December 19, 2016

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SUBMITTED VIA EMAIL: hwtrrulemaking@ecy.wa.gov

To Whom It May Concern:

Stericycle, Inc. (Stericycle) appreciates the opportunity to comment on the Department of Ecology's (Ecology) proposed rule: Draft Amendments to the Dangerous Waste Regulations, Chapter 173-303 WAC, September 2016. Stericycle is a publically traded corporation (NASDAQ: SRCL) based in Lake Forest, Illinois. In 2015, we had estimated revenues of approximately $3.5B. We operate over 250 medical and hazardous waste facilities for customers throughout the U.S. primarily in the healthcare field. Our services include compliant collection, transportation and treatment of medical waste, collection/disposal of pharmaceutical waste and hazardous waste, management of pharmaceutical and medical device recalls and returns for major drug and device manufacturers, and consulting/training programs to help educate our customers on the proper handling of these regulated waste streams. Our corporate vision is to be leaders in "Protecting People and Reducing Risk."

Stericycle is also an active member of the Healthcare Waste Institute (HWI), a division of the National Waste and Recycling Association. As part of our membership activities, we have reviewed the HWI written comments that are being submitted and fully endorse those comments as well.

Stericycle appreciates the efforts of Ecology to proactively provide draft amendments to the Washington Administrative Code (WAC) in preparation of the changes anticipated by the Federal Environmental Protection Agency (EPA). This type of stakeholder participation and preparation helps industry members understand and have better input into the regulatory process. Stericycle has conducted an in depth analysis of the proposed rule. Additionally, Stericycle has submitted comments to the Federal EPA Management Standards for Hazardous Waste Pharmaceuticals; Proposed Rule (40 CFR Parts 261, 262, 266, *et al.*; September 25, 2015; 80 Federal Register No. 186) and its companion rule "Hazardous Waste Generator Improvements" (September 25, 2015; 80 Federal Register No. 186 which has since been finalized). We are providing a copy of the submittal for your convenience as many of the comments made in the EPA Pharmaceutical proposed submittal are relevant to the modifications proposed to the WAC under these proposals.

In addition to our section by section review of the Federal EPA proposed regulations submittal in ATTACHMENT A, outlined below is a summary of main points that are different than the Federal proposed rule or those proposed by Ecology we would like to further emphasize.

WA Ecology Draft Amendments
WAC 173-303
December 19, 2016
Stericycle, Inc.

MEDICAL WASTE SHARPS AND HAZARDOUS WASTE PHARMACEUTICALS

Stericycle has extensive experience with regulated medical and sharps wastes throughout the country. We provide services to generators of sharps, both collecting them in conjunction with pharmaceuticals and without. Below outlines in further detail our response as it relates to proper management of sharps with pharmaceutical residue:

- Ecology in its proposed rule goes beyond the proposed Federal EPA proposed rule by stating that any residue remaining in the syringe must still be considered a dangerous or hazardous waste. And that in order for the syringe to be considered a true sharp that it must be fully depressed. It is important to note, in many cases, it is not possible to identify the residue that remains in the syringe, within the sharps containers. Additionally, once the sharp is placed into the sharps container, there is no feasible way for the generator or the waste handling facility to safely retrieve this material. Needless to say, this inability to identify the material can present enforcement challenges and confusion and legal debate between the generator and medical waste treatment facilities as well as regulatory agencies, for a very nominal quantity of waste.
- As it relates to the safety for healthcare providers, Stericycle believes it is critical to exempt these materials so that healthcare providers are able to avoid sharps injuries and ensure compliance with Occupational Safety and Health Administration's (OSHA) Bloodborne Pathogen Standard (BBP) 29 CFR 1910.1030. OSHA BBP regulations state that sharps containers must be easily accessible to personnel. As identified in the OSHA Fact Sheet "Protecting Yourself When Handling Contaminated Sharps" https://osha.gov/OshDoc/data_BloodborneFacts/bbfact02.html , the following is stated: "*Prompt Disposal: Employers must also ensure that contaminated sharps are disposed of in sharps disposal containers immediately or as soon as feasible after use. Sharps disposal containers must be readily accessible and located as close as feasible to the area where sharps will be used. In some cases, they may be placed on carts to prevent patients, such as psychiatric patients or children, from accessing the sharps. Containers also must be available wherever sharps may be found, such as in laundries."* Stericycle concludes that by having these materials managed as sharps in the regulated medical waste stream, there is a reduction in potential risk to healthcare and waste workers throughout the waste handling process.
- Department of Transportation (DOT) regulations state that regulated medical waste division 6.2 is typically more dangerous than other types of hazardous materials (49 CFR 173.2a(c)(3)). Thus the waste is managed as a regulated medical waste, 6.2, under the DOT regulations. The waste is appropriately classified for the hazard associated with sharps and is protective of waste handling employees and emergency responders. This also helps to eliminate potential misinterpretation of regulatory regimes.
- Stericycle has an extensive list of pharmaceutical NDCs that it has evaluated (approximately 80,000 validated FDA NDCs) and of the total amount, approximately 2000 are injectable and of that there is only a small percentage that is considered hazardous. We estimate, based on the materials identified in our database, that currently only 0.13% of the 80,000 are hazardous injectable materials. This issue of determining the proper management of these small amounts of pharmaceuticals being included in the sharps has been a great source of confusion.

In our experience, this issue has created a lot of confusion, misinterpretation and risk. Based on the information presented, we believe that the risks to eliminate potentially small amounts of hazardous waste pharmaceuticals from the environment is outweighed by the potential safety risk to healthcare and waste workers. Stericycle would be strongly against a State provision that exempts only fully depressed syringes and would rather see that there be an exemption for syringes with residue, regardless of the amount of material remaining within the syringe. This corresponds to what has been proposed by EPA.

FIRST TIME NO CREDIT IS GIVEN

Ecology has taken a more stringent position for "creditable waste". Under Ecology's proposed definition the "creditable dangerous waste pharmaceuticals are limited to one year past the expiration of the product and that after the first time the material does not receive credit it is no longer eligible without additional documentation. It is recommended that there not be a specific expiration date or time limit of products because these will be dependent on the manufacturer's crediting policies, which change regularly. With regard to the first time credit is not given, that circumstance could be due to issues other than just the credit being issued for that product. It could be a particular lot or other damage discovered or other issues. Claiming the first time credit is not issued is the end of the pharmaceutical being eligible for credit is unreasonable and will create undue burden and hardship on all the entities involved in the process. Again, both the amount of time and when the credit is provided is different between healthcare facilities and are negotiated between these facilities and their wholesalers/distributors or directly with the pharmaceutical manufacturers. This means there will be several different circumstances that would be limited by these proposed rules.

SQG: FACILITY MANAGEMENT AND CONSOLIDATION OPTIONS

Stericycle comments on this same issue for the Federal EPA proposed rule. There are many entities which will not fall under these new regulations as they are a Small Quantity Generator (SQG under WAC 173-303-070). However, it will be very important to ensure that there is clear communication to this community of generators as to what their responsibilities will be. Many SQGs in the healthcare industry (including retail and convenience stores etc. that may have over the counter drugs) may not realize that there will be a new set of regulations. We encourage Ecology to have a strong outreach program. Below is a summary of our detailed comments, (also see ATTACHMENT A) based on our interactions with customers who fall under this SQG category.

- Ecology should clarify that the determination of the generator type should be identified before applying this section. This will provide a more accurate account for the generator of what type of generator they are. This will be important for the new generator group of Long Term Care Facilities (LTCF) who may not have counted this waste stream before. This will also be critical for retail pharmacies and smaller hospitals.
- Ecology should clarify that true SQGs (generators that were in SQG status before applying the rule to their status and not counting the waste generated against their generator status) must still adhere to the regulations under WAC 173-303-070 (8) if they chose not to fully utilize this

new rule. As a provider of compliance services and training, this becomes very complicated when SQGs look for support in complying with both sets of regulations.

- Consolidation of non-creditable pharmaceutical wastes at a consolidation location could have its advantages for the SQG, however it presents challenges to the receiving facility. The Ecology states that the SQG does not have to mark the material with what is inside and they are not required to manifest it or provide any shipping description information or follow any specific packaging requirements, yet the receiving facility must maintain records of the shipment. What would the receiving facility keep record of?
- Many of the issues stated above would be equally true of potentially creditable waste being shipped to a reverse distributor. There needs to be minimum requirements set so that the receiving facility understands and can track material that is intended to be shipped as creditable hazardous waste to a potential reverse distributor. This would mean that the receiving facility would need to identify that material and track it through the system somehow. It is not clear how the receiving facility is to manage that material and how the originating SQG would be identified as the facility to receive the credit value or receive rejection notifications, etc. and who would be the regulated entity if there were an issue with the shipment? For these reasons we do not believe that consolidation of potentially creditable pharmaceuticals should be adopted into the rule.
- Consolidation of pharmaceuticals could occur across state lines which may have differing requirements for SQGs. We have experienced this problem under the current regulatory regime and it has been very confusing and frustrating for the generator, transporter and regulator. Should the waste be generated in Washington State and sent to another state this could create potential regulatory issues.

Stericycle recommends that there be some minimum standards set for the proper tracking and shipment of pharmaceuticals (either for consolidation, waste destruction or reverse distribution) for SQGs. Stericycle recommends that the Ecology take the opportunity to clearly state what is required for SQGs and what they can or cannot do if they chose not to manage their wastes under this rule.

MANAGEMENT OF DANGEROUS WASTE PHARMACEUTICAL RESIDUES IN CONTAINERS

The issue of the management of pharmaceutical containers and the residues was a very difficult issue. Both within the Ecology and EPA proposed rule there was a requirement for the management of the containers themselves and residue remaining. One main issue is the destruction of containers prior to disposal. It is not realistic for the generator to "destroy" the containers prior to placing them in the trash. However, defacing or covering the markings on the containers would be less invasive and perhaps more realistic. Destroying containers could expose workers to additional hazards from trace residues becoming airborne or through direct contact, containers being sharp and injuring workers. We suggest including an exemption for the containers and revising the packaging destruction requirements so that workers are not exposed.

Further, it is not clear what problem this destruction requirement purports to solve. Is it Ecology's concern that there would be misuse of these containers after discarded; counterfeiting or diversion? As written, this requirement will create numerous problems and add significant costs for managing and processing these containers. The risks that Ecology is trying to mitigate will be out of proportion to the risks and expense created. Lastly, we believe addressing these risks is beyond Ecology's jurisdiction and charge, to require container destruction.

Additionally, we strongly recommend that Ecology retain the current definition of "empty" for U-listed or WA Dangerous chemotherapy drugs with respect to IV bags and tubing. Currently, the majority of facilities manage these items as "trace chemotherapy" waste and segregate them into yellow bins that are sent to hospital medical infectious waste incinerators (HMIWI) at a regulated medical waste facility. This works very well and is an operation that is widely accepted and it is already protective of the environment. Under these proposed rules, essentially all chemotherapy IV bags and tubing would need to be managed as hazardous waste. This would significantly increase the cost of disposal. One way to insure this type of handling would be to offer the option of either managing empty IV bags and tubing for U-listed chemotherapy as hazardous waste or as trace chemotherapy waste destined for HMIWI facility. This is also true for managing all "trace contaminated" gowns, gloves, pads, etc. as hazardous waste. These also are managed as trace chemotherapy waste and incinerated at a HMIWI facility. We again encourage Ecology to offer this option as an alternative to hazardous waste management to reduce costs while maintaining environmental protection.

REQUIREMENTS FOR PHARMACEUTICAL REVERSE DISTRIBUTORS (PRD): TIME LINES AND RECALL MANAGEMENT, INVENTORY RECORDKEEPING AND CLOSURE

Below is an overview of some of the comments made relating to the EPA proposed rule (Stericycle comments attached). We thought it would be important to share the outline with Ecology as well.

- Based on Stericycle's extensive experience with recall processes we do not support any time limitation on recalled products. These materials are not waste at the time that they are placed into recall. They must be evaluated according to other regulatory agencies that have authority over the recalled product (Food and Drug Administration - FDA), by the manufacturer, or as directed through potential pending litigation. These materials could remain in holding for months, if not years. They are not a waste until directed to be discarded. Having to request for additional holding time and having it be at the discretion of Ecology or a regional EPA director is not reasonable, especially if the holding facility has no control over the length of time the product must be maintained. At the time that the material is released, the pharmaceuticals would need to be managed under these regulations.
- Recordkeeping requirements for reverse distributors are already fairly secure. We understand that Ecology wants to hold PRD accountable for more as they tend to have more consolidated waste streams and it is likely to have fewer employees to manage the wastes (unlike healthcare with a large diverse staff and retail which may have seasonal employees with less training),

however some requirements are unreasonable or unclear. Under section 12(a)(ii) *Standards for the management of creditable dangerous waste pharmaceuticals and evaluated dangerous waste pharmaceuticals at a pharmaceutical reverse distributor,* it states that the PRD *"must maintain an inventory of all the creditable dangerous waste pharmaceuticals and evaluated dangerous waste pharmaceuticals that are accumulated on-site."* This is not unreasonable, however later in the section under (ix) Recordkeeping it states that "A copy of its inventory for as long as the facility is subject to this subpart and. . ." It is not reasonable to require that the inventory be maintained for the life of the facility. Stericycle would recommend that the inventory be maintained for five years as is required of all other reasonable recordkeeping requirements.

- Time Limitation: Additional comments on the reporting time intervals outlined in the regulations. The time limitations are overlapping and could cause added confusion:
    - 7 days for the healthcare facility to identify that the potentially creditable material was received at the reverse distributor is too short and does not account for anomalies in the shipping process. This should be extended to 21 days.
    - 15 days for the reverse distributor to report when non-creditable or nonconforming waste is sent is not reasonable if Ecology does not allow for appropriate time to evaluate materials coming in. Ecology does not provide allowance for the 21 day evaluation period. What happens if the potentially creditable materials are identified within the 21 days that it is not creditable? It must be clarified that the 15 day time period starts after the 21 day evaluation period has concluded.
    - Ecology has placed a 90 day total holding time limit of the hazardous waste pharmaceuticals, however Stericycle recommends 180 days which we believe is more reasonable. Additionally, while the waste is being evaluated for credit, it should not be considered a waste yet.

TRAINING COMPLIANCE FOR HEALTHCARE

We agree with Ecology's requirement that many healthcare providers including hospitals, clinics, doctor's offices, long term care facilities, etc. be required to provide proper training to all employees affecting the management of these waste streams. We would recommend that there be an extensive outreach program to ensure that all generators, especially LTCFs are aware of the new requirements. The proposed rule contemplates training requirements for employees, but it is very limited in what it requires and does not require documentation or any requirement to repeat training. Stericycle recommends there be some basic level of training which should be required, so that employees managing these materials are aware not only of the potential hazards but also the potential need for segregation. The rule should specify that healthcare workers that "generate, dispose of and or manage hazardous waste pharmaceuticals need training." This training should be conducted at the beginning of job function (after the rule passes and for any new hires thereafter) and, based on our experience, with the rate of turnover and the amount of change in healthcare settings, training repeated annually.

Training must be documented; Stericycle feels strongly that if there is no specific documented training requirement in the rule that this regulation will not have the intended effect and that current practices will continue.

SUMMARY

We applaud the efforts of Ecology to develop a solution to the important issue of pharmaceutical waste management. We appreciate the opportunity to submit comments on this important rule. We look forward to the next phase of the rule making process and will provide additional more detailed comments during that phase as well. We also understand that there will be a further delay in the Federal EPA rule. We strongly recommend that Ecology wait to see the changes made in that rule before going to full rulemaking on this proposal to ensure consistency.

Should there be any additional stakeholder process we would appreciate the opportunity to participate. If you have any further questions or comments please feel free to contact me at 847-943-6685 or via email at shoboy@stericycle.com.

Sincerely,

Selin Hoboy
VP of Legislative and Regulatory Affairs
Stericycle, Inc.

Enclosures

CC: Matt Marra – SVP Environmental Safety and Health, Stericycle, Inc.
Anne Germain – Director, Healthcare Waste Institute

ATTACHMENT A

STERICYCLE COMMENTS SUBMITTED TO FEDERAL EPA PROPOSED MANAGEMENT STANDARDS FOR HAZARDOUS WASTE PHARMACEUTICALS

December 22, 2015

RCRA Docket
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Attn: Docket ID No. EPA-HQ-RCRA-2007-0932
SUBMITTED ELECTRONICALLY THROUGH FEDERAL eRULEMAKING PORTAL

To Whom It May Concern:

Stericycle, Inc. (Stericycle) appreciates the opportunity to comment on the proposed rule: Management Standards for Hazardous Waste Pharmaceuticals (September 25, 2015; 80 Federal Register No. 186). Stericycle is a publically traded corporation (NASDAQ: SRCL) based in Lake Forest, Illinois. In 2015, we had estimated revenues of approximately $3.5B. We operate over 250 medical and hazardous waste facilities for customers throughout the U.S. primarily in the healthcare field. Our services include compliant collection, transportation and treatment of medical waste, collection/disposal of pharmaceutical waste and hazardous waste, management of pharmaceutical and medical device recalls and returns for major drug and device manufacturers, and consulting/training programs to help educate our customers on the proper handling of these regulated waste streams. Our corporate vision is to be leaders in "Protecting People and Reducing Risk."

Stericycle is also an active member of the Healthcare Waste Institute (HWI), a division of the National Waste and Recycling Association. As part of our membership activities, we have reviewed the HWI written comments that are being submitted and fully endorse those comments as well.

Stericycle applauds the efforts of the US Environmental Protection Agency ("EPA" or "Agency") " *to revise the regulations to improve the management and disposal of hazardous waste pharmaceuticals and tailor them to address the specific issues that hospitals, pharmacies and other healthcare-related facilities face*". While significant progress has been made to that effort from the original proposal under the Universal Waste Rule proposal in 2008/2009, there is still work to be done. Stericycle has conducted an in depth analysis of the proposed rule. Stericycle respectfully submits the enclosed attachment which has comments to specific sections as outlined in the proposed regulations. Stericycle will be submitting additional comments to the companion rule "Hazardous Waste Generator Improvements" (September 25, 2015; 80 Federal Register No. 186) under separate cover. We would like to point out however, that if the Hazardous Waste Generator Improvements rule is finalized and the pharmaceutical waste rule is not, there could be significant detrimental impact on the healthcare industry and supporting industries in complying with the generator rules.

In addition to our section by section review in ATTACHMENT A, outlined in this document below is a summary of our main points.

MEDICAL WASTE SHARPS AND HAZARDOUS WASTE PHARMACEUTICALS

Stericycle has extensive experience with regulated medical and sharps wastes throughout the country. We provide services to generators of sharps, both collecting them in conjunction with pharmaceuticals and without. Below outlines in further detail our response as it relates to proper management of sharps with pharmaceutical residue:

- EPA makes a very clear assertion that pharmaceuticals should not be autoclaved. They state this in a couple of sections, but their rational is not relevant to EPA's mission of reducing environmental risks. Under section V.E.3.c (FR pg. 58056) EPA states "*EPA is concerned that the residues remaining in the syringes could be aerosolized during autoclaving and inadvertently expose workers to aerosolized hazardous waste residues, posing risks (via pulmonary exposure) to those present during venting of the autoclave. Research suggests that autoclaving may even increase the toxicity of certain drugs. EPA seeks comment on the extent of risks associated with autoclaving hazardous waste residues leftover in syringes and whether it is necessary to place a limit on the volume of residue or the volume of the syringe to which this conditional exemption would apply or whether any other conditions would be appropriate."* Stericycle agrees autoclaving is not the ideal waste management process for hazardous waste pharmaceuticals. Regardless, Stericycle wants to be clear that there have been no known situations where an employee has had a direct exposure to pharmaceuticals due to aerosolization, resulting in an exposure due to the venting of the autoclave.

  It is important to note however, in many cases, it is not possible to t identify the residue that remains in the syringe, within the sharps containers. Additionally, once the sharp is placed into the sharps container, there is no feasible way for the generator or the waste handling facility to safely retrieve this material. Needless to say, this inability to identify the material can present enforcement challenges, confusion and legal debate, between the generator and medical waste treatment facilities as well as regulatory agencies, for a very nominal quantity of waste.
- As it relates to the safety for healthcare providers, Stericycle believes this is critical to exempt these materials so that healthcare providers are able to avoid sharps injuries and ensure compliance with Occupational Safety and Health Administration's (OSHA) Bloodborne Pathogen Standard (BBP) 29 CFR 1910.1030. OSHA BBP regulations state that sharps containers must be easily accessible to personnel. As identified in the OSHA Fact Sheet "Protecting Yourself When Handling Contaminated Sharps" https://osha.gov/OshDoc/data_BloodborneFacts/bbfact02.html , the following is stated: "P*rompt Disposal: Employers must also ensure that contaminated sharps are disposed of in sharps disposal containers immediately or as soon as feasible after use. Sharps disposal containers must be readily accessible and located as close as feasible to the area where sharps will be used. In some cases, they may be placed on carts to prevent patients, such as psychiatric patients or children, from accessing the sharps. Containers also must be available wherever sharps may be found, such as in laundries."* Stericycle concludes that by having these materials managed as sharps in the regulated medical waste stream, there is a reduction in potential risk to healthcare and waste workers throughout the waste handling process.
- Department of Transportation (DOT) regulations state that regulated medical waste division 6.2 is typically more dangerous than other types of hazardous materials (49 CFR 173.2a(c)(3)). Thus

the waste is managed as a regulated medical waste, 6.2, under the DOT regulations. The waste is appropriately classified for the hazard associated with sharps and is protective of waste handling employees and emergency responders. This also helps to eliminate potential misinterpretation of regulatory regimes.

- Stericycle has an extensive list of pharmaceutical NDCs that it has evaluated (approximately 80,000 validated FDA NDCs) and of the total amount, approximately 2000 are injectable and of that there is only a small percentage that is considered hazardous. We estimate, based on the materials identified in our database, that currently only 0.13% of the 80,000 are hazardous injectable materials. This issue of determining the proper management of these small amounts of pharmaceuticals being included in the sharps has been a great source of confusion.
- Lastly, some States regulate ALL sharps, regardless of contents, as regulated medical waste. EPA and these States would finally be aligned in the proper disposal of sharps containing hazardous pharmaceutical waste.

In our experience, this issue has created a lot of confusion, misinterpretation and risk. Based on the information presented, we believe that the risks to eliminate potentially small amounts of hazardous waste pharmaceuticals from the environment is outweighed by the potential safety risk to healthcare and waste workers. Stericycle strongly supports that there be an exemption for syringes with residue, regardless of the amount of material remaining within the syringe.

USE OF HOSPITAL MEDICAL INFECTIOUS WASTE INCINERATORS (HMIWI)

Throughout the proposed rule , the Agency refers generators to the use of either hazardous waste combustors (HWC) or in some circumstances the use of municipal waste combustors (MWC), however does not discuss the use of Hospital Medical Infectious Waste Incinerators (HMIWI). We are unclear if this was an oversight by the Agency or intentional, but Stericycle respectfully requests that the Agency reevaluate HMIWI capabilities and include them as part of the overall solution of proper pharmaceutical waste disposal. Stericycle provides services today to generators of hazardous and nonhazardous waste pharmaceuticals who would be greatly impacted by these regulations, as described below. Additionally, we believe there are opportunities for HMIWI facilities to provide additional services to generators on wastes being generated that would now be covered under this new proposed regulation.

A. As US EPA Clean Air Act regulations have gotten tighter, the number of HMIWI has gone from the thousands to only 11 commercially available and 33 total incinerators in the country today. Stericycle owns and operates 8 HMIWI at 6 locations throughout the country. Stericycle has invested millions of dollars through the years for upgrades to apply the best available technology and ensure compliance with the regulations. In recent history, regulatory constraints have driven the incineration industry to the verge of extinction. However, this has also resulted in the remaining facilities to be more environmentally protective. These facilities provide services to healthcare facilities throughout the country today for best management of, or state regulatory requirements for, non-hazardous waste pharmaceuticals. Below provides additional detail.

1. In 2009 under the Clean Air Act the EPA promulgated new regulations for HMIWI which further tightened air pollution limits. With these new regulations existing operations had to come into compliance in October of 2014 and any new facilities had to be in compliance with unprecedented limits imposed by the rule. With that in mind, HMIWI have limits that are well

below operating limits for MWC and very close or more stringent than permitted HWC (see ATTACHMENT B). The following are practices already being followed by the healthcare industry which have proven to be environmentally protective and are now engrained in worker waste disposal practices:

- DEA controlled substances are often sent for proper destruction at HMIWI facilities.
- IV bags of spent trace chemotherapy have been routinely sent to HMIWI facilities for decades without incident. This is actually already part of many state medical waste regulations which require medical waste incineration of this material. Forcing the placement of these materials into a new container will require significant change and retraining for all generators. The Agency stated in the preamble the reason for this change is that they believe the remaining waste in IV bags is being drain disposed, however this has not been the experience for Stericycle customers as it relates to chemotherapy waste IV bags. These are processes already in place in many cases and this regulatory change would be detrimental to the healthcare industry for a process that is working appropriately to protect the environment. We recognize that the Agency is not looking solely at cost, but this will also have a tremendous cost to the healthcare industry, which was not evaluated in the preamble.

B. Based on this extensive experience, Stericycle requests that the EPA take into consideration that HMIWI, if appropriately permitted, be included in the menu of options for disposal of certain hazardous waste pharmaceuticals outlined in the proposed rule as described below:

1. While Stericycle agrees with the conditional exemption for the Resource Conservation Recovery Act (RCRA) requirements for pharmaceuticals that are both RCRA hazardous waste and DEA controlled substances, we would request that the EPA also allow the use of HMIWI incinerators for the proper incineration of these pharmaceutical wastes. Often these materials are already in vials or syringes that are considered sharps.
2. HMIWI should be considered for the types of wastes they are permitted to handle, which could also include household generated pharmaceuticals exempt from these regulations.

For these reasons, Stericycle urges EPA to allow the use of HMIWI under Subpart P for the wastes as described above.

CESQG: FACILITY MANAGEMENT AND CONSOLIDATION OPTIONS

There are many entities which will not fall under these new regulations as they are a Conditionally Exempt Small Quantity Generator (CESQG or Very Small Quantity Generator (VSQG) under the new proposed Generator Improvement Rule; CESQG will be used throughout this document for ease of use). However, it will be very important to ensure that there is clear communication to this community of generators what their responsibilities will be. Many CESQGs in the healthcare industry (including retail and convenience stores etc. that may have over the counter drugs) may not realize that there will be a new set of regulations. We encourage EPA to have a strong outreach program. Below is a summary of our detailed comments, (also see ATTACHMENT A) based on our interactions with customers who fall under this CESQG category.

- EPA should clarify that the determination of the generator type should be identified before applying Subpart P. This will provide a more accurate account for the generator of what type of

generator they are. This will be important for the new generator group of Long Term Care Facilities (LTCF) who may not have counted this waste stream before. This will also be critical for retail pharmacies and smaller hospitals. This needs to be more clearly stated in the preamble, but also clarified in the regulation for future generators to understand how regulations will apply to them.

- EPA should clarify that true CESQGs (generators that were in CESQG status before applying the rule to their status and not counting the waste generated against their generator status) must still adhere to the regulations under 40 CFR 261.5 if they will not fully utilize Subpart P. What is and what is not applicable to them is still somewhat difficult to apply and explain. As a provider of compliance services and training, this becomes very complicated when CESQG's look for support in complying with both sets of regulations.
- Consolidation of non-creditable pharmaceutical wastes at a consolidation location could have its advantages for the CESQG, however it presents challenges to the receiving facility. The EPA states that the CESQG does not have to mark the material with what is inside and they are not required to manifest it or provide any shipping description information or follow any specific packaging requirements, yet the receiving facility must maintain records of the shipment for 3 years. What would the receiving facility keep record of? Additionally, EPA states in sections throughout that they are concerned about security of material and diversion. Even though we do not believe diversion issues are really within EPA's purview, these untracked shipments of pharmaceuticals are fraught with potential for diversion.
- Many of the issues stated above would be equally true of potentially creditable waste being shipped to a reverse distributor. There needs to be minimum requirements set so that the receiving facility understands and can track material that is intended to be shipped as creditable hazardous waste to a potential reverse distributor. This would mean that the receiving facility would need to identify that material and track it through the system somehow. It is not clear how the receiving facility is to manage that material and how the originating