardous waste pharmaceuticals generated on the premises of long-term care facilities.

Under EPA's current RCRA interpretation published in the Federal Register on December 2, 2008 (i.e., the preamble to the proposal to add pharmaceuticals to the Universal Waste program), hazardous wastes (including pharmaceuticals) generated on the premises of a long-term care facility can fall under two categories: (a) RCRA Subtitle C hazardous waste, or (b) household hazardous waste exempt from RCRA Subtitle C regulation. EPA explained in 2008 that LTCFs themselves may generate hazardous wastes as a result of their central management of pharmaceuticals in its pharmacy or pharmacy-like area. EPA laid out that these hazardous pharmaceutical wastes would be subject to the RCRA hazardous waste generator regulations since the pharmaceuticals are under the control of the facility, and thus, the resulting wastes are generated by that facility. However, at that time, EPA also noted that patients and residents themselves may generate pharmaceutical hazardous wastes. EPA determined that those pharmaceuticals under the control of the patient or resident of the LTCF, when discarded, would be subject to RCRA's household hazardous waste exclusion of 40 CFR 261.4(b)(1).

Pursuant to this section of the proposed rule, EPA is providing notice that it intends to revise its interpretation which was published on December 2, 2008. Specifically, hazardous waste (including pharmaceuticals) generated at long-term care facilities will no longer be considered exempt as household hazardous waste, but will be subject to the appropriate RCRA Subtitle C management standards, including the standards being proposed. EPA is informing the regulated community that hazardous waste generated at long-term care facilities does not meet the criteria for the household hazardous waste exemption. In other words, LTCFS will need to manage their hazardous waste pharmaceuticals in accordance with the healthcare facility specific management standards in this proposal and their non-pharmaceutical hazardous wastes in accordance with the applicable RCRA hazardous waste generator requirements in 40 CFR 261.5 (for CESQGs) or 40 CFR part 262 (for SQGS and LQGs).

Although CT DEEP supports the fundamental change in interpretation, we have some concerns. First, CT DEEP believes that there will be a substantial learning curve for not only the residents of LTCFs, but for the care givers at such facilities as well. Second, the cost associated with managing all hazardous waste that used to fall under the household hazardous waste exemption may be significant. Many LTCFs operate close to their profit margins. Third, CT DEEP believes that training would have been simplified and disposal costs would have been reduced through designation of pharmaceuticals as a Universal Waste.

CT DEEP requests EPA to explain what "non-pharmaceutical hazardous wastes" are expected to be found at LTCFs.

Finally, CT DEEP requests EPA to explain how pharmaceuticals which have been paid for under Medicare or Medicaid must be managed when they become wastes.

- b. Conditionally Exempt Small Quantity Generators (CESQGs) are briefly discussed under Section V.B.1.c. For the most part, the proposed rulemaking does not change the regulatory structure for CESQGs. As proposed, healthcare facilities that generate hazardous waste pharmaceuticals and qualify as CESQGs will maintain their conditional exemption provided they comply with 40 CFR 261.5(f)(3) and (g)(3). However, as EPA points out, CESQGs are limited as to where they may send hazardous wastes for treatment and disposal. CESQGs are not allowed to send hazardous wastes to a reverse distributor. Therefore, EPA is proposing to allow CESQGs the ability to send their “potentially creditable hazardous waste pharmaceuticals” to a “pharmaceutical reverse distributor”.

CT DEEP supports the proposal above concerning CESQGs and CT DEEP also supports EPA’s proposed CESQG/VSQG reform through the Hazardous Waste Generator Improvements Rule.

EPA is proposing to make the change discussed above within 40 CFR part 266, new subpart P. However, EPA requests comment on whether stakeholders would prefer this change to be made within 40 CFR 261.5 instead.

CT DEEP suggests that the proposed change be made in both 40 CFR 261.5 and 40 CFR part 266, new subpart P because CESQGs may not think to look for regulatory changes that may apply to them in the new subpart.

- c. EPA states under Section V.B.1.d. that “pharmaceutical reverse distributors” are only subject to this proposed rule for the accumulation of “potentially creditable hazardous waste pharmaceuticals” and “evaluated hazardous waste pharmaceuticals”.

CT DEEP requests clarification as to whether pharmaceutical manufacturers that are also acting as “pharmaceutical reverse distributors” will be allowed to accept “evaluated hazardous waste pharmaceuticals” under the proposed rule. CT DEEP does not believe that pharmaceutical manufacturers that are also acting as pharmaceutical reverse distributors should be allowed to accept evaluated hazardous waste pharmaceuticals from another pharmaceutical reverse distributor because such activity is comparable to activities requiring a TSDF permit.

## 6. **Section V.B.2. To What Facilities Does this Rule Not Apply?**

- a. CT DEEP suggests EPA emphasize that the proposed rule only applies to reverse distribution activities and operations when a pharmaceutical manufacturer is also acting as “pharmaceutical reverse distributor”.
- b. EPA points out in subsection b. that they have recommended that household waste pharmaceuticals that have been collected at take-back events or as part of collection programs be incinerated— preferably at a permitted hazardous waste incinerator, or at a large or small municipal waste combustor when incineration at a permitted hazardous waste incinerator is not feasible. EPA believes that such practice is already common among collection programs since one goal is to divert pharmaceuticals from municipal landfills. Despite the fact, EPA is proposing to make their recommendation a requirement as part of the proposed rule.

CT DEEP supports changing this recommendation to a requirement for pharmaceutical collection programs.

7. **Section V.B.3. Which Hazardous Wastes Are Addressed by this Proposed Rule?**

- a. EPA acknowledges that it is difficult to manage hazardous waste pharmaceuticals that are also controlled substances. As a result, EPA is proposing to conditionally exempt from RCRA regulatory requirements those pharmaceuticals that are a RCRA hazardous waste and a DEA controlled substance, provided such hazardous waste pharmaceuticals are combusted at a permitted or interim status hazardous waste incinerator, or a permitted municipal solid waste incinerator.

CT DEEP supports the conditional exemption from RCRA regulation pharmaceuticals that are a RCRA hazardous waste and a DEA controlled substance, provided such hazardous waste pharmaceuticals are combusted at a permitted or interim status hazardous waste incinerator, or a permitted municipal solid waste incinerator.

- b. EPA points out that hazardous waste pharmaceuticals which also contain a radioactive component subject to the Atomic Energy Act of 1954 (i.e., “mixed waste”) are regulated by multiple agencies. The hazardous waste component is regulated under RCRA, while either the Nuclear Regulatory Commission (NRC) or the Department of Energy (DOE) regulates the radioactive component of the waste under the AEA. “Healthcare facilities” would be able to manage the hazardous waste component of hazardous waste pharmaceuticals under the proposed rule.

Again, CT DEEP requests EPA clarify to what extent, if any, would the LLMWR apply to hazardous waste pharmaceuticals that contain a radioactive component. If the LLMWR does not apply, CT DEEP suggests EPA modify the LLMWR to note that hazardous waste pharmaceuticals containing a radioactive component are no longer regulated by such rule.

8. **Section V.B.4. Management of Waste Generated at Healthcare Facilities That Are Not Included in the Scope of this Proposed Rule.**

- a. EPA discusses under subsection a. that a large portion of the pharmaceutical wastes generated at “healthcare facilities” will not meet the definition of a RCRA hazardous waste and that the proposal does not require “healthcare facilities” to manage non-hazardous waste pharmaceuticals under the proposed rule. However, non-hazardous waste pharmaceuticals are still considered solid wastes under the federal regulations and must be managed in accordance with applicable federal, state and/or local regulatory requirements. Notwithstanding, a “healthcare facility” may choose to manage its non-hazardous and hazardous waste pharmaceuticals together (as hazardous waste pharmaceuticals) under the proposed regulatory requirements. EPA points out that managing non-hazardous waste pharmaceuticals as hazardous waste pharmaceuticals under new subpart P would not affect a “healthcare facility’s” hazardous waste generator category because all “healthcare facilities” will be regulated in the same way regardless of the quantity of hazardous waste pharmaceuticals generated.

CT DEEP requests EPA to refer back to the Northeast Waste Management Officials’ Association’s (NEWMOA’s) February 21, 2012 letter to Suzanne Rudzinski, Director, Office of Resource Conservation and Recovery. The letter was follow-up to a July 25, 2011 NEWMOA-sponsored conference call to discuss RCRA

pharmaceutical waste management. In the referenced letter NEWMOA stated "...EPA was 'missing the forest for the trees' with respect to the regulation of pharmaceutical waste. Increasing amounts of pharmaceuticals are being prescribed, dispensed, or purchased over the counter, resulting in a growing amount of unused, expired, and /or waste pharmaceuticals requiring proper disposal. Meanwhile, in recent years, pharmaceutical compounds have been detected in drinking water supplies and in landfill leachate. The participating NEWMOA members believe that these issues cannot be adequately addressed through a rule that applies only to the handful of pharmaceutical wastes that are currently RCRA-regulated. ... We believe that a lengthy rulemaking effort focused on regulating pharmaceutical wastes under RCRA Subtitle C only addresses the 'tip of the iceberg' and would do little to enhance environmental protection." The NEWMOA letter referenced and quoted herein concluded by stating "...the portion of the pharmaceutical waste stream that is currently regulated under RCRA Subtitle C is very small compared to the overall universe of waste pharmaceuticals. Given that both state and federal hazardous waste programs are facing significant resource constraints, we believe that we must keep state RCRA programs focused on the most critical hazardous waste management issues. We recommend that EPA's approach should be to re-examine and clarify which waste pharmaceuticals should be subject to full RCRA regulation and then with other federal agencies develop a holistic approach to the safe management of the remaining majority of waste pharmaceuticals outside of the RCRA regulatory system. We believe that federal establishment of streamlined but concise standards for the management of all pharmaceutical wastes would improve environmental protection and public safety."

- b. EPA also recommends under subsection a. that if a "healthcare facility" decides to segregate its non-hazardous pharmaceuticals from its hazardous pharmaceuticals that they follow the best management practices (BMPs) outlined in "Managing Pharmaceutical Waste: A 10-Step Blueprint for Healthcare Facilities in the United States" (Practice Greenhealth, Revised August 2008) for the management, treatment, storage and disposal of their non-hazardous waste pharmaceuticals.

CT DEEP endorses the recommended BMPs found in the Blueprint for all non-hazardous waste pharmaceuticals possessing hazardous waste-like qualities, including pharmaceuticals with more than one active ingredient listed on the P- or U-lists, chemotherapeutic agents characterized as bulk wastes, pharmaceuticals which meet the NIOSH Hazardous Drug Criteria, pharmaceuticals listed in Appendix VI of the OSHA Technical Manual, pharmaceuticals with LD50s  $\leq$  50 mg/kg, pharmaceuticals that are carcinogenic or endocrine disrupting compounds, and vitamin/mineral preparations containing heavy metals, and those not possessing hazardous waste-like qualities.

9. **Section V.C. What are the Proposed Standards for Healthcare Facilities that Manage Non-creditable Hazardous Waste Pharmaceuticals?**

- a. Notification requirements for healthcare facilities managing non-creditable hazardous waste pharmaceuticals

Except for "healthcare facilities" that are CESQGs, EPA is proposing to require a "healthcare facility" to submit a one-time notification as a "healthcare facility" to the appropriate EPA Regional Administrator or state regulatory agency. Healthcare facilities subject to 40 CFR part 266, new subpart P will have to submit a

notification even if they have previously obtained an EPA identification number. EPA states that the required notification will enable EPA and the states to identify the universe of healthcare facilities managing hazardous waste pharmaceuticals subject to the proposed rule and will allow EPA and the states to track healthcare facilities for enforcement and inspection purposes (i.e., ensuring the hazardous waste pharmaceuticals are managed in accordance with the proposed regulations). EPA is proposing that this notification occur via the RCRA Subtitle C Site Identification Form (EPA Form 8700-12 or Site Identification Form). However, EPA is proposing to allow healthcare facilities to submit their notification as part of the Biennial Report, if the healthcare facility will be required to submit a Biennial Report due to its non-pharmaceutical hazardous waste.

EPA believes that the proposed notification requirement will not place any undue economic burden on the environmental regulatory agencies that will process these notifications.

CT DEEP disagrees that the proposed notification requirement will not place any undue economic burden on the environmental regulatory agencies that will process these notifications. Processing the proposed notifications will place an administrative and therefore, economic burden on state RCRA programs, particularly because of dwindling RCRA program resources. CT DEEP requests EPA also refer to NEWMOA's letter commenting on this issue through the docket ID referenced above. Presently, CT DEEP has one state-funded person managing notifications within RCRAInfo within the scope of a myriad of other duties. Inputting notifications, and tracking and verifying compliance (and enforcing) this notification requirement will be extremely burdensome on our RCRA program. CT DEEP recommends EPA develop a "smart-form" tool for RCRAInfo which would enable hazardous waste notifiers to directly input reporting information and allow them the capability to update and verify such information on a regular basis to EPA. Despite the burden of processing the proposed notifications and the absence of a "smart-form" tool, CT DEEP must support the notification requirement.

CT DEEP much prefers healthcare facilities submit notifications on the RCRA Subtitle C Site Identification Form. CT DEEP does not support allowing healthcare facilities to submit their notification as part of the Biennial Report. Allowing a healthcare facility to notify at the time of its next biennial report submission could allow up to two years before the notification is submitted. This time frame is excessively long, and will inhibit the ability of regulatory agencies to learn of the existence of the facility, provide outreach and assistance, and/or conduct inspections, as appropriate.

CT DEEP also requests clarification from EPA on how an authorized state that currently processes hazardous waste notifications should manage pharmaceutical notifications if the authorized state has not yet adopted the proposed rule.

b. Personnel training requirements for healthcare facilities managing non-creditable hazardous waste pharmaceuticals

EPA contends that the RCRA training requirements for LQGs is excessive for healthcare workers, but believe it is necessary that healthcare facility personnel have some familiarity with the dangers that hazardous waste pharmaceuticals can pose. EPA is proposing healthcare facility-specific personnel training requirements that are similar to the training requirements for SQGs and small quantity universal waste handlers. That is, healthcare facilities must inform all employees that handle or have responsibility for

generating and/or managing hazardous waste pharmaceuticals of the proper handling and emergency procedures appropriate to their responsibilities during normal facility operations and emergencies.

CT DEEP agrees that the proposed personnel training requirements are appropriate and will be sufficient for communicating key procedures to healthcare workers that generate and/or manage hazardous waste pharmaceuticals.

EPA is seeking comment on whether documentation of training is necessary in order to verify compliance with the training requirement.

CT DEEP feels that documentation of training is necessary to verify compliance with the training requirement. Further, CT DEEP believes that training documentation should be kept for at least three years and be available on-site at the time of a compliance inspection.

c. Making a hazardous waste determination for non-creditable hazardous waste pharmaceuticals

EPA states that "...healthcare facilities will still be required to make a hazardous waste determination on pharmaceutical wastes prior to managing them under the proposed cradle-to-grave standards. However, unlike the existing generator requirements, the healthcare facility does not need to identify the specific waste codes applying to the pharmaceutical wastes. If the pharmaceutical waste is determined to be a hazardous waste, then the healthcare facility must manage the hazardous waste pharmaceuticals in accordance with these proposed requirements instead of 40 CFR part 262."

CT DEEP does not understand EPA's rationale for not requiring healthcare facilities to identify the specific waste codes that apply to the pharmaceutical wastes. First, the requirement to perform a hazardous waste determination is the "keystone of RCRA". Second, CT DEEP views this proposal to be inconsistent with the proposed standards in the EPA Hazardous Waste Generators Improvements Rule which clearly establishes more detailed information for waste characterization, handling and tracking. Third, an integral part of performing a hazardous waste determination is apply the appropriate hazardous waste code(s). Fourth, waste codes are necessary to complete the EPA Form 8700-12 or Site Identification Form (i.e., see Box #11 Description of Hazardous Wastes). Fifth, waste codes are necessary to fill out hazardous waste manifests and Land Disposal Restriction (LDR) notifications. CT DEEP finally requests EPA to refer to comment numbers 10.h.and i. below.

d. Elimination of central accumulation area and satellite accumulation area requirements for healthcare facilities managing non-creditable hazardous waste pharmaceuticals

Under the proposed rule, a healthcare facility accumulating hazardous waste pharmaceuticals will not be subject to the satellite accumulation area regulations or the central accumulation area regulations.

CT DEEP understands the rationale for not requiring healthcare facilities to be subject to satellite accumulation area regulations. However, we have concerns for the elimination of central accumulation area requirements. First, CT DEEP believes that non-creditable hazardous waste pharmaceuticals should be stored in a designated accumulation area near or within a less than 90-day or less than 180-day hazardous waste storage area. Second, even if healthcare facilities are not required to manage non-creditable

hazardous waste pharmaceuticals within such an area, compatibility and incompatibility issues must still be considered.

CT DEEP requests that EPA clarify whether closure requirements apply to the storage location(s) for non-creditable hazardous waste pharmaceuticals. If closure will not be required, CT DEEP requests EPA provide the rationale for not requiring closure of such storage location(s).

e. Container standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals

EPA notes that due to the “relatively” small quantities of hazardous waste pharmaceuticals that are accumulated and stored at a healthcare facility, containers are typically used to manage waste pharmaceuticals. Moreover, other types of waste management units, such as tanks, are not used for the management of waste pharmaceuticals. Therefore, EPA only outlines management standards for containers in the proposed rule.

CT DEEP agrees with EPA in that containers are primarily used to accumulate and store waste pharmaceuticals at healthcare facilities. If no other types of waste management units are currently used to store waste pharmaceuticals, CT DEEP suggests EPA prohibit other types of accumulation and waste storage units from being used in the future.

Under the proposed rule, EPA is proposing that healthcare facilities must pack hazardous waste pharmaceuticals into containers which are structurally sound and are compatible with the hazardous waste pharmaceuticals that will be contained within them. EPA states that they intend for “...this requirement to mean that containers used for holding hazardous waste pharmaceuticals must be in good condition, with no severe rusting, apparent structural defects, or deterioration. Containers also must not have any evidence of leakage, spillage or damage that could result in the release of waste under reasonably foreseeable circumstances.” Furthermore, EPA “...is proposing to require that incompatible wastes not be placed in the same container, unless the co-mingling of incompatible hazardous wastes is conducted in such a way that it does not have the potential to (1) generate extreme heat or pressure, fire or explosion, or violent reaction; (2) produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health; (3) produce uncontrollable flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions; (4) damage the structural integrity of the facility or container containing the hazardous waste pharmaceuticals; or (5) through other like means threaten human health or environment.”

Although CT DEEP agrees with the requirements described above, CT DEEP believes that EPA needs to clarify what is meant by the “container”. For example, CT DEEP staff have encountered numerous instances when hazardous waste pharmaceuticals are accumulated or stored in plastic bags. Would such bags be considered acceptable containers? Also, CT DEEP has seen situations in which a pill bottle is placed inside a re-sealable plastic bag which is then placed within a large cardboard box. In this situation, which of these is the “container”? The pill bottle? The re-sealable plastic bag? The cardboard box?

The preamble language states that hazardous waste pharmaceuticals that cannot be incinerated must be accumulated separately from organic wastes destined for incineration. The corresponding language found in proposed 40 CFR 266.502(d)(4) reads “A healthcare facility may accumulate hazardous waste pharmaceuticals and non-hazardous pharmaceutical waste in the same container, except that hazardous

waste pharmaceuticals prohibited from being combusted because of the dilution prohibition of 40 CFR 268.3(c) must be accumulated in separate containers.”

CT DEEP is concerned that healthcare facilities will not understand what they need to do pursuant to the requirement described above.

CT DEEP requests EPA clarify what “closed” means in the context of accumulation and storage containers for hazardous waste pharmaceuticals.

f. Labeling standards on containers for healthcare facilities managing non-creditable hazardous waste pharmaceuticals

EPA proposes that during the period of accumulation and storage, containers of hazardous waste pharmaceuticals be marked with the words “Hazardous Waste Pharmaceuticals.”

CT DEEP understands from stakeholder input within the state that inclusion of the word “pharmaceutical” on the label may be of concern. Therefore, CT DEEP suggests as an alternative healthcare facilities label containers with the words “Hazardous Waste” and under the description of contents add the words “characteristic” and/or “P-listed” and/or “U-listed”.

CT DEEP reiterates here the need for EPA to clarify what is the container because it corresponds to the labeling requirement.

g. Accumulation time limits for healthcare facilities managing non-creditable hazardous waste pharmaceuticals

Since healthcare facilities often do not generate sufficient quantities of hazardous waste pharmaceuticals within the current allowed accumulation period to make off-site shipments using a permitted hazardous waste transporter cost-effective, EPA is proposing to allow healthcare facilities the ability to accumulate hazardous waste pharmaceuticals for up to one year. EPA is also proposing to allow healthcare facilities the ability to request an extension past one year from the appropriate EPA Regional Administrator or state regulatory agencies for any unforeseen circumstances beyond their control (e.g., a recall or litigation).

However, CT DEEP recommends an extension beyond one year be limited to up to 30 days which is consistent with 40 CFR 262.34(f). Non-creditable hazardous waste pharmaceuticals should not be subject to either a recall or litigation.

h. Land disposal restrictions for non-creditable hazardous waste pharmaceuticals

Since healthcare facilities are generators, EPA is requiring that they comply with the LDR notification requirements of 40 CFR part 268. In general, hazardous waste generators apply the appropriate hazardous waste codes so that TSDFs may determine the specific treatment standard(s) for each prohibited waste. As stated above, EPA is proposing to allow healthcare facilities to not have to assign hazardous waste codes to these wastes. EPA also restates here that healthcare facilities must be aware that while most hazardous waste pharmaceuticals are organic in nature and will be incinerated, some may not be suitable for incineration (e.g., characteristic metal wastes prohibited from being combusted because of the dilution prohibition of 40 CFR 268.3(c), mercury wastes under waste code U151, selenium sulfide, and arsenic

trioxide, unless they contain greater than 1% total organic carbon). These wastes must be segregated from organic wastes.

CT DEEP believes that it is necessary for EPA to incorporate into the regulations a requirement for segregation of these wastes.

- i. Procedures for shipping non-creditable hazardous waste pharmaceuticals off-site from healthcare facilities

The requirement that a hazardous waste manifest be prepared for each off-site shipment of non-creditable hazardous waste pharmaceuticals from healthcare facilities is being maintained. However, EPA is proposing that hazardous waste codes do not need to be listed on the manifest. EPA maintains that this will accommodate the fact that healthcare providers are generally unfamiliar with RCRA and are focused on providing healthcare to patients.

CT DEEP indicates in number 9. above why we believe hazardous waste codes remain necessary. CT DEEP recognizes that not every healthcare provider will have a full understanding of RCRA. However, the concept of waste codes should not be a difficult topic to grasp. Plus, each healthcare provider will not need to know how to assign a specific waste code to each hazardous waste pharmaceutical. Nowadays, formularies can be uploaded into a vendor's software program to facilitate the assignment of waste codes.

CT DEEP also does not understand how a healthcare facility is not sophisticated enough to understand hazardous waste codes, but is expected to understand Department of Transportation (DOT) requirements for hazardous materials. Generators need at least one hazardous waste code for each DOT description.

Equally important, CT DEEP requests EPA to discuss whether the lack of hazardous waste codes will cause problems with the soon-to-be released e-manifest system. If section 13 (i.e., Waste Codes) is a required field on the e-manifest, the absence of a waste code may pose a problem for anyone responsible for proper management, treatment and/or disposal of this waste.

- j. Procedures for managing rejected shipments of non-creditable hazardous waste pharmaceuticals from healthcare facilities

According to EPA, a healthcare facility may send its non-creditable hazardous waste pharmaceuticals to a designated facility that on occasion is unable to manage them. For such situations, EPA is proposing for healthcare facilities to follow the same procedures described in 40 CFR 262.23(f). EPA states "...it is appropriate to continue current practices for rejected shipments because rejected shipments are relatively rare...the procedures currently used for rejected shipments is relatively straightforward...healthcare facilities should be familiar with these procedures already."

CT DEEP deems such procedures are important and agrees that they should be kept.

- k. Reporting requirements for healthcare facilities managing non-creditable hazardous waste pharmaceuticals

EPA is proposing that healthcare facilities managing non-creditable hazardous waste pharmaceuticals be subject to the exception reporting requirements under 40 CFR 262.44(b) and the additional reporting requirement of 40 CFR 262.44(c). CT DEEP agrees that both of these requirements are appropriate.

In addition, EPA is proposing that healthcare facilities that are LQGs would no longer be required to include their hazardous waste pharmaceuticals on their biennial report (BR). CT DEEP concurs with EPA since the data will be captured by pharmaceutical reverse distributors and TSDFs.

I. Recordkeeping requirements for healthcare facilities managing non-creditable hazardous waste pharmaceuticals

Under the proposed rule, EPA is proposing healthcare facilities managing non-creditable hazardous waste pharmaceuticals to maintain records similar to the records required by generators regulated pursuant to 40 CFR 262.40. In other words, healthcare facilities will be required to keep a signed copy of each hazardous waste manifest for three years from the date the non-creditable hazardous waste pharmaceutical was accepted by the initial hazardous waste transporter.

CT DEEP supports this requirement and asks EPA to further require that such records be kept on-site. Moreover, healthcare facilities should be required to enter hazardous waste codes on manifests so that state regulatory agencies are able to determine if non-creditable hazardous waste pharmaceuticals were properly disposed.

EPA is further proposing that if a healthcare facility is required to file an exception report that the healthcare facility must keep a copy of such report for a period of at least three years from the due date of the report.

CT DEEP supports this requirement and asks EPA to further require that such records be kept on-site.

Lastly, healthcare facilities must keep records of any test results, waste analyses or other determinations made on hazardous waste pharmaceuticals for three years from the date of the test, analysis, or other determination.

CT DEEP supports this requirement and asks EPA to further require that such records be kept on-site.

m. Procedures for responses to releases by healthcare facilities managing non-creditable hazardous waste pharmaceuticals

EPA is proposing basic spill response procedures identical to those specified in the Universal Waste Rule. The proposal includes the requirement for healthcare facilities to immediately contain all releases of, and other residues from, the spill or release of hazardous waste pharmaceuticals. In addition, healthcare facilities will be required to determine whether any material, residue, or debris resulting from the spill or release is, or contains, a hazardous waste pharmaceutical and, if so, to manage such materials under the proposed management standards for hazardous waste pharmaceuticals.

CT DEEP concurs with the proposed requirements.

n. Special requirements for long-term care facilities managing non-creditable hazardous waste pharmaceuticals

CT DEEP does not have any additional comments on the information provided by EPA in this section.

o. Conditions for healthcare facilities that accept hazardous waste pharmaceuticals from off-site CESQGs

EPA is proposing to enable "...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..." all four of the following conditions are met:

- \* The receiving healthcare facility must be contracted to supply pharmaceutical products to a CESQG long-term care facility, or the CESQG healthcare facility and the receiving healthcare facility must both be under the control of the same person, as defined by 40 CFR 260.10.
- \* The receiving healthcare facility must manage its hazardous waste pharmaceuticals in accordance with the regulations of the proposed rule.
- \* The hazardous waste pharmaceuticals from the CEQSG must be managed by the receiving healthcare facility as hazardous waste pharmaceuticals in accordance with the regulations of this proposed rule once the shipment arrives at the receiving healthcare facility.
- \* The receiving healthcare facility must keep and maintain records of the hazardous waste pharmaceuticals received from the off-site CESQG healthcare facilities for three years from receipt of shipment.

CT DEEP requests EPA to clarify the specific intent of the phrase "healthcare facilities that are CESQGs operating under this subpart". Specifically, do CESQG healthcare facilities have to comply with all applicable aspects of the proposed rule or only the proposed sewer ban?

The first requirement specifies "The receiving healthcare facility must be contracted to supply pharmaceutical products to a CESQG long-term care facility. CT DEEP requests EPA consider specifying that a "documented and verifiable business relationship" exists between the CESQG and the receiving healthcare facility.

EPA believes the conditions prescribed above "...should ensure the proper management of the hazardous waste pharmaceuticals, in that once they are received by the healthcare facility, they are subject to the same management standards EPA is proposing for hazardous waste pharmaceuticals managed by healthcare facilities, while at the same time would not impose an undue burden on healthcare facilities that are CESQGs, especially since these healthcare facilities always have the option of sending their hazardous waste pharmaceuticals to a municipal or non-municipal solid waste landfill."

CT DEEP agrees with the remainder of the proposal and does not feel that additional conditions are necessary.

10. **Section V.D. How Does this Proposed Rule Address Healthcare Facilities that Accumulate Potentially Creditable Hazardous Waste Pharmaceuticals Prior to Shipment to Pharmaceutical Reverse Distributors?**

- a. Potentially Creditable Hazardous Waste Pharmaceuticals are not Products

Two previous agency policy memos set out EPA's current and outdated interpretation of the status of pharmaceuticals that are shipped to reverse distributors to obtain manufacturer's credit. The first was a

1981 letter to Merck Sharp & Dohme which stated that pharmaceuticals sent for credit may be reclaimed and are not wastes since the decision to discard a particular material does not occur until after the product has been returned to the manufacturing plant. The second occurred ten years later in a 1991 letter to BFI Pharmaceutical Services, Inc. This letter stated, "...to the extent that the materials involved are unused commercial chemical products with a reasonable expectation of being recycled in some way when returned, the materials are not considered as wastes until a determination has been made to discard them."

EPA reiterated the above interpretation in their Pharmaceutical Universal Waste proposal published in the Federal Register on December 2, 2008. EPA stated in this proposal, "Because unused or expired pharmaceuticals are returned (via the reverse distributor) for possible manufacturer's credit, they still have potential value to the pharmacy or hospital and are thus not considered wastes."

However, EPA is now proposing to modify their longstanding position described above concerning the waste status of pharmaceuticals sent to a reverse distributor. In this proposal "EPA confirms the general rule under RCRA that materials that are discarded are solid wastes, regardless of the economics of the system in which those discarded materials are handled. Therefore, the fact that a material may have monetary value (e.g., through a manufacturer's credit) does not determine whether that material is a solid waste. Rather, the "decision point" on whether a pharmaceutical is a solid waste is when it has been discarded, or the decision has been made to discard the material. That is, a discarded pharmaceutical may retain value in the reverse distribution system, but still be considered a solid waste."

EPA is finally acknowledging in writing that pharmaceuticals shipped or transported to reverse distributors to receive credit are rarely, if ever, repurposed, recycled, or reused. EPA further acknowledges that in most, if not all cases, pharmaceuticals that are shipped or transported to reverse distributors for credit are discarded by the reverse distributor. EPA has announced in this proposal, that for those reasons, the decision to send a pharmaceutical to a reverse distributor is essentially a decision to discard the pharmaceutical. Therefore, once a healthcare facility decides to send a hazardous waste pharmaceutical to a reverse distributor, it is a solid waste at the healthcare facility.

CT DEEP applauds EPA for conclusively debunking their previous policy memos. Since at least 1998, CT DEEP has steadfastly administered RCRA as promulgated and held, with concurrence from EPA, the position that once a pharmaceutical has been removed from a pharmacy shelf that it is non-dispensable and a decision has been made to discard such pharmaceutical. In other words, the point of generation is the hospital, retail pharmacy, veterinarian's office, clinic, or outpatient center, and not the reverse distributor. Documentation of Connecticut's position includes the September 14, 1998 letter to the Department of the Army responding to their proposal for managing unused pharmaceutical products that were to be returned by Army medical centers to wholesalers, retailers, and/or third party service companies for ultimate disposition. In our letter we told the Army that their proposal appeared to be based on the assumption that all returned pharmaceuticals had the potential for reuse. We also stated that we supported programs for pharmaceutical products being returned for reuse provided such program is used as a means to facilitate the legitimate reuse of the pharmaceutical products.

CT DEEP has maintained that opinion. As such, CT DEEP issued eight consent orders to CVS Pharmacy in January, 2013, a consent order was issued to The Danbury Hospital in 2012, and we have issued numerous

other Notices of Violation to both hospitals and retail pharmacies since that time for the mismanagement of hazardous waste pharmaceuticals including those being sent to reverse distributors. CT DEEP has also made numerous presentations over the years on the subject of the proper management and disposal of pharmaceutical waste.

b. Hazardous Waste Determination for Potentially Creditable Hazardous Waste Pharmaceuticals

Under the proposed rule, EPA states "...a healthcare facility must determine which potentially creditable pharmaceuticals are listed or characteristic hazardous wastes, in order to determine which potentially creditable pharmaceuticals are subject to regulation under this subpart." Potentially creditable hazardous waste pharmaceuticals must be managed under this subpart, while pharmaceuticals that do not meet the definition of hazardous waste but are potentially creditable, do not have to be managed under this subpart."

EPA further explains that a healthcare facility "...may choose to manage all of its potentially creditable pharmaceuticals (both hazardous and non-hazardous) as potentially creditable hazardous waste pharmaceuticals..." and if such approach is chosen, the healthcare facility would not need to make individual hazardous waste determinations. In other words, the healthcare facility is reaching the decision to manage all of their potentially creditable pharmaceuticals in accordance with new subpart P.

Despite the fact that a healthcare facility may decide to manage all of their potentially creditable pharmaceuticals pursuant to the proposed rule, the healthcare facility will nonetheless have to perform hazardous waste determinations for the numerous reasons CT DEEP related in number 9. above (e.g., What are the Proposed Standards for Healthcare Facilities that Manage Non-creditable Hazardous Waste Pharmaceuticals?)

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

EPA is not proposing specific management standards for the accumulation of potentially creditable hazardous waste pharmaceuticals because EPA believes these pharmaceuticals present less of a risk of release than patient care hazardous waste pharmaceuticals.

Regardless, CT DEEP believes EPA should require specific management standards should be required. Compared to non-creditable hazardous waste pharmaceuticals, potentially creditable hazardous waste pharmaceuticals probably retain considerable more monetary value, are more likely to be the subject of pilfering, often have high street value that makes them susceptible to diversion, and can easily be diverted for illicit purposes. Therefore, potentially creditable hazardous waste pharmaceuticals should be required to be accumulated and stored either within the pharmacy or in locked storage lockers, closets or rooms where only pharmacy personnel have access until they are either transported or shipped to a reverse distributor.

Accumulation and storage containers holding potentially creditable hazardous waste pharmaceuticals should be required to be kept closed except when adding or removing said pharmaceuticals. All accumulation and storage containers holding potentially creditable hazardous waste pharmaceuticals should be stored in a way that prevents the release of pharmaceuticals or pharmaceutical components to the environment. The potentially creditable hazardous waste pharmaceuticals should only be placed in

accumulation and storage containers that are structurally sound and compatible with the potentially creditable hazardous waste pharmaceuticals that will be contained within them. In other words, such containers must be in good condition, with no severe rusting, apparent structural defects, or deterioration, must not have any evidence of leakage, spillage or damage that could result in the release of a potentially creditable hazardous waste pharmaceutical under reasonably foreseeable circumstances. Finally, incompatible potentially creditable hazardous waste pharmaceuticals should not be placed in the same container.

The proposed rule states “...as a best management practice, EPA encourages healthcare facilities to place the original containers and packaging containing liquids and aerosols...” in separate individual containers, such as a sealed storage bag before placing them in the container that will be shipped.

CT DEEP requests EPA provide specifications for the “sealed storage bags” which would meet such best management practice.

EPA is also proposing not to require specific labeling standards for containers holding potentially creditable hazardous waste pharmaceuticals while they accumulate on-site.

CT DEEP believes that containers holding potentially creditable hazardous waste pharmaceuticals must be labeled. Unlabeled waste is easily forgotten or mismanaged and ends up stored in unsecured locations where it is even more subject to diversion or improper disposal.

**11. Section V.E.1. What Are the Proposed Novel Prohibitions, Exemptions and Other Unique Management Requirements for Hazardous Waste Pharmaceuticals? – Sewer Disposal Prohibition**

- a. Under subsection a. of this section, EPA reminds stakeholders that pursuant to 40 CFR 261.4(a)(1)(ii), “Any mixture of domestic sewage and other wastes that passes through a sewer system to a publicly-owned treatment works (POTW) for treatment” is not a solid waste for purposes of RCRA Subtitle C regulations. EPA also discusses the July 24, 1990 final rule which prohibits the discharge of pollutants which create a fire or explosion hazard in the POTW. This includes, but is not limited to, waste streams having a closed cup flashpoint of less than 140 degrees Fahrenheit or 60 degrees Celsius using the test methods specified in 40 CFR 261.21. This rule which bans the discharge of liquid ignitable hazardous wastes with hazardous waste code D001 into a POTW was established under the national pretreatment standards of 40 CFR 403.5(b)(1). The pretreatment standards are under the Clean Water Act (CWA) regulations. Therefore, EPA seeks comment on whether it would be helpful to incorporate in 40 CFR 261.4(a)(1)(ii), a cross-reference to the CWA regulations prohibiting the sewerage of liquid ignitable hazardous wastes.

CT DEEP thinks it would be helpful to incorporate in 40 CFR 261.4(a)(1)(ii) a cross-reference to 40 CFR 403.5(b)(1) which prohibits the sewerage of liquid ignitable hazardous wastes.

- b. In subsection b. EPA discusses the prevalence of flushing in lieu of hazardous waste management, in subsection c. the inadequacy of POTW treatment to remove pharmaceuticals, and in subsection d. the adverse impacts to human health and the environment due to pharmaceuticals in the environment. EPA states in subsection e., “Given the demonstrated negative ecological effects and the potential for negative

human health effects, EPA is proposing to impose a sewer ban on all hazardous waste pharmaceuticals managed by healthcare facilities and pharmaceutical reverse distributors that are subject to this proposed rule—that is, they are prohibited from disposing of pharmaceuticals that are listed hazardous waste and/or exhibit one or more of the four hazardous waste characteristics (i.e., ignitability, corrosivity, reactivity, or toxicity) by putting them down a drain (e.g., sink, toilet, or floor drain). EPA is proposing that the sewer ban of hazardous waste pharmaceuticals also apply to healthcare facilities that are CESQGs.”

CT DEEP concurs with the proposed sewer ban on all hazardous waste pharmaceuticals from healthcare facilities and pharmaceutical reverse distributors that are subject to this proposed rule unless explicitly authorized by a National Pollutant Discharge Elimination System (NPDES) or State pretreatment permit. Second, CT DEEP concurs with extending the sewer ban to include healthcare facilities that are CESQGs. Third, CT DEEP does not believe there is an unfavorable risk trade-off inherent in prohibiting sewer disposal. Finally, CT DEEP is pleased that EPA is strongly recommending as a BMP for facilities to not sewer any waste pharmaceutical, except when sewerage is specifically directed by FDA guidance as noted on pharmaceutical packaging. CT DEEP would like to see a ban on the sewerage of all non-hazardous waste pharmaceuticals. It should be emphasized that under the Clean Water Act regulations, both the NPDES regulations and the pretreatment regulations, persons are not authorized to discharge pharmaceuticals down the drain without a permit. Further, CT DEEP’s current hazardous waste management regulations essentially ban sewer disposal of RCRA waste by requiring all generators in Connecticut, including CESQGs, to ensure delivery by a licensed waste transporter with an EPA I.D. Number to a facility authorized to receive the waste.

12. **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**

- a. In paragraph one, EPA points out that when a discarded pharmaceutical is both a hazardous waste and a controlled substance, it is regulated under both the RCRA Subtitle C hazardous waste regulations and the Controlled Substances Act (CSA). EPA indicates, and CT DEEP agrees, that there are only a few pharmaceuticals which are both hazardous waste and controlled substances. Therefore, such pharmaceuticals are subject to dual regulation by both EPA and the DEA.

EPA notes in Table 7 that although phentermine is a controlled substance, its medicinal form is a phentermine salt, and the salts are no longer considered to be within the scope of the P046 listing. EPA refers stakeholders to RCRA Online memo #14831 dated February 17, 2012.

CT DEEP believes that EPA should not maintain the policy of the referenced memo, but instead modify the P046 definition to include both base phentermine and phentermine salts.

- b. In paragraph five, EPA provides a discussion of their rationale behind their proposal to conditionally exempt hazardous waste pharmaceuticals that are also controlled substances.

- \* In the past, healthcare facilities used sewerage and incineration to comply with DEA regulations, but DEA's new regulations require controlled substances be destroyed so that they are "non-retrievable." Flushing does not meet the new non-retrievable standard. EPA fully supports this position.
- \* EPA is concerned that healthcare facilities will continue to flush controlled substances. This is due to a 2009 EPA report which concluded, "controlled substances are the pharmaceuticals most commonly poured down the drain, especially the partially-used IVs containing controlled substances."
- \* Stakeholders have told EPA that it is not only difficult to manage controlled substances which are also hazardous wastes under both DEA and EPA regulatory schemes, but expensive. Therefore, the controlled substances are often sewerage on-site in order to avoid the expense of complying with both sets of regulations while being transported to an incinerator.

Therefore, EPA is proposing that hazardous waste pharmaceuticals that are also controlled substances will be exempt from all RCRA Subtitle C requirements, including new subpart P of 40 CFR part 266, as long as healthcare facilities ensure that such hazardous waste pharmaceuticals are:

- (i) Combusted at a permitted large or small municipal waste combustor or a permitted or interim status hazardous waste combustor (incinerator or cement kiln), and
- (ii) Managed and disposed of in compliance with all applicable DEA regulations for controlled substances.

CT DEEP supports EPA's rationale for their proposal to conditionally exempt hazardous waste pharmaceuticals that are also controlled substances and believe that the DEA standards are safe and protective of human health and the environment. CT DEEP recognizes that only a handful of pharmaceuticals in common usage are both hazardous waste and controlled substances, and therefore, the complexity and cost created from dual regulation by both EPA and DEA will be addressed through the conditional exemption

- c. EPA requests stakeholders comment on whether there are additional technologies besides incineration that would be appropriate to add for the destruction of hazardous waste pharmaceuticals that are also controlled substances.

CT DEEP is not aware of any new technologies that would be appropriate to add for the destruction of hazardous waste pharmaceuticals, including controlled substances. However, CT DEEP believes that DEA should be required to consult with EPA before approving any new treatment technologies to verify that they are environmentally appropriate.

- d. With respect to tracking, EPA explains in paragraph eight that DEA's regulatory program is similar RCRA Subtitle C requirements since both track the regulated material from cradle to grave. Before a DEA registrant can ship a schedule II controlled substance, they must submit a DEA Form 222 to the supplier of the schedule II controlled substance. The supplier must indicate on the DEA Form 222, the quantity of packages shipped and the date the packages were shipped. Similar to a manifest, the DEA Form 222 is a numerically controlled form which contains certain pre-printed information, must accompany the shipment, and must be kept by both the supplier and purchaser for at least two years. A hazardous waste manifest must be kept for at least three years. Suppliers and distributors may utilize the electronic version of the DEA

Form 222, which requires the same information and retention period. Similarly, when a registrant ships DEA Schedule III, IV and V controlled substances, the shipment must be accompanied by an invoice detailing the inventory of the contents. A copy of the invoice must be retained by the supplier and purchaser of the controlled substances for a period of two years. EPA states that they believe that the DEA tracking and shipping requirements are sufficient to act in lieu of RCRA hazardous waste manifesting and transporter requirements.

CT DEEP agrees that the DEA tracking, shipping, recordkeeping requirements are sufficient in lieu of RCRA's similar requirements.

- e. In an October 17, 2014 letter to registrants, the DEA clarified "...controlled substance 'pharmaceutical wastage' may be disposed of in accordance with applicable federal, state, and local laws, regulations, and healthcare facility policies, to include sewerage or putting down the drain." In this context, the term "pharmaceutical wastage" means leftover, unadministered pharmaceuticals. That is, some of the pharmaceutical substance remains in a vial, tube, transdermal patch, or syringe after administration, but cannot or may not be further utilized. However, in the proposed rule, hazardous waste pharmaceuticals that are also controlled substances would be exempt from RCRA, but only if they are incinerated at a permitted hazardous or municipal solid waste incinerator and managed in accordance with DEA regulations. Therefore, under the proposed rule, if pharmaceutical wastage is both a hazardous waste and controlled substance, it would have to be incinerated.

As an alternative, EPA is requesting stakeholders comment on whether to allow the sewerage of pharmaceutical wastage for the hazardous waste pharmaceuticals that are also controlled substances.

CT DEEP believes that EPA should not consider allowing the sewerage of pharmaceutical wastage for hazardous waste pharmaceuticals that are also controlled substances. EPA notes, however, that they are concerned that this alternative approach will lead to the sewerage of all pharmaceutical wastage because they feel it is unlikely that healthcare providers will keep track of which hazardous waste pharmaceuticals are allowed to be seweraged and which are not. First, CT DEEP agrees with EPA in that allowing the sewerage of pharmaceutical wastage for hazardous waste pharmaceuticals that are also controlled substances will lead to the sewerage of additional pharmaceutical wastage. Second, CT DEEP requests EPA clarify that as part of this rulemaking the proposed sewer ban not only applies to all healthcare facilities, but includes wastage from hazardous waste pharmaceuticals.

- f. Subsection b. of this section is entitled "Household Hazardous Waste Collected in DEA Authorized Collection Receptacles". Under this subsection, EPA is proposing to exclude from RCRA regulation household waste pharmaceuticals (i.e., solid wastes, as defined in 40 CFR 261.2, that also meets the definition of pharmaceutical, as defined in this proposed rule, but is not a hazardous waste because it is exempt from RCRA Subtitle C regulation by the household waste exclusion in 40 CFR 261.4(b)(1)) that are collected in DEA authorized collection receptacles, provided such pharmaceuticals are:
- i) Combusted at a municipal solid waste or hazardous waste combustor, and
  - ii) Managed in accordance with all applicable DEA regulations.

CT DEEP agrees with the provisions proposed by EPA and finds them to be appropriate.

13. **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**

- a. In subsection a. of the above noted section, EPA describes much of the necessary regulatory background concerning the status of containers that once held hazardous waste pharmaceuticals, especially those that contained P-listed pharmaceuticals. First, 40 CFR 261.33 directs:

“The following materials or items are hazardous wastes if and when they are discarded or intended to be discarded...(c) Any residue remaining in a container or in an inner liner removed from a container that has held any commercial chemical product or manufacturing chemical intermediate having the generic name listed in paragraphs (e) or (f) of this section, unless the container is empty as defined in [§] 40 CFR 261.7(b). [emphasis added]”

There are two ways that a container or inner liner removed from a container holding a non-acute hazardous waste pharmaceutical can be considered “RCRA empty” and managed as a non-hazardous waste. The contents must have been removed by a commonly employed practice (e.g., pouring, aspirating, pumping) and either has ≤ one inch of residue remaining or has 3 % or less by weight of the total capacity of the container remaining.

However, if a container or inner liner removed from a container holding a non-acute hazardous waste pharmaceutical did not have its contents removed by a commonly employed practice and either has ≤ one inch of residue remaining or has 3 % or less by weight of the total capacity of the container remaining, then the container is not considered “RCRA empty” even if the pharmaceutical may have been fully dispensed.

If a pharmaceutical container is not “RCRA empty,” then the pharmaceutical residues are regulated as hazardous waste. Further, since the pharmaceutical residues are held by the container, the container must also be managed as hazardous waste.

There are three ways that a container or inner liner removed from a container holding an acute hazardous waste pharmaceutical can be considered “RCRA empty”. First, the container or the inner liner has been triple rinsed using a solvent capable of removing the acute hazardous waste pharmaceutical. Second, the container or inner liner has been cleaned by another method that has been shown in the scientific literature, or by tests done by the generator, to be equivalent to triple rinsing. Third, for the container alone, the inner liner has been removed. If the container or inner liner removed from a container is not “RCRA empty”, the residues must be managed as an acute hazardous waste pharmaceutical.

On November 11, 2011 EPA issued a memo entitled “Containers that Once Held P-listed Pharmaceuticals”. EPA stated in the referenced memo that they had received numerous inquiries regarding the regulatory status of containers that once held P-listed pharmaceuticals, and that the majority of the questions surrounded pill bottles that once held warfarin, but others concerned packaging that once held nicotine gum

and patches. EPA also indicated that the guidance in the memo was a short-term solution only and offered the following three approaches that a generator could employ to address their concerns:

- i) Count only the weight of the residue toward generator status; or
- ii) Demonstrate an equivalent removal method to render containers “RCRA empty”; or
- iii) Show that the warfarin concentration in the residue is below P-listed concentration.

Three different regulatory approaches for different types of pharmaceutical containers are now being proposed by EPA. The first approach is for unit-dose containers such as packets, wrappers, blister packs, cups and delivery devices; dispensing bottles that contained up to 1,000 tablets/capsules; and vials containing as much as one liter of solution. Subsection b. explains the approach for these types of pharmaceutical containers. EPA is proposing a conditional exemption from the empty container regulations of 40 CFR 261.7 for containers referenced herein from which pharmaceuticals have been fully dispensed. EPA based this conditional exemption on a few things. First, EPA wants to eliminate the sewerage of pharmaceuticals and is concerned that if containers are triple rinsed in a healthcare setting that the rinsate will be poured down the drain.

CT DEEP would also like to see an end to the practice of sewerage of pharmaceuticals. CT DEEP has coordinated with officials from Connecticut’s Department of Consumer Protection to come up with alternatives to drain disposal. In 2004, the Connecticut Healthcare Environmental Roundtable (CHER) was formed. CT DEEP’s Office of Pollution Prevention coordinates with CHER to provide a setting for hospitals, nursing homes and other healthcare facilities to learn from each other by sharing ideas, presenting success stories, keeping up-to-date on available resources and discussing issues that affect the health care industry. CHER also works closely with the Connecticut Green Building Council’s Healthcare Committee, the Connecticut Children’s Medical Center, Practice Greenhealth and the US EPA Region 1. The group meets several times a year at a different host facility. The workshop in November 2004 was meant to facilitate an understanding of RCRA and State environmental regulations. Workshops in September 2005, April 2007, and September 2014 featured pharmaceutical waste management.

EPA received data from three stakeholders (i.e., a consulting firm, a large retailer, and California’s Riverside County Department of Environmental Health) and EPA’s Office of Research and Development (ORD). EPA maintains that the results from these studies demonstrate “...there is very little residue remaining in fully dispensed containers of pharmaceuticals.” The results from each of the four sources were summarized in the proposed rule.

CT DEEP feels the data presented raises some concerns. The large retailer provided data showing the weight of the active pharmaceutical ingredient residues remaining in bulk containers (i.e., 100-count) of various dosage strengths of warfarin. The average warfarin residue left in a bottle of low dose warfarin (1-3 mg) was 0.155 mg, in medium dose warfarin (5-7.5 mg) 0.712 mg remained, and in high dose warfarin (10 mg) 1.196 mg remained. Therefore, it would only take ten “empty” bottles of low-dose warfarin to equal one low dose tablet, ten “empty” bottles of medium-dose warfarin to equal the upper end of a medium dose warfarin tablet, and ten “empty” bottles of high dose warfarin to exceed one high dose warfarin tablet. In the seventeen bottles of low dose warfarin tested, 2.638 mg of warfarin residue remained; in the eighteen

bottles of medium dose warfarin tested, 12.820 mg of warfarin residue remained; and in the eighteen bottles of high dose warfarin tested, 21.530 mg of warfarin residue remained. This study shows that at least one tablet of low dose up to at least ten capsules of low dose warfarin remained in the seventeen or eighteen containers tested.

The Riverside County study investigated whether the warfarin residue concentrations remaining in warfarin pill bottles was greater than 0.3% and therefore met the listing criteria for P001 or whether the residues were at or below 0.3% and therefore met the listing criteria for U248. Forty one pill bottles and three 30-pill blister packs (e.g., “bingo cards”) were analyzed. The analyses revealed that the concentration of warfarin remaining in the pill bottles was greater than 0.3 % and the concentration from the blister packs was less than 0.3%. The total weight of residue from the pill bottles ranged from 3.5 to 7.6 mg of warfarin. However, the total weight of residue from the 30-pill blister pack ranged from 134.8 to 273 mg of warfarin or equivalent to at least one hundred tablets of low-dose warfarin.

EPA states in the third to the last paragraph that “...given the size of the containers involved and the nominal quantities of residues involved, the Agency is proposing to allow the residues in single-unit dose containers/packaging and dispensing bottles, vials and ampules that once held pharmaceuticals to be managed as non-hazardous waste pharmaceuticals provided the pharmaceutical product has been fully dispensed (e.g., all pills have been removed).”

First, CT DEEP does not agree that the residues remaining in the containers can be defined as “nominal”, especially as noted for warfarin. Since EPA is proposing that hazardous waste pharmaceuticals will no longer be counted toward a healthcare facility’s generator status, CT DEEP believes that empty pharmaceutical containers that once held acute hazardous waste pharmaceuticals should continue to be managed as hazardous waste under new subpart P of 40 CFR part 266. Unfortunately, if this proposal is finalized, this means that in most states empty pharmaceutical containers will be allowed to be disposed in the trash. However, this will not be true in Connecticut as Connecticut requires all hazardous waste including that from CESQGs to be transported to a permitted facility. Healthcare facilities will continue to be required to manage empty pharmaceutical containers either as non-creditable hazardous waste pharmaceuticals or non-RCRA hazardous waste.

Finally, EPA is concerned that empty pharmaceutical containers will be susceptible to diversion from the municipal waste stream and used for illicit purposes, such as packaging counterfeit pharmaceuticals. Therefore, EPA is proposing that “RCRA empty” pharmaceutical containers that are original pharmaceutical packages be destroyed prior to placing them in the trash. EPA does not believe that defacing labels is sufficient. Destruction methods include crushing or shredding.

CT DEEP shares EPA’s concerns about diversion. However, we are more concerned about worker safety and the possible release of pharmaceutical residues to the environment.

With respect to dispensed syringes, “EPA is proposing a conditional exemption for syringes that have been used to administer pharmaceuticals that are listed or characteristic hazardous waste when discarded. The residues remaining in a dispensed syringe would not be regulated as hazardous waste provided the syringe has been used to administer a pharmaceutical to a patient and the syringe is placed in a sharps container (if appropriate) and is managed in accordance with all applicable state and federal medical waste regulations.”

However, EPA also noted that syringes in sharps containers are usually autoclaved prior to being disposed is concerned that syringe residues could be aerosolized during autoclaving posing risks via pulmonary exposure to workers during venting of the autoclave. EPA also points to a 2010 study conducted by EPA's National Exposure Research Laboratory which suggested that autoclaving may even increase the toxicity of certain drugs.

CT DEEP does not support the disposal of non-empty syringes in sharps containers for the reasons cited above by EPA.

Finally, EPA is proposing that residues remaining in other types of unused or used containers, including delivery devices such as IV bags and tubing, inhalers, aerosols, nebulizers, tubes of ointment, gels, or creams will be regulated as a hazardous waste if such residues are P- or U-listed or exhibit a hazardous waste characteristic. Since hazardous waste pharmaceuticals managed under this proposed rule will not be counted towards a healthcare facility's generator status, EPA indicates that managing these residues and containers as hazardous waste under proposed 40 CFR part 266, subpart P should not pose the same burden that generators currently face with keeping track of the monthly amount of residues in containers that are not "RCRA empty."

CT DEEP agrees with EPA proposed management standards outlined in this paragraph.

#### 14. **Section V.F. What are the Proposed Standards for Shipping Hazardous Waste Pharmaceuticals?**

- a. Shipping standards for non-creditable hazardous waste pharmaceuticals from healthcare facilities to TSDFs

As discussed previously, EPA is proposing compliance with existing RCRA Subtitle C pre-transport requirements for packaging, labeling and marking, shipping using a permitted hazardous waste transporter, and tracking using a hazardous waste manifest. However, EPA is proposing that hazardous waste codes will not be required to be entered on hazardous waste manifests for non-creditable hazardous waste pharmaceuticals. Instead, EPA is proposing that the words, "hazardous waste pharmaceuticals" be entered in box #14 of the manifest (e.g., the "special handling and additional information" box). Further all existing RCRA recordkeeping requirements for manifests and all applicable DOT shipping requirements will continue to apply.. EPA requests comment on this proposed approach for manifesting non-creditable hazardous waste pharmaceuticals from a healthcare facility.

CT DEEP disagrees on this point and refers EPA back to our previous comments under number 9. above.

- b. Shipping standards for evaluated hazardous waste pharmaceuticals from pharmaceutical reverse distributors to TSDFs

When evaluated hazardous waste pharmaceuticals are shipped from a pharmaceutical reverse distributor, EPA is again proposing compliance with existing RCRA Subtitle C pre-transport requirements for packaging, labeling and marking, shipping using a permitted hazardous waste transporter, and tracking using a hazardous waste manifest. However, unlike manifesting requirement for non-creditable hazardous waste pharmaceuticals, EPA is proposing pharmaceutical reverse distributors list the appropriate hazardous waste codes on the manifest.

CT DEEP supports requiring compliance with the existing pre-transport requirements, shipping using a permitted transporter and tracking using a manifest. CT also believes requiring waste codes on the manifest is appropriate.

c. Shipping Standards for Potentially Creditable Hazardous Waste Pharmaceuticals

EPA believes that the act of shipping potentially creditable hazardous waste pharmaceuticals present a low risk of release to the environment. Therefore, EPA is proposing to allow potentially creditable hazardous waste pharmaceuticals to be shipped without a hazardous waste manifest and without using hazardous waste transporters when a healthcare facility is sending potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor, or if a pharmaceutical reverse distributor is sending potentially creditable hazardous waste pharmaceuticals to another pharmaceutical reverse distributor.

Instead, EPA is proposing an alternate type of tracking. First, for each shipment, healthcare facilities and pharmaceutical reverse distributors must provide in writing (via letter or electronic communication), advance notice of the shipment to the pharmaceutical reverse distributor. Second, for each shipment, the receiving pharmaceutical reverse distributors must provide confirmation to the healthcare facility or pharmaceutical reverse distributor that initiated the shipment that the shipment of potentially creditable hazardous waste pharmaceuticals has arrived.

CT DEEP is concerned with EPA's alternate tracking proposal because it does not ensure a reconciliation between what was sent by the healthcare facility or pharmaceutical reverse distributor versus what was received by the pharmaceutical reverse distributor. Therefore, CT DEEP advocates that the advance notice must include a detailed inventory of the contents shipped and the confirmation of delivery must affirm that everything which was shipped was received and either was or was not credit worthy.

Also, EPA notes that DOT shipping requirements continue to apply to shipments of potentially creditable hazardous waste pharmaceuticals. The preamble explains that "...healthcare facilities and pharmaceutical reverse distributors must meet the applicable Pipeline and Hazardous Materials Safety Administration (PHMSA) Hazardous Materials Regulation (HMR; 49 CFR Parts 171-180) shipping requirements, including preparing proper shipping papers when shipping potentially creditable hazardous waste pharmaceuticals. A RCRA hazardous waste that does not meet DOT hazard classes 1-8 in the HMR, are only Class 9 hazardous materials when defined as a RCRA hazardous waste[s] that requires a manifest. As a result, the DOT shipping requirements will apply when potentially creditable hazardous waste pharmaceuticals are shipped to pharmaceutical reverse distributors only when the hazardous wastes are DOT class 1-8 hazardous materials."

CT DEEP requests EPA clarify what is meant by the above noted paragraph. We believe that many of the potentially creditable hazardous waste pharmaceuticals in question would fall under US DOT hazard classes 1-8; and predominately in US DOT hazard classes 3 and/or 6.1. Further, some of the more likely proper shipping names would appear to be toxic solid, n.o.s.; toxic liquid, n.o.s.; medicine, liquid, toxic, n.o.s.; medicine, liquid, flammable, toxic, n.o.s. CT DEEP also requests EPA clarify the point being made with respect to class 9 hazardous materials.

Another important question which CT DEEP needs clarification on is “Would potentially creditable hazardous waste pharmaceuticals that are shipped to a pharmaceutical reverse distributor be eligible to use the “consumer commodity” exceptions in the HMR?” If so, what specific criteria would need to be met? The definition of “consumer commodity” in 49 CFR 171.8 means “...a material that is packaged and distributed in a form intended or suitable for sale through retail sales agencies or instrumentalities for consumption by individuals for purposes of personal care or household use. This term also includes drugs or medicines.” This interpretation is important because if potentially creditable hazardous waste pharmaceuticals shipped to a pharmaceutical reverse distributor could still meet the definition of consumer commodity they could be reclassified as an ORM-D material, at least in certain situations, when being shipped off-site under the provisions of 49 CFR 173.153(c)(2). Based on the current proposal, potentially creditable hazardous waste pharmaceuticals are a solid waste. Therefore, CT DEEP does not believe that a healthcare facility or pharmaceutical reverse distributor could say they are “intended” for sale. However, could they still be packaged (but not distributed) in a manner “suitable” for sale, and therefore, still be able to meet the definition of consumer commodity and be eligible for reclassification as an ORM-D material? If so, what specific packaging standards would meet “suitable for sale” criteria, as intended in the definition of consumer commodity?

- d. EPA is proposing that “If a healthcare facility or pharmaceutical reverse distributor initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor and does not receive delivery confirmation from the intended recipient within seven calendar days,...that the healthcare facility or pharmaceutical reverse distributor that initiated the shipment must contact the shipper and the intended recipient promptly to 1) report that the confirmation was not received and 2) to determine the status and whereabouts of the potentially creditable hazardous waste pharmaceuticals that were shipped.”

CT DEEP agrees with the proposed requirements for exception reporting, but believes that there should also be requirements for discrepancy reporting.

- e. EPA is proposing “...that healthcare facilities and reverse distributors that initiate a shipment to another pharmaceutical reverse distributor keep 1) records of advance notification regarding shipments of potentially creditable hazardous waste pharmaceuticals, 2) shipping papers, and 3) confirmation of receipt of shipment for three years after the shipment was initiated.” EPA is also proposing that the periods of retention be automatically extended during unresolved enforcement activity, or at the request of the EPA Regional Administrator.

CT DEEP requests clarification on what specifically is meant by “shipping papers”? It would be helpful if EPA would provide a definition for “shipping papers”.

EPA seeks 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.

CT DEEP recommends that the healthcare facility and pharmaceutical reverse distributor submit a letter to the Regional Administrator describing the discrepancy, the date of the shipment, the attempts made to reconcile and/or resolve the discrepancy, a copy of the advance notification including an inventory, a copy of the “shipping papers”, and a copy of any confirmations of receipt including an inventory.

15. **Section V.G. What are the Proposed Standards for Pharmaceutical Reverse Distributors?**

a. Background on Pharmaceutical Reverse Distributor Operations

In the first paragraph of Section V.G.1. EPA notes that pharmaceutical reverse distributors act as intermediaries between healthcare facilities and pharmaceutical manufacturers. In other words they receive shipments of potentially creditable hazardous waste pharmaceuticals from healthcare facilities and, on behalf of manufacturers, facilitate the process of crediting healthcare facilities for these pharmaceuticals.

CT DEEP requests EPA define the word “facilitate” in the context of the proposed rule.

EPA points out in the third paragraph “Because manufacturers’ return goods policies change over time, sometimes a pharmaceutical reverse distributor receives a potentially creditable hazardous waste pharmaceutical that is not eligible for credit immediately, and the pharmaceutical reverse distributor retains the potentially creditable hazardous waste pharmaceutical on-site until it is credit eligible.”

The practice of retaining a potentially creditable hazardous waste pharmaceutical on-site until it is credit eligible is of concern to CT DEEP since it is perceived to mirror speculative accumulation.

EPA is proposing in Section V.G.2.a.ix. for the evaluation process at the pharmaceutical reverse distributor be completed within 21 day of a shipment’s arrival. Therefore, CT DEEP suggests that EPA require that if a potentially creditable hazardous waste pharmaceutical is not credit eligible within 21 days of arriving at the pharmaceutical reverse distributor that such hazardous waste pharmaceutical be deemed non-creditable.

It is noted by EPA in the fourth paragraph that “...even after the pharmaceutical reverse distributor has awarded credit, a pharmaceutical manufacturer may request that the hazardous waste pharmaceuticals be transported back to the manufacturer to inventory and verify the amount of pharmaceuticals and credit.” In EPA’s example, CT DEEP feels that the manufacturer is acting more like a TSDF than a pharmaceutical reverse distributor. CT DEEP notes that EPA’s proposed definition of pharmaceutical reverse distributor is “any person that receives and accumulates potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer’s credit.” CT DEEP argues that once a potentially creditable hazardous waste pharmaceutical has been evaluated for credit, it is no longer a potentially creditable hazardous waste pharmaceutical, but an evaluated hazardous waste pharmaceutical which must be managed as a hazardous waste and shipped to a TSDF under the proposed rule.

CT DEEP requests EPA clarify that a manufacturer acting as a pharmaceutical reverse distributor cannot accept evaluated hazardous waste pharmaceuticals.

Finally, in the last paragraph EPA states that they are not aware of any pharmaceutical reverse distributors that also has an interim status or a permit to treat or dispose of hazardous waste on-site. However, EPA should acknowledge that a TSDF with a RCRA Part B permit in Connecticut has indicated that they may be interested in entering the market as a pharmaceutical reverse distributor.

b. EPA’s Rationale for Proposing New RCRA Management Standards for Pharmaceutical Reverse Distributors

In Section V.G.2. of the preamble, EPA discusses its rationale for proposing new RCRA management standards for pharmaceutical reverse distributors. In one part of this discussion (Page 58060, Column 1 – Page 58061, Column II), EPA discusses the status under the proposed rule of “smaller pharmaceutical reverse distributors [that] might stay under the hazardous waste quantity limits for CESQGs, which would mean that under the [current] federal RCRA requirements, these CESQG pharmaceutical reverse distributors would not have to notify EPA as a generator and their hazardous waste pharmaceuticals could be disposed of with municipal and non-municipal solid waste.” EPA indicates that, despite the standing of these reverse distributors as CESQGs with respect to the waste they generate, it is proposing to require all pharmaceutical reverse distributors (including those that generate less than hazardous waste quantity limits for CESQGs) would be subject to the same, single set standards. This would specifically require notification and the disposal of their hazardous pharmaceuticals at a RCRA-permitted facility, and otherwise complying with the proposed requirements for reverse distributors.

CT DEEP strongly supports EPA’s proposals with respect to smaller (CESQG) reverse distributors, and agrees with EPA that the prospect of such distributors not notifying under RCRA and disposing of their hazardous pharmaceuticals in the trash is troublesome in numerous ways. However, CT DEEP requests clarification on some aspects of this proposal. In particular, would a small (CESQG) reverse distributor be required to comply with the proposed requirements regardless of the type of healthcare facility that the hazardous pharmaceuticals come from? More specifically, CT DEEP notes that such a small reverse distributor could receive two distinct types of potentially-creditable hazardous pharmaceuticals that might be subject to differing requirements: (1) potentially-creditable hazardous pharmaceuticals from healthcare facilities whose hazardous pharmaceuticals are fully-regulated (i.e., facilities that would otherwise be classified as SQGs or LQGs with respect to their generation of hazardous pharmaceuticals); and, (2) potentially-creditable hazardous pharmaceuticals from health care facilities that are themselves CESQGs, and whose hazardous pharmaceuticals would not be required to be managed under the proposed Subpart P standards.

The distinction between these two types of hazardous pharmaceuticals is significant because EPA has consistently stated in past policy letters and memoranda that waste generated by CESQGs continues to remain conditionally exempt, even if it is later accumulated and aggregated at another site. This raises the question as to whether small (CESQG) reverse distributors would have to “count” hazardous pharmaceuticals that they receive from healthcare facilities that are CESQGs towards their own status, and if they would have to manage hazardous pharmaceuticals from CESQGs under the proposed subpart P rules. Furthermore, would the answer to this question depend at all on whether or not the CESQG healthcare facility opted (or did not opt) to voluntarily manage their hazardous pharmaceuticals under the proposed Subpart P rules?

CT DEEP believes that both types of hazardous pharmaceuticals from CESQG healthcare facilities should be managed the same when sent to a CESQG reverse distributor, regardless of how the CESQG healthcare facility manages them at their site (i.e., under the proposed subpart P or under the rules for CESQGs). CT DEEP urges EPA to specifically state this in the final rule preamble and/or rule language, as appropriate.

**c. Section V.G.3.a. Detailed Discussion of Proposed Pharmaceutical Reverse Distributor Standards - Standards for Pharmaceutical Reverse Distributors**

i. Notification

A pharmaceutical reverse distributors must notify EPA of its hazardous waste pharmaceutical activities via the Site ID form (EPA form 8700-12). A pharmaceutical reverse distributor that does not have an EPA ID number will be required to submit the Site ID form to obtain one. For those pharmaceutical reverse distributors that already have an EPA ID number, they will need to re-notify EPA as a pharmaceutical reverse distributor.

CT DEEP supports all three possible notification requirements proposed by EPA.

ii. Inventory

EPA is proposing that pharmaceutical reverse distributors keep an inventory of the potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that are on-site. Such inventory must include the identity (e.g., name or national drug code (NDC)) and quantity of each potentially creditable hazardous waste pharmaceutical and evaluated hazardous waste pharmaceutical. EPA is also recommending as a BMP that pharmaceutical reverse distributors keep an inventory of their non-hazardous waste pharmaceuticals as well.

CT DEEP is supportive of the idea that pharmaceutical reverse distributors keep an inventory of the potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that are on-site. This requirement will be a very important inspection tool. However, EPA does not give a time frame for how often this inventory must be updated. CT DEEP suggests that the inventory must be updated at least every 72 hours.

iii. Security of the Pharmaceutical Reverse Distributor

EPA is proposing that pharmaceutical reverse distributors meet a performance-based security requirement which is based on interim status TSDF security requirements found at 40 CFR 265.14 –a facility requirement to “...prevent the unknowing entry, and minimize the possibility for the unauthorized entry, of persons or livestock onto the active portion of his facility.” Pharmaceutical reverse distributors must prevent unknowing entry, and minimize the possibility for the unauthorized entry into the portion of the facility where potentially creditable and evaluated hazardous waste pharmaceuticals are kept (e.g., a receiving area and accumulation area).

CT DEEP does not think that the proposed language goes far enough since we agree with EPA that pharmaceuticals, including potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals, are subject to increased thefts. CT DEEP recommends the proposed language read “Pharmaceutical reverse distributors must prevent the unknowing entry, and prevent the possibility for the unauthorized entry into the portion of the facility where potentially creditable and evaluated hazardous waste pharmaceuticals are kept including receiving areas, accumulation areas, and shipping areas.”

iv. Maximum 90-Days for On-Site Accumulation and Petition for an Extension of Accumulation Time

First, EPA is not proposing specific container management standards for pharmaceutical reverse distributors. CT DEEP disagrees with EPA that not proposing specific container management standards for pharmaceutical reverse distributors is appropriate. As CT DEEP stated in number 10. above with respect to healthcare facilities managing potentially creditable hazardous waste pharmaceuticals, accumulation and storage containers holding potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals should be required to be kept closed except when adding or removing said pharmaceuticals. All accumulation and storage containers holding potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals should be stored in a way that prevents the release of pharmaceuticals or pharmaceutical components to the environment. The potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals should only be placed in accumulation and storage containers that are structurally sound and compatible with the potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals that will be contained within them. In other words, such containers must be in good condition, with no severe rusting, apparent structural defects, or deterioration, must not have any evidence of leakage, spillage or damage that could result in the release of a potentially creditable hazardous waste pharmaceutical or evaluated hazardous waste pharmaceuticals under reasonably foreseeable circumstances. Finally, incompatible potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals should not be placed in the same container.

Second, EPA proposes that pharmaceutical reverse distributors may accumulate potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals on-site for up to 90 calendar days without having interim status or a permit. The 90-day time limit begins when the potentially creditable hazardous waste pharmaceuticals initially arrive at the pharmaceutical reverse distributor and follows the potentially creditable hazardous waste pharmaceutical even after it becomes an evaluated hazardous waste pharmaceutical (e.g., there is a single 90-day accumulation limit for the hazardous waste pharmaceutical at each pharmaceutical reverse distributor).

CT DEEP supports the proposal that the 90-day time period begins on the day the potentially creditable hazardous waste pharmaceuticals arrive at the pharmaceutical reverse distributor. This should prevent the incentive for a pharmaceutical reverse distributor to accumulate potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals for longer than 90-days.

EPA explains under this subsection that pharmaceutical returns sometime need to be consolidated for greater than 90-days because they are subject to litigation and the pharmaceutical reverse distributor is not allowed to move them, or may need to handle large recalls of hazardous waste pharmaceuticals and might not be able to process all of the returned items within 90 days. Therefore, EPA is proposing to allow a pharmaceutical reverse distributor to request an extension for situations when the hazardous waste pharmaceuticals are involved in litigation, a recall, or in unforeseen circumstances beyond the control of the pharmaceutical reverse distributor. Further, EPA is proposing that if a pharmaceutical reverse distributor seeks an extension they must submit a written request to the EPA Regional Administrator (in writing or electronically), explaining the reason for the extension, the approximate volume or weight of the hazardous waste pharmaceuticals that will be stored for more than 90-days and the amount of additional time requested. Due to the complex nature of pharmaceutical litigation and

recalls, EPA is proposing to allow the EPA Regional Administrator to grant a time extension at their discretion on a case-by-case basis.

CT DEEP supports the proposal described herein. However, CT DEEP suggests that the extension request include the name of the drug and the corresponding NDC number.

v. Contingency Plan and Emergency Procedures

EPA is proposing that pharmaceutical reverse distributors meet standards that are the same as the LQG requirements found in 40 CFR 265, subpart D for developing a contingency plan and emergency procedures. "EPA believes that a pharmaceutical reverse distributor should be prepared to respond to potential emergencies just like LQGs and TSDFs. Since many pharmaceutical reverse distributors are already LQGs, they should already have contingency plans to address the hazards on-site."

CT DEEP agrees with EPA's assessment and supports EPA's requirement for pharmaceutical reverse distributors to develop a contingency plan and emergency procedures as found in 40 CFR 265, subpart D.

vi. Closure

EPA is proposing a performance-based closure standard as set forth in 40 CFR 265.111 because of the value of the hazardous waste pharmaceuticals accumulated on-site and the belief that hazardous waste pharmaceuticals pose a "generally low risk of release". This means that when a pharmaceutical reverse distributor closes its operations that are related to hazardous waste pharmaceuticals, the pharmaceutical reverse distributor must control or minimize post-closure releases of hazardous waste constituents into the environment. EPA specifically states "This will entail removing the containers of hazardous waste pharmaceuticals (both potentially creditable hazardous waste pharmaceuticals as well as evaluated hazardous waste pharmaceuticals) from the facility before closure."

CT DEEP does agree that the performance-based closure standard of 40 CFR 265.111 is protective enough and believes that the closure requirements of 40 CFR 254.113(a), (b), and (c), and 40 CFR 265.114 should be added.

CT DEEP also suggests that EPA require notification of closure activities as is being proposed in the Hazardous Waste Generator Improvements Rule. Specifically, EPA should require notification of closure activities within 30 days of the start of closure activities and ninety days of the completion of closure activities. The initial notification should include a time frame for completion of closure. Finally, EPA should require that the pharmaceutical reverse distributor maintain documentation demonstrating closure.

vii. Reporting

EPA notes in the first paragraph of this section that "In some instances, a pharmaceutical reverse distributor may receive a shipment from a healthcare facility that includes items that are not potentially creditable pharmaceuticals." CT DEEP knows that this statement is true. In fact, CT DEEP has been informed on more than one occasion by pharmaceutical reverse distributors that they not only accept

pharmaceuticals that are not potentially creditable, but have encouraged healthcare facilities to include in their shipments both non-creditable pharmaceuticals and other pharmacy related wastes in order to continue servicing such healthcare facility.

Therefore, as a result of EPA being aware that pharmaceutical reverse distributors receive items that are not potentially creditable pharmaceuticals, "EPA is proposing that if a pharmaceutical reverse distributor receives a shipment from a healthcare facility that includes hazardous waste that it is not authorized to receive, such as non-creditable hazardous waste or hazardous waste that is not a pharmaceutical, the pharmaceutical reverse distributor must submit an unauthorized waste report to the EPA Regional Administrator within 15 days of receiving the hazardous waste."

EPA is also proposing two additional requirements enhance the submission of the authorized waste report. The pharmaceutical reverse distributor must send a copy of the unauthorized hazardous waste report to the healthcare facility that sent the unauthorized hazardous waste and the pharmaceutical reverse distributor must manage the unauthorized hazardous waste that it has received in accordance with all applicable regulations.

CT DEEP is very supportive of the proposed requirements summarized in the two above paragraphs. CT DEEP hopes that such requirements will indeed act as an incentive for healthcare facilities to not ship unauthorized hazardous wastes to pharmaceutical reverse distributors.

EPA concludes this section by recommending as a BMP that pharmaceutical reverse distributors avoid sorting through shipments that contain non-creditable waste since the shipment may include hazardous waste, including infectious or radioactive healthcare waste.

First, CT DEEP agrees with the BMP for pharmaceutical reverse distributors to not sort a shipment if it clearly contains non-pharmaceutical waste in order to prevent exposing employees to unnecessary risk. However, CT DEEP questions how such BMP would ensure proper management of the waste. As EPA points out, shipments may contain patient care waste (e.g., IV tubing), medical waste, infectious waste, etc.

#### viii. Recordkeeping

EPA states that they are proposing to require pharmaceutical reverse distributors comply with the following three recordkeeping requirements for the movement of potentially creditable hazardous waste pharmaceuticals.

- 1) A copy of the Site Identification Form (EPA form 8700-12) indicating that it is a pharmaceutical reverse distributor operating under 40 CFR part 266, subpart P must be kept for as long as it is subject such requirements.
- 2) Copies of the records associated with shipments of potentially creditable hazardous waste pharmaceuticals that it receives must be kept for three years from the date the pharmaceutical reverse distributor receives the shipment. This includes a copy of the advance notification from the healthcare facility or other pharmaceutical reverse distributor, a copy of delivery confirmation, shipping papers and any unauthorized waste reports.

- 3) A copy of its current inventory at all times as long as the pharmaceutical reverse distributor remains in operation. The inventory is a living document that will constantly be updated and must be available for inspection.

EPA is also proposing that the periods of record retention outlined will be automatically extended during an enforcement action, or as requested by the EPA Regional Administrator to ensure that the appropriate records are available and can be reviewed as part of any enforcement action.

CT DEEP supports all of the recordkeeping requirements that are proposed by EPA in this subsection. In addition, EPA requests comment on whether additional recordkeeping is necessary to document cases when shipments of potentially creditable hazardous waste pharmaceuticals do not reach their intended destination within seven calendar days. Similar to what CT DEEP offered previously in number 9.i. above, CT DEEP believes that if a pharmaceutical reverse distributor is required to file an exception report, that such report should be required to be kept for at least three years from the due date of the report.

ix. Evaluating Potentially Creditable Hazardous Waste Pharmaceuticals within 21 Days.

EPA explains that when a pharmaceutical reverse distributor receives a shipment of potentially creditable hazardous waste pharmaceuticals the shipment is sorted to determine which pharmaceuticals are creditable and which must be shipped to another pharmaceutical reverse distributor. EPA is proposing that this evaluation process be completed within 21 days of arriving at the pharmaceutical reverse distributor.

CT DEEP is supportive of the proposed timeframe of 21 days for the evaluation of potentially creditable pharmaceuticals.

EPA notes that if the pharmaceutical reverse distributor is a manufacturer that "...the manufacturer must finish verifying the appropriate credit within 21 calendar days of receiving the shipment of potentially creditable hazardous waste pharmaceuticals."

CT DEEP would like EPA to please refer back to our comment number 15.a. above regarding evaluated pharmaceuticals being shipped to manufacturers for verification of credit.

EPA also emphasized "...that the 21 calendar days for evaluating the potentially creditable hazardous pharmaceuticals counts as part of the total 90 calendar days that the hazardous waste pharmaceuticals are allowed to accumulate on-site."

CT DEEP is very supportive that the 21 calendar days for the evaluation process counts as part of the total 90 calendar days that hazardous waste pharmaceuticals are allowed to be accumulated on-site.

d. **Section V.G.3.b. Detailed Discussion of Proposed Pharmaceutical Reverse Distributor Standards - Additional Standards for Pharmaceutical Reverse Distributors Managing Potentially Creditable Hazardous Waste Pharmaceuticals Destined for Another Pharmaceutical Reverse Distributor**

i. Where Potentially Creditable Hazardous Waste Pharmaceuticals Can Be Sent

EPA acknowledges that stakeholders were concerned that the 2008 Pharmaceutical Universal Waste proposal would have allowed hazardous waste pharmaceuticals to be shipped repeatedly and indefinitely from one universal waste handler to another.

Stakeholders expressed to CT DEEP during its stakeholder meetings to state-list hazardous pharmaceutical waste as a Universal Waste a similar concern. CT DEEP definitely agrees that hazardous waste pharmaceuticals should not be allowed to be shipped repeatedly and indefinitely.

EPA explains under this section that “The proposed regulations for pharmaceutical reverse distributors are structured so that there is a limit to the number of transfers of potentially creditable hazardous waste pharmaceuticals that may occur before they are ultimately transported to a TSDf for treatment and disposal.” EPA states that they believe three transfers of potentially creditable hazardous waste pharmaceuticals is a reasonable limit before the pharmaceutical hazardous waste is ultimately transported to a TSDf. EPA lists the three possible types of transfers as:

- 1) A healthcare facility may send potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor, which may or may not be a manufacturer;
- 2) The first pharmaceutical reverse distributor may send the potentially creditable hazardous waste pharmaceuticals to another pharmaceutical reverse distributor, which may or may not be a manufacturer;
- 3) The second pharmaceutical reverse distributor can only send the potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor that is a manufacturer.

On face value alone, the third type of transfer appears to make sense. However, CT DEEP would like EPA to consider the following three scenarios.

- 1) AAA Healthcare Facility (AAA) ships a potentially creditable hazardous waste pharmaceutical to ACME Pharmaceutical Reverse Distributor (ACME). ACME cannot issue AAA a credit for their potentially creditable hazardous waste pharmaceutical because they do not have a contract with the manufacturer that manufactures AAA’s potentially creditable hazardous waste pharmaceutical. Therefore, ACME ships AAA’s potentially creditable hazardous waste pharmaceutical to the manufacturer so that the manufacturer can determine if AAA’s potentially creditable hazardous waste pharmaceutical is creditable or not. Once the manufacturer has made the determination as to whether a credit can be issued or not, AAA’s potentially creditable hazardous waste pharmaceutical becomes an evaluated hazardous waste pharmaceutical. CT DEEP believes that this scenario complies with the proposed definitions and the allowable transfers.
- 2) AAA Healthcare Facility (AAA) ships a potentially creditable hazardous waste pharmaceutical to ACME Pharmaceutical Reverse Distributor (ACME). ACME cannot issue AAA a credit for their potentially creditable hazardous waste pharmaceutical because they do not have a contract with the manufacturer that manufactures AAA’s potentially creditable hazardous waste pharmaceutical. However, the manufacturer has a contract with BEST Pharmaceutical Reverse Distributor. Therefore, ACME ships AAA’s potentially creditable hazardous waste pharmaceutical to BEST so that

BEST can determine if AAA's potentially creditable hazardous waste pharmaceutical is creditable or not. Once BEST has made the determination as to whether a credit can be issued or not, AAA's potentially creditable hazardous waste pharmaceutical becomes an evaluated hazardous waste pharmaceutical. CT DEEP believes that this scenario also complies with the proposed definitions and the allowable transfers.

- 3) AAA Healthcare Facility (AAA) ships a potentially creditable hazardous waste pharmaceutical to ACME Pharmaceutical Reverse Distributor (ACME). ACME cannot issue AAA a credit for their potentially creditable hazardous waste pharmaceutical because they do not have a contract with the manufacturer that manufactures AAA's potentially creditable hazardous waste pharmaceutical. However, the manufacturer has a contract with BEST Pharmaceutical Reverse Distributor. Therefore, ACME ships AAA's potentially creditable hazardous waste pharmaceutical to BEST so that BEST can determine if AAA's potentially creditable hazardous waste pharmaceutical is creditable or not. BEST determines that AAA's potentially creditable hazardous waste pharmaceutical is creditable and issues AAA credit for such pharmaceutical. Once BEST has made the determination as to whether a credit can be issued or not, AAA's potentially creditable hazardous waste pharmaceutical becomes an evaluated hazardous waste pharmaceutical. However, the manufacturer does not completely trust BEST and requires BEST to forward AAA's evaluated pharmaceutical to them to make sure that the issuance of a credit was indeed warranted. CT DEEP believes that this scenario does not comply with the proposed definitions but does comply with the allowable transfers.

As demonstrated in CT DEEP's third scenario, CT DEEP argues that evaluated hazardous waste pharmaceuticals should not be allowed to be shipped from a pharmaceutical reverse distributor to a manufacturer. Therefore, CT DEEP requests EPA clarify that evaluated pharmaceuticals cannot be shipped to a manufacturer unless the manufacturer is also a TSDF.

CT DEEP agrees that three transfers of potentially creditable hazardous waste pharmaceuticals is a reasonable limit before the pharmaceutical hazardous waste is ultimately transported to a TSDF.

EPA requests comment on whether CESQG healthcare facilities would benefit from being able to consolidate potentially creditable hazardous waste pharmaceuticals off-site. According to EPA, they will consider allowing a fourth transfer (depending on the comments received and for this limited situation) when potentially creditable hazardous waste pharmaceuticals are sent from a CESQG healthcare facility to an off-site healthcare facility for accumulation.

CT DEEP is supportive of allowing CESQG healthcare facilities the ability to send potentially creditable hazardous waste pharmaceuticals to another healthcare facility for accumulation. Records should be required to be maintained by both the CESQG healthcare facility initiating the shipment and the healthcare facility receiving the shipment. Finally, CT DEEP does not necessarily agree that adding a fourth transfer will be necessary based on our comments under this subsection.

- ii. Recordkeeping for Pharmaceutical Reverse Distributors Shipping of Potentially Creditable Hazardous Waste Pharmaceuticals to Another Pharmaceutical Reverse Distributor

EPA points out that “Pharmaceutical reverse distributors must keep records (paper or electronic) for each shipment of potentially creditable hazardous waste pharmaceuticals that it initiates to another pharmaceutical reverse distributor (whether it is a manufacturer or not). This includes a copy of the advance notification provided to the other pharmaceutical reverse distributor, a copy of delivery confirmation, as well as shipping papers or bill of lading. We propose that these shipping records must be kept for 3 years from the date it initiates the shipment.”

CT DEEP supports the requirements for the records that must be maintained and that such records must be maintained for three years. However, as stated in number 14.e. above, CT DEEP requests clarification on what specifically is meant by “shipping papers”? It would be helpful if EPA would provide a definition for “shipping papers”.

CT DEEP also requests that EPA repeat the requirement in this section that the periods of record retention outlined will be automatically extended during an enforcement action, or as requested by the EPA Regional Administrator to ensure that the appropriate records are available and can be reviewed as part of any enforcement action.

**e. Section V.G.3.c. Detailed Discussion of Proposed Pharmaceutical Reverse Distributor Standards - Additional Standards for Pharmaceutical Reverse Distributors Managing Evaluated Hazardous Waste Pharmaceuticals**

**i. Accumulation Area**

EPA is proposing that pharmaceutical reverse distributors must establish an on-site accumulation area where evaluated hazardous waste pharmaceuticals will be accumulated. EPA states that this “...on-site accumulation area is needed so that the evaluated hazardous waste pharmaceuticals are segregated and clearly distinguished from the potentially creditable hazardous waste pharmaceuticals.”

CT DEEP supports the proposed requirement for pharmaceutical reverse distributors to establish an on-site accumulation area for evaluated hazardous waste pharmaceuticals.

**ii. Weekly Inspections**

EPA is proposing that the on-site accumulation area for evaluated hazardous waste pharmaceuticals be inspected at least weekly to ensure containers are not leaking and that diversion of the evaluated hazardous waste pharmaceuticals is not occurring.

CT DEEP believes that weekly inspections, as we typically think of them pursuant to RCRA Subtitle C regulations, will not establish whether or not diversion of evaluated hazardous waste pharmaceuticals is occurring. Requirements for what inspections shall include must be established by EPA. Security provisions, in addition to inspections, are a key component in determining whether diversion is occurring or has occurred.

iii. Personnel Training

EPA is proposing to require that pharmaceutical reverse distributors meet the same federal classroom or on-the-job personnel training requirements that LQGs must meet (e.g., 40 CFR 265.16). However, under this proposed rulemaking EPA states that the personnel which require training are those who handle evaluated hazardous waste pharmaceuticals in the on-site accumulation area. EPA believes that these personnel are the ones handling and managing hazardous waste pharmaceuticals and must have appropriate hazardous waste training. EPA requests comment on whether the training standards are appropriate for the specific reverse distributor personnel.

Although CT DEEP supports the applicability of the training requirements under 40 CFR 265.16, CT DEEP does not agree that requiring training of only those personnel that handle and manage evaluated hazardous waste pharmaceuticals is sufficient. Since there is not an inherent difference between the hazards posed by the handling and management of potentially creditable hazardous waste pharmaceuticals versus evaluated hazardous waste pharmaceuticals at pharmaceutical reverse distributors, CT DEEP believes that personnel handling and managing potentially creditable hazardous waste pharmaceuticals should have the same level of classroom or on-the-job training as is being proposed for personnel handling and managing evaluated hazardous waste pharmaceuticals. In addition, the emergency coordinator, alternate emergency coordinator(s), and personnel having manifesting duties should have the same such training. Finally, all other pharmaceutical reverse distributor personnel must be thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies.

iv. Labeling and Management of Containers in On-Site Accumulation Area

EPA is proposing that containers of hazardous waste pharmaceuticals stored in an accumulation area be marked with the words, "Hazardous Waste Pharmaceuticals." EPA is proposing this term to distinguish them from non-hazardous waste pharmaceuticals and hazardous waste pharmaceuticals that are still considered potentially creditable.

CT DEEP agrees that hazardous waste pharmaceuticals stored in a pharmaceutical reverse distributor's on-site accumulation area be marked with the words "Hazardous Waste Pharmaceuticals".

EPA is not proposing to require an accumulation start date on the container label because they believe the reverse distributor's inventory will likely be used to verify the accumulation start date.

CT DEEP thinks that the date upon which each period of accumulation begins must be marked and visible for inspection on each container.

EPA is proposing to require that only containers with hazardous waste pharmaceuticals that are liquids or gels be kept closed because EPA believes that hazardous waste pharmaceuticals in a solid form have a low potential for release. EPA further states "However, because most potentially creditable hazardous waste pharmaceuticals are in their original packaging, if the original packaging for gels or liquids is intact and sealed or the pharmaceuticals have been repackaged (e.g., for unit dosing) and the repackaged packaging for gels and liquids is intact and sealed, they are considered to meet the closed container

standard. EPA requests comment on whether additional forms of hazardous waste pharmaceuticals (other than liquids and gels) need to be specified in the regulations and subject to the closed container requirement.”

CT DEEP considers the closed container standard for liquids and gels to be perplexing. It is unclear to CT DEEP whether EPA is referring to the outer container or the inner container. CT DEEP requests clarification with respect to the proposed closed container standard for liquids and gels. Despite the fact, CT DEEP believes that all containers should remain closed except when adding or removing waste.

EPA is also proposing that containers of hazardous waste pharmaceuticals must be maintained in good condition to prevent leaks and the container material must be compatible with the hazardous waste pharmaceuticals placed in the container.

CT DEEP agrees with EPA’s proposal such that containers must be maintained in good condition and the container material must be compatible with the hazardous waste pharmaceuticals placed in the container.

In addition, EPA is proposing to require pharmaceutical reverse distributors who manage ignitable or reactive hazardous waste pharmaceuticals or who mix or commingle incompatible hazardous waste pharmaceuticals to manage the container to prevent dangerous situations, such as fire, explosion, or release of toxic fumes.

CT DEEP requests EPA explain further what is meant by “manage the container to prevent dangerous situations, such as fire explosion or release of toxic fumes.” Instead, CT DEEP asks whether EPA should just prohibit a pharmaceutical reverse distributor from mixing or commingling incompatible hazardous waste pharmaceuticals in the same container.

EPA is proposing that pharmaceutical reverse distributors “...must segregate pharmaceuticals that are prohibited from being combusted because of the dilution prohibition of 40 CFR 268.3(c) and accumulate them in separate containers from other evaluated hazardous waste pharmaceuticals.”

As stated under number 9.e. above for healthcare facilities, CT DEEP is concerned that pharmaceutical reverse distributors may not completely understand what they need to do to be in compliance with 40 CFR 268.3(c).

There are several other accumulation standards which EPA believes are not necessary to include for the management of evaluated hazardous waste pharmaceuticals. First, EPA does not think it is necessary to include accumulation units such as tanks, containment buildings, or drip pads because pharmaceutical reverse distributors do not currently use these types of accumulation units.

CT DEEP agrees with EPA in that containers are primarily used to accumulate and store waste pharmaceuticals at pharmaceutical reverse distributors. If no other types of waste management units are currently used to store waste pharmaceuticals, CT DEEP suggests EPA prohibit other types of accumulation and waste storage units from being used in the future.

v. Hazardous Waste Numbers (Codes)

EPA is proposing to require that the containers of evaluated hazardous waste pharmaceuticals be labeled with the appropriate hazardous waste codes. EPA is further proposing that hazardous waste codes may be placed on the label at any time during on-site accumulation, but the codes must be added prior to transportation off-site.

CT DEEP supports the proposal to require hazardous waste codes be placed on container labels prior to being transported off-site.

vi. Shipping Evaluated Hazardous Waste Pharmaceuticals

EPA explains here that although it is already stated in 40 CFR 266.508(a) under the section of the regulations pertaining to shipping standards (i.e., the applicable DOT packaging, marking and labeling requirements, and the requirement to utilize a hazardous waste manifest when shipping evaluated hazardous waste pharmaceuticals to a designated facility), for clarity, they propose to repeat in 40 CFR 266.510 (the pharmaceutical reverse distributor section of the regulations) the requirement that pharmaceutical reverse distributors who ship evaluated hazardous waste pharmaceuticals off-site are required to do so in accordance with the proposed shipping standards of 40 CFR 266.508(a).

CT DEEP agrees that the cross-reference noted above is appropriate.

vii. Rejected Shipments

EPA "...is proposing to require in [§] 40 CFR 266.510(c)(7) that pharmaceutical reverse distributors meet the same procedures as LQGs must meet for rejected shipments in [§] 40 CFR 262.42(c)." EPA explains that if a designated permitted or interim status TSD identified on a manifest cannot accept a shipment of evaluated hazardous waste pharmaceuticals from a pharmaceutical reverse distributor and the TSD returns the shipment to the pharmaceutical reverse distributor, the pharmaceutical reverse distributor must sign the applicable item on the manifest.

CT DEEP contends that the regulatory citation given at the end of the first sentence of this subsection, 40 CFR 262.42(c), is incorrect and that the correct regulatory citation is 40 CFR 265.72(c).

EPA is also proposing to allow the pharmaceutical reverse distributor to consolidate the rejected hazardous waste pharmaceuticals on-site for up to 90 days provided they are managed in the on-site accumulation area and in accordance with the proposed pharmaceutical reverse distributor standards for evaluated hazardous waste pharmaceuticals.

CT DEEP does not believe, in the case of a rejected shipment, that a pharmaceutical reverse distributor needs another 90 days to re-ship the hazardous waste pharmaceuticals to another designated permitted or interim status TSD. An additional thirty days should be sufficient. CT DEEP also does not deem appropriate for a pharmaceutical reverse distributor be allowed to consolidate a rejected shipment.

viii. Land Disposal Restrictions

First, EPA is proposing that pharmaceutical reverse distributors be subject to the same LDRs that apply to LQGs with respect to their evaluated hazardous waste pharmaceuticals.

CT DEEP agrees that this requirement is appropriate.

Second, EPA is proposing to amend the testing, tracking, and recordkeeping requirements for generators, treaters and disposal facilities at 40 CFR 268.7 to add the words, "pharmaceutical reverse distributors" to the title of that section to make the applicability of the treatment standards clear.

CT DEEP agrees with the above noted language change in the title of 40 CFR 268.7. However, CT DEEP noticed that EPA also added the words "and pharmaceutical reverse distributors" after the phrase "Requirements for generators" in 40 CFR 268.7(a). EPA should note such additional revision under subsection V.G.3.c.viii.

ix. Reporting by a Pharmaceutical Reverse Distributor for Evaluated Hazardous Waste Pharmaceuticals

(1) Biennial Report

EPA is proposing pharmaceutical reverse distributors submit a biennial report for the evaluated hazardous waste pharmaceuticals transported to a TSDF so that EPA may have as complete a picture of the amount of hazardous waste generated, treated, stored, or disposed of annually. However, EPA is proposing that the biennial report only include the evaluated hazardous waste pharmaceuticals, and not the potentially creditable hazardous waste pharmaceuticals that a pharmaceutical reverse distributor sends to another pharmaceutical reverse distributor.

CT DEEP supports the proposed requirement for pharmaceutical reverse distributors to include on their biennial report the information concerning evaluated hazardous waste pharmaceuticals, and not the information concerning potentially creditable hazardous waste pharmaceuticals that a pharmaceutical reverse distributor sends to another pharmaceutical reverse distributor.

(2) Exception Reporting

EPA is proposing pharmaceutical reverse distributors provide an exception report when a TSDF does not return a hazardous waste manifest to the pharmaceutical reverse distributor for a shipment of hazardous waste pharmaceuticals shipped to a designated facility. Likewise, EPA is proposing pharmaceutical reverse distributors meet LQG exception reporting requirements when a shipment from a pharmaceutical reverse distributor is rejected by the designated facility and forwarded onto an alternate facility.

CT DEEP supports both of the proposed exception reporting requirements.

x. Recordkeeping by a Pharmaceutical Reverse Distributor for Evaluated Hazardous Waste Pharmaceuticals

EPA is proposing five recordkeeping requirements pertaining to evaluated hazardous waste pharmaceuticals at pharmaceutical reverse distributors.

- (1) A log (written or electronic) of its weekly inspections of the on-site accumulation area,
- (2) Manifests,
- (3) Biennial Reports,
- (4) Exception reports, and
- (5) Training documentation pursuant to 40 CFR 265.16.

EPA believes that the recordkeeping requirements specified above are appropriate for pharmaceutical reverse distributors since many currently LQGs, but requests comment on this requirement.

CT DEEP considers hazardous waste determination records to be important records needing to be retained at pharmaceutical reverse distributors. It is also important for contingency plans to be kept. Further, there should also be a requirement that pharmaceutical reverse distributors be subject to the additional reporting requirements of 40 CFR 262.43 (i.e., additional reports concerning the quantities and disposition of wastes identified or listed in 40 CFR part 261) or for other waste identified or listed pursuant to this proposed rulemaking.

**f. Section V.G.3.d. Detailed Discussion of Proposed Pharmaceutical Reverse Distributor Standards - When a Pharmaceutical Reverse Distributor Must have a RCRA Hazardous Waste Permit**

EPA is proposing to not require pharmaceutical reverse distributors to have a RCRA permit or interim status for accumulating potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals as long as the pharmaceutical reverse distributor follows all the conditions of specified in new 40 CFR 266.510 Standards for the Management of Potentially Creditable Hazardous Waste Pharmaceuticals and Evaluated Hazardous Waste Pharmaceuticals at Pharmaceutical Reverse Distributors.

CT DEEP requests EPA consider our comments above when performing any redrafting of the proposed rule as they specifically relate to the management of potentially creditable and evaluated hazardous waste pharmaceuticals as pharmaceutical reverse distributors.

EPA is proposing that a pharmaceutical reverse distributor have a RCRA permit (or interim status) if it treats or disposes of hazardous waste on-site or if it accepts manifested hazardous waste from off-site.

CT DEEP supports the proposed requirement for a pharmaceutical reverse distributor have a RCRA permit (or interim status) if it treats or disposes of hazardous waste on-site or if it accepts manifested hazardous waste from off-site.

EPA is also proposing that a pharmaceutical reverse distributor must reject shipments of manifested hazardous waste that it may inadvertently receive from off-site because a pharmaceutical reverse distributor is not a designated facility, and therefore, is not eligible to receive hazardous waste via a manifest.

CT DEEP supports the proposed requirement that a pharmaceutical reverse distributor must reject shipments of manifested hazardous waste received from off-site.

CT DEEP would also like to point out a problem concerning the proposed rule language in proposed 40 CFR 262.10(m) because it has a corresponding relationship here. In the preamble of the proposed rule, EPA states that both creditable and non-creditable pharmaceutical hazardous wastes are regulated as solid wastes from the healthcare facility onward, and that pharmaceutical reverse distributors are, as a result, receiving hazardous waste (in particular, potentially-creditable pharmaceuticals). Under RCRA, any facility that receives hazardous waste from off-site is required to obtain a permit, unless it is specifically exempted from the requirement to have a permit under 40 CFR 264.1(g), 265.1(c), and 270.1(c)(2). Although proposed 40 CFR 262.10(m) appropriately directs pharmaceutical reverse distributors to proposed subpart P, the language of the proposed rule does not include the addition of any exemptions in 40 CFR 264.1(g), 40 CFR 265.1(c), or 40 CFR 270.1(c)(2), as is the case, for example for facilities that receive Universal Wastes from off-site (e.g., see 40 CFR 264.1(g)(11), 40 CFR 265.1(c)(14), and 40 CFR 270.1(c)(2)(viii)).

#### 16. **Section VI.A. Implementation and Enforcement - Healthcare Facilities**

##### a. Determining Whether a Healthcare Facility is Subject to Part 266, Subpart P

CT DEEP found this subsection of the preamble to be confusing, and therefore anticipate that healthcare facilities, especially CESQG healthcare facilities, will not understand whether they continue to fall under 40 CFR 261.5 or are subject to 40 CFR part 266, subpart P. The second paragraph of this section states “EPA is proposing that potentially creditable hazardous waste pharmaceuticals transported to a pharmaceutical reverse distributor will be considered solid waste from the point of generation at the healthcare facility and therefore must be counted when determining whether the healthcare facility is a CESQG regulated under [§] 40 CFR 261.5, or whether it is regulated under 40 CFR part 266, subpart P. This differs from current practice where, although a healthcare facility must count the non-creditable hazardous waste pharmaceuticals it generates each calendar month toward its hazardous waste generator category, it does not count the potentially creditable hazardous waste pharmaceuticals it sends to a pharmaceutical reverse distributor. **Therefore, although a healthcare facility currently may be considered a CESQG, when it begins counting its potentially creditable hazardous waste pharmaceuticals, it may no longer be a CESQG. In that case, the healthcare facility would be subject to the 40 CFR part 266, subpart P requirements.”**

First, CT DEEP understands that under the proposed rules, if a generator is determining their generator status with respect to compliance with generator requirements for regular hazardous waste (e.g., 40 CFR 261.5 for CESQGs and 40 CFR 262.34 for SQGs and LQGs), they would not count their pharmaceutical hazardous waste. Second, proposed 40 CFR 262.10(n) requires each healthcare facility to determine if they are subject to 40 CFR part 266, subpart P based on the total hazardous waste it generates per calendar month, including pharmaceutical hazardous waste and non-pharmaceutical hazardous waste. Furthermore, proposed 40 CFR 262.10(n) states that healthcare facilities that generate or accumulate more than the following amounts of combined hazardous waste are subject to 40 CFR part 266, subpart P with respect to the management of their hazardous waste pharmaceuticals:

- \* 100 kg per calendar month of hazardous waste per calendar month; or,
- \* 1 kg per calendar month of acute hazardous waste; or,

- \* 100 kg per calendar month of cleanup debris resulting from the spill of acute hazardous waste.

Therefore, CT DEEP suggests that the two bolded sentences above be annotated to read as follows:

***“Therefore, although a healthcare facility currently may be considered a CESQG because current EPA policy does not require it to count potentially creditable hazardous pharmaceuticals towards its generator status, when it begins counting its potentially creditable hazardous waste pharmaceuticals as required by proposed 40 CFR 262.10(n), it may no longer be under the monthly generation limits of a CESQG. In that case, the healthcare facility would be subject to the 40 CFR part 266, subpart P requirements.”***

It is not clear to CT DEEP in reading the proposed rule whether the applicability of new subpart P was based on the generation of greater than CESQG amounts of both regular and pharmaceutical hazardous waste. CT DEEP had concluded that the applicability of new subpart P was based solely on the generation of pharmaceutical hazardous waste. If that is not the case, some healthcare facilities could be pulled into proposed subpart P for generating very small amounts of pharmaceutical hazardous waste, if the facility generates enough “regular” hazardous waste to push the total over CESQG amounts. For example, if a health care facility generates 100 kg of regular hazardous waste plus pharmaceutical hazardous waste consisting of just a single discarded Coumadin pill, the healthcare facility could be subject to proposed subpart P for that one Coumadin pill. While CT DEEP thinks that it would be very uncommon for healthcare facilities to have situations this extreme, an example like this does make this aspect of the rule seem rather illogical. Therefore, CT DEEP recommends that applicability of proposed 40 CFR part 266, subpart P be based solely on the generation of pharmaceutical hazardous waste, and that it should not include “regular” hazardous waste.

CT DEEP finds that there may be a complication with respect to the language of proposed 40 CFR 261.5(c)(8). Specifically, this is the language that would add “hazardous waste pharmaceuticals managed under 40 CFR part 266, subpart P” to the list of wastes that do not need to be counted when determining generator status. CT DEEP thinks that the problem has to do with the phrase “managed under 40 CFR part 266, subpart P.” While this phrase makes sense with respect to the determination of generator status for a generator that does not generate hazardous waste pharmaceuticals, it raises some questions regarding generators that do generate hazardous waste pharmaceuticals. In particular, what is the meaning of this phrase if the hazardous waste pharmaceuticals are not managed under 40 CFR part 266, subpart P (e.g., due to non-compliance with that subpart)? Does that mean that the hazardous waste pharmaceuticals would now have to be counted for determining hazardous waste generator status? Also, how should this phrase be interpreted with respect to healthcare facilities that meet the criteria as CESQGs, as set forth in proposed 40 CFR 262.10(n)? Would a CESQG healthcare facility’s hazardous waste pharmaceuticals be considered to be “managed under 40 CFR part 266, subpart P” or not?

CT DEEP would also like to point out that there is an inconsistency in the language of the proposed rule with respect to CESQGs as defined by proposed 40 CFR 262.10(n). Specifically, proposed 40 CFR 262.10(n) states that healthcare facilities that generate greater than CESQG amounts of both regular and pharmaceutical hazardous waste are subject to proposed 40 CFR part 266, subpart P. This language is silent with respect to healthcare facilities that do not generate more than CESQG amounts of both regular and pharmaceutical

hazardous waste. CT DEEP believes that the only reasonable way to read proposed 40 CFR 262.10(n) is that such healthcare facilities are not subject to proposed 40 CFR part 266, subpart P. However, proposed 40 CFR 266.501(a) specifically addresses healthcare facilities that are CESQGs and requires them to comply with proposed 40 CFR 266.504 (regarding healthcare facilities that are CESQGs), 40 CFR 266.505 (regarding the prohibition on sewerage), and 40 CFR 266.507(a) and (b) (regarding the management of containers and syringes). CT DEEP does not understand how a CESQG healthcare facility would ever think to look at the provisions of proposed 40 CFR 266.501(a) if proposed 40 CFR 262.10(n) implies that they are exempt from all of proposed 40 CFR part 266, subpart P? As a result of this problem, CT DEEP thinks that EPA should either:

- \* Add a sentence to the end of proposed 40 CFR 262.10(n) which reads “Healthcare facilities that do not generate more than the amounts specified above are not subject to 40 CFR part 266, subpart P except as specified in 40 CFR 266.501(a)”; or
- \* Indicate in proposed 40 CFR 262.10(n) that all healthcare facilities are subject to proposed 40 CFR part 266, subpart P, and move the special “counting” requirements for hazardous waste pharmaceutical CESQGs in proposed 40 CFR 262.10(n) into proposed subpart P so that all healthcare facilities will have to go to proposed subpart P, figure out whether or not they are a “CESQG” under subpart P and determine if they are subject to all of subpart P, or just the sections specified in proposed 40 CFR 266.501(a) for CESQGs.

b. Healthcare Facilities Managing Hazardous Waste Pharmaceuticals under Part 266, Subpart P

Under the proposed rule, all healthcare facilities, with the exception of CESQGs, will be subject to the same regulations for the management of their hazardous waste pharmaceuticals, regardless of the quantity of hazardous waste pharmaceuticals generated.

CT DEEP agrees with that this requirement is appropriate.

**17. Section VI.B. Implementation and Enforcement – Pharmaceutical Reverse Distributors**

a. Pharmaceuticals Sent to Pharmaceutical Reverse Distributors are Solid Wastes

Under this subsection, EPA restates that the decision by a healthcare facility to send a pharmaceutical to a pharmaceutical reverse distributor is the decision to discard the pharmaceutical. Therefore, once the healthcare facility makes the decision to send a pharmaceutical to a pharmaceutical reverse distributor for credit, it is a solid waste at the healthcare facility.

CT DEEP requests EPA refer back to our comments under number 10.a. above.

b. Pharmaceutical Reverse Distributors Managing Hazardous Waste Pharmaceuticals under 40 CFR Part 266, Subpart P

EPA’s proposal pursuant to this subsection is that all pharmaceutical reverse distributors will be subject to 40 CFR part 266, subpart P, regardless of the amount of hazardous waste pharmaceuticals they manage.

CT DEEP supports this proposal.

18. **Section VI.C. Implementation and Enforcement - Healthcare Facilities and Pharmaceutical Reverse Distributors Managing Non-pharmaceutical Hazardous Waste in Accordance with 40 CFR Part 262 or Part 273**

EPA discusses a few important items under this section. EPA reminds us that most, if not all, healthcare facilities and pharmaceutical reverse distributors generate hazardous wastes other than pharmaceuticals, and that these non-pharmaceutical hazardous wastes are regulated under 40 CFR part 262 (and other applicable Subtitle C regulations). However, EPA clarifies that because a healthcare facility or pharmaceutical reverse distributor operating under 40 CFR part 266, subpart P no longer has to count its hazardous waste pharmaceuticals, including acute hazardous waste pharmaceuticals, there could be a change in a facility's generator category resulting in how the non-pharmaceutical hazardous waste must be managed.

CT DEEP feels that it is positive for EPA to reinforce the management standards for non-pharmaceutical hazardous wastes.

Similarly, retail stores and grocery stores are likely to have hazardous wastes that must be managed in accordance with RCRA Subtitle C requirements. In addition, they certainly have items which they return to a reverse distributor. On February 14, 2014, EPA published in the Federal Register under Docket ID No. EPA-HQ-RCRA-2012-0426 a Notice of Data Availability (NODA) and Request for Comment entitled "Hazardous Waste Management and the Retail Sector: Providing and Seeking Information on Practices to Enhance Effectiveness to the Resource Conservation and Recovery Act Program".

CT DEEP submitted comments on the NODA dated May 30, 2014 and hopes to see a proposed rule in the near future. CT DEEP deems that the decision to send a retail item to a reverse distributor is the point at which a decision has been made to discard the item.

19. **Section VI.D. Implementation and Enforcement - State Enforcement Activities and Interpretations**

CT DEEP would like to thank EPA for acknowledging in this section of the preamble the enforcement work that Connecticut accomplished against a major retailer doing business in the State of Connecticut, and especially the fact that EPA, in the proposed rule, has mirrored some of the practices required by the consent orders that were negotiated in Connecticut.

20. **Section VII. Request for Comment on EPA's Efforts to Identify Additional Pharmaceutical Hazardous Wastes**

CT DEEP is disappointed that EPA did not put forward any additional pharmaceuticals to those already listed pursuant to RCRA Subtitle C regulations as part of this proposed rulemaking. EPA explains in this section that in response to comments on the 2008 Universal Waste proposal, they began gathering and reviewing information related to pharmaceuticals that may exhibit hazardous properties. EPA identified 204 drugs, which included 172 drugs that the National Institute for Occupational Safety and Health (NIOSH) and the Occupational Safety and

Health Administration (OSHA) identified as hazardous, and 32 drugs that NIOSH proposed to add to its hazardous drug list. According to EPA, they also collected toxicity data and other information for these 204 drugs. EPA points out that these findings, along with additional information regarding the management of pharmaceutical wastes, are presented in the final report entitled *Data Collection on the Toxicity, Use, and Disposal of Hazardous Drugs Report (September 2011)*. Eleven drugs on the NIOSH or OSHA lists of hazardous drugs met the specific criteria for acute toxicity, 114 drugs had lethal doses for other animals or humans, and 79 drugs had limited human or animal toxicity data. Based on the work that NIOSH and OSHA has done to support their listings, CT DEEP believes that EPA could follow suit.

EPA asks if they should 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.

CT DEEP thinks that EPA should not only look at acute toxicity, but should also consider chronic toxicity. For instance, EPA could consider criteria similar to what is found in 40 CFR 261.11(a)(3)(ix) and (xi). Specifically, EPA could consider the nature and severity of the human health and environmental damage that has occurred as a result of the improper management of the wastes and/or such other factors as may be appropriate. CT DEEP therefore presumes that EPA could introduce a new K code for all chemotherapy agents, mutagens, carcinogens, and endocrine disruptors.

Finally, CT DEEP requests EPA to refer back to the Northeast Waste Management Officials' Association's (NEWMOA's) February 21, 2012 letter to Suzanne Rudzinski, Director, Office of Resource Conservation and Recovery. The letter was follow-up to a July 25, 2011 NEWMOA-sponsored conference call to discuss RCRA pharmaceutical waste management. In the referenced letter NEWMOA stated

“...EPA was ‘missing the forest for the trees’ with respect to the regulation of pharmaceutical waste. Increasing amounts of pharmaceuticals are being prescribed, dispensed, or purchased over the counter, resulting in a growing amount of unused, expired, and /or waste pharmaceuticals requiring proper disposal. Meanwhile, in recent years, pharmaceutical compounds have been detected in drinking water supplies and in landfill leachate. The participating NEWMOA members believe that these issues cannot be adequately addressed through a rule that applies only to the handful of pharmaceutical wastes that are currently RCRA-regulated. ... We believe that a lengthy rulemaking effort focused on regulating pharmaceutical wastes under RCRA Subtitle C only addresses the ‘tip of the iceberg’ and would do little to enhance environmental protection.” The NEWMOA letter referenced and quoted herein concluded by stating “...the portion of the pharmaceutical waste stream that is currently regulated under RCRA Subtitle C is very small compared to the overall universe of waste pharmaceuticals. Given that both state and federal hazardous waste programs are facing significant resource constraints, we believe that we must keep state RCRA programs focused on the most critical hazardous waste management issues. We recommend that EPA’s approach should be to re-examine and clarify which waste pharmaceuticals should be subject to full RCRA regulation and then with other federal agencies develop a holistic approach to the safe management of the remaining majority of waste pharmaceuticals outside of the RCRA regulatory system. We believe that federal establishment of streamlined but concise standards for the management of all pharmaceutical wastes would improve environmental protection and public safety.”

21. **Section VIII.C. Request for Comment on EPA's Efforts to Amend the Acute Hazardous Waste Listing for Nicotine and Salts (Hazardous Waste No. P075) - Rationale for EPA's Efforts to Amend the P075 Listing**

As noted previously, EPA issued a NODA and Request for Comment on February 14, 2014. According to EPA, the most detailed comments concerning unsold low-concentration nicotine products were submitted jointly by the Retail Industry Leaders Association (RILA), the Food Marketing Institute (FMI), the National Association of Chain Drug Stores (NACDS), the National Retail Federation, and their members. The retail associations asked EPA to remove low-concentration nicotine products from the acute hazardous waste listing since they believed these products do not meet RCRA's requirements for acute hazardous waste and "...is inappropriately making them subject to RCRA's LQG requirements."

To defend their position, they "...state that EPA's listing for nicotine and salts warrants a reevaluation, because in more recent literature concerning nicotine toxicity, doubts have been expressed about the estimated oral LD50 toxicity to humans of 1 mg/kg, used as a key basis for the listing." Further, according to the commenters, "...the estimated oral LD50 toxicity to humans of 1 mg/kg was based on extrapolations from toxicological effects observed as result of 'self-experiments' performed with nonfatal doses of nicotine." In addition, "...there are doubts about the 1 mg/kg estimate because people have survived after ingesting much larger amounts of nicotine." Moreover, the commenters state that "in 1980, when EPA listed nicotine and salts as acute hazardous wastes, the nicotine products in the market contained a high concentration of the chemical (e.g., pesticides which contained 40 percent nicotine sulfate), but that these products are no longer on the market" and "... the current nicotine products on the market are low-concentration nicotine products that do not meet the regulatory criteria for acutely hazardous wastes." These products were identified as nicotine replacement therapy (NRT) products (e.g., gums, lozenges, patches, inhalers, and nasal sprays) and e-cigarettes. According to the retail associations, these products generally contain less than 3 percent nicotine.

EPA maintains

"While it may be reasonable for the commenters to conclude that toxicity is higher at higher concentrations of a chemical and lower at lower concentrations of a chemical, EPA currently lacks sufficient information to conclude that low-concentration nicotine-containing products are not acutely toxic as defined under 40 CFR 261.11(a)(2). In addition, except for warfarin and zinc phosphide, the listings for commercial chemical products under 40 CFR 261.33(e) are not concentration-based listings. The warfarin and zinc phosphide listings were changed to concentration-based listings because companies using products containing lower concentration formulations of warfarin and zinc phosphide petitioned EPA to amend the listings and provided LD50 data for animals for the lower concentration products to support their petition (see 49 FR 19922; May 10, 1984). The Agency does not think that linear extrapolations from toxicity levels determined using higher-concentration nicotine products can be used to characterize the acute toxicity of low-concentration nicotine-containing products. Furthermore, although nicotine pesticides are no longer available, high concentration nicotine products still exist. For example, manufacturers of nicotine-containing products, such as e-cigarettes, buy concentrated nicotine solutions and dilute them for consumer use."

CT DEEP supports EPA's conclusion that they lack sufficient information to conclude that low-concentration nicotine-containing products are not acutely toxic as defined under 40 CFR 261.11(a)(2). CT DEEP has noted that

the retail associations are professing that they have a very large stake in the outcome of EPA's decision. However, under the proposed rule, retail stores are considered healthcare facilities and would no longer be considered an LQG if the disposal of nicotine replacement therapy products are the only thing causing them to be an LQG.

**22. Section VIII.D. Request for Comment on EPA's Efforts to Amend the Acute Hazardous Waste Listing for Nicotine and Salts (Hazardous Waste No. P075) - Two Possible Approaches for Amending the P075 Listing**

a. Exemption from P075 Listing for FDA-Approved Over-the-Counter Nicotine-Containing Smoking Cessation Products

Nicotine replacement therapy (NRT) products are approved by the Food and Drug Administration (FDA), which ensures that with proper use and handling, the risk to the public using these products have been evaluated. The preamble explains that EPA is trying to obtain the risk evaluation data for these products from FDA in the hopes that they may provide data on the exact concentration of nicotine in the NRT products and any animal and/or human toxicity data associated with use of these products. The preamble also states that EPA is trying to gather any publicly available animal and/or human toxicity data for these products, in particular toxicity data that could be compared to the acute toxicity criteria pursuant to 40 CFR 261.11(a)(2). According to EPA, if they are able to obtain the toxicity data to support the conclusion that FDA-approved NRT products do not meet the criteria for listing as an acutely hazardous waste, then they will propose to exempt these products from the P075 listing.

CT DEEP supports exempting NRT products from the P075 listing provided EPA obtains the necessary FDA toxicity data.

This section of the preamble also discusses e-cigarettes. The FDA has not approved e-cigarettes as smoking cessation products. Therefore, EPA does not anticipate receiving animal or human toxicity data from the FDA on nicotine concentrations in e-cigarettes. EPA also indicates that the concentration of nicotine in e-cigarettes is unpredictable. As a result, the proposed exemption will not include e-cigarettes.

CT DEEP does not support including e-cigarettes in any exemption from the P075 listing. However, CT DEEP would like EPA to clarify that flavorings contained in e-cigarettes are not considered active ingredients.

b. Concentration-Based Exemption from P075 Listing for Low-Concentration Nicotine-Containing Products

EPA reiterates here that the comments from the retail associations have stressed that low concentration nicotine products generally contain less than 3 % nicotine. EPA explains that if the toxicological data for NRT products at maximum concentrations of nicotine show that such products are not acutely toxic, then they could propose a concentration-based exemption for these products (including e-cigarettes) from the P075 listing. However, EPA further explains that depending on the toxicity data, they could alternatively propose to list the P075 exempt NRT products as non-acute hazardous wastes (U-listed wastes) under 40 CFR 261.33(f). The latter approach would be similar to what EPA proposed for warfarin and zinc phosphide listings.

CT DEEP would support a proposal for a concentration-based exemption for NRT products, not including e-cigarettes, similar to what was proposed for warfarin and zinc phosphide if the toxicological data show that NRT products are not acutely toxic.

**23. Section VIII.E. Request for Comment on EPA’s Efforts to Amend the Acute Hazardous Waste Listing for Nicotine and Salts (Hazardous Waste No. P075) - Request for Comments**

EPA maintains here that depending on the information received during the comment period concerning nicotine, EPA could finalize in the future one of the approaches discussed above without a separate proposed rulemaking.

EPA requests comments under this section as to whether they should exempt FDA-approved inhalers and nasal sprays from the P075 listing since they require a prescription to purchase.

CT DEEP does not support exempting inhalers and nasal sprays since they require a prescription.

Finally, with respect to nicotine, EPA requests comment on whether they should include e-cigarettes and nicotine-containing e-liquids within the scope of the definition of pharmaceutical.

CT DEEP is ambivalent at this time whether EPA should include e-cigarettes and nicotine-containing e-liquids within the scope of the definition of pharmaceutical. On the one hand, CT DEEP agrees with EPA that high concentration nicotine products still exist. As EPA states, “ manufacturers of nicotine-containing products, such as e-cigarettes, buy concentrated nicotine solutions and dilute them for consumer use” and the concentration of nicotine in e-cigarettes is not limited by any regulation or approval process and is therefore unpredictable. However, e-cigarettes are sold at places that are not ordinarily thought of as a healthcare facility (e.g., the gas station “quick mart” or corner bodega). Therefore, these facilities would not only have to be aware of the one kilogram acute hazardous waste storage limit, but have an understanding of RCRA Subtitle C regulations.

**24. Section IX.B. State Authorization - Effect on State Authorization**

The proposed rule is being proposed in part under the authority of the Hazardous and Solid Waste Amendments of 1984 (HSWA) and in part under non-HSWA authority. The bulk of 40 CFR part 266, subpart P is being proposed under non-HSWA authority. However, the prohibition of sewerage pharmaceutical hazardous wastes is being proposed under HSWA. Therefore, the amendments promulgated under the authority of HSWA would be applicable on the effective date of the final rule in all states. In addition, this proposed rule is considered, on the whole, to be more stringent than the current federal standards resulting in authorized states being required to modify their programs to adopt the amendments when finalized.

CT DEEP is encouraged that the sewer ban is being proposed under HSWA authority and will go into effect upon promulgation.

EPA has identified the proposed rule as being more stringent than existing RCRA Subtitle C regulatory requirements.

CT DEEP disagrees with EPA's conclusion that the proposed rule is more stringent than existing RCRA Subtitle C regulatory requirements. However, with the EPA conclusion that the proposed rule is more stringent, CT DEEP recommends, consistent with HSWA, that this re-interpretation should be made effective on the date the rule is finalized rather than after authorized states have amended their hazardous waste management regulations.

25. **Section IX.C. State Authorization - Effect on State Authorization in States that Have Added Pharmaceuticals to the Universal Waste Program**

The last sentence of this section announces “...states may not add hazardous waste pharmaceuticals to their Universal Waste program in the future.”

CT DEEP was extremely disappointed to see that EPA included a provision in the proposed rule (specifically new 40 CFR 273.80(d)) that would prohibit any state from adding pharmaceutical hazardous waste as a new category of state Universal Waste. As EPA knows, CT DEEP has been involved in a multi-year effort to make just such a change to its Universal Waste regulations. CT DEEP believes that this move on EPA's part is unprecedented and questions EPA's authority to do so. CT DEEP is not aware of any instance in which EPA has indicated that any particular waste was categorically prohibited for consideration as a state Universal Waste. For EPA to go even further and specifically codify such a prohibition is even more unprecedented – no other such prohibition exists anywhere else in 40 CFR 273.80, the remainder of the Universal Waste Rule, or 40 CFR 260.20 or 40 CFR 260.23. CT DEEP questions EPA's authority to prohibit any state from adding pharmaceutical hazardous waste as a new category of state Universal Waste, and therefore requests EPA to explain such authority.

CT DEEP notes that EPA's intent as expressed in the May 11, 1995 Final Rule Preamble for the Universal Waste Rule was for states to have a great deal of latitude in adopting new categories of Universal Waste. In particular, on Page 25512 of the Final Rule Preamble (Column II, middle), EPA noted that:

“States may apply for and be granted authorization to implement any part of today's amendments to the hazardous waste regulations. This includes the petition process for inclusion of additional wastes in the universal waste program. Thus, in States authorized for the universal waste regulations and the petition process, petitions may be submitted to the State agency to regulate management of a waste or waste category under the universal waste regulations within that State. The State agency would then grant or deny petitions, using the criteria established for evaluating waste streams for inclusion in the program. If a petition is granted, the waste would be managed under the streamlined universal waste requirements within that state.”

Similarly, beginning on Page 25537 of the Final Rule Preamble (Column I, top), EPA states the following, under Section V.D.1., entitled “Addition of New Universal Wastes to State Programs”:

“The Agency notes that States, if they so choose, may seek authorization for the portions of 40 CFR 260.20 that address petitions to add new universal wastes, and for 40 CFR 260.23 and subpart G of part 273, which address the petition process and include the factors to be used to evaluate petitions.”

and

“States authorized for the petition process would use evaluation factors analogous to those in 40 CFR 273.81 to review petitions and make decisions as to whether to add hazardous wastes to the State universal waste regulations. Management standards for these wastes would also be developed by the State using the criteria in subpart G of part 273. The individual wastes and management standards would not be subject to the authorization revision provisions in 40 CFR 271.21, since the State would already be authorized for the universal waste regulations and the regulation of hazardous wastes.”

and

“It should be noted that States are not required to apply for or obtain authorization to receive and review petitions to add new wastes. If they so choose, States may apply for and obtain authorization to implement the part 273 universal waste regulations other than subpart G. These States would still have the ability to adopt wastes that EPA adds to its universal waste program.”

[emphasis added]

CT DEEP believes that EPA’s proposal to prohibit state adoption of a Universal Waste category for pharmaceuticals is inconsistent with EPA’s intent with respect to state adoption of Universal Waste categories, as expressed in the above excerpts from the 1995 Universal Waste Final Rule.

## 26. **Section X. Adding and Reserving Part 266, Subpart O**

EPA is proposing to add and reserve 40 CFR part 266, subpart O. On May 22, 2001, EPA finalized a Project XL rule in 40 CFR part 266, subpart O (66 FR 28066) for US Filter Recovery Services. However, on July 2, 2008, EPA published a rule that withdrew 40 CFR part 266, subpart O (73 FR 37858). EPA explains that “...in order to avoid the potential for confusion that might be caused by reusing a subpart, EPA reserves a subpart that has already been used and removed. In 2008, when we removed 40 CFR part 266, subpart O, we neglected to reserve it. Consequently, we are proposing to add and reserve 40 CFR part 266, subpart O.”

To be clear, CT DEEP concludes that EPA is adding more confusion than they are preventing. EPA should not add and reserve 40 CFR Part 266, Subpart O.

## 27. **Suggested corrections, language revision, comments and questions**

CT DEEP requests EPA review and consider the suggested corrections, language revision, comments and questions included in balloons on Attachment A. These corrections, language revisions, comments and questions have not otherwise been discussed in CT DEEP’s comments above.

**28. Epinephrine and epinephrine salts**

EPA issued a policy memo on October 15, 2007 which stated that epinephrine salts are not covered by the P042 definition. In CT DEEP's comment letter to EPA dated March 4, 2009 in response to the December 2, 2008 proposed rule entitled "Amendment to the Universal Waste Rule: Addition of Pharmaceuticals (Docket ID No. EPA-HQ-RCRA-2007-0932), CT DEEP noted that we believed that EPA should not maintain this policy, but instead modify the P042 definition to cover both base epinephrine and epinephrine salts since the salts are more water-soluble and therefore more amenable to absorption by the human body than base epinephrine. Further, the available toxicology data on common epinephrine salts such as epinephrine hydrochloride and epinephrine bitartrate show that epinephrine salts are of comparable toxicity and in some cases more toxic than base epinephrine. As in 2009, CT DEEP continues to believe that EPA should revise the P042 definition to include epinephrine salts.

Although this would increase the amount of hazardous waste pharmaceuticals generated by healthcare facilities, CT DEEP believes that it is justified by the need to ensure that the pharmaceuticals are properly managed. Furthermore, the concern that generators of hazardous waste pharmaceuticals had when EPA established its 2007 interpretation regarding the potential for epinephrine salts to make them subject to LQG requirements would no longer be an issue under the proposed rule. Epinephrine salts would be just another hazardous waste pharmaceutical subject to this rule, and would not affect the requirements that applied to them.

This concludes CTDEEP's comments on the Proposed Rule. Please contact Michele DiNoia of my staff if you should have any questions on the foregoing. Ms. DiNoia may be reached by phone at (860) 424-3816, or by email at [michele.dinoia@ct.gov](mailto:michele.dinoia@ct.gov).

Sincerely,

Michael Sullivan  
Deputy Commissioner

Enclosure: Attachment A – CT DEEP Proposed Rule Language Changes, Comments, and Questions

cc: Terri Goldberg, NEWMOA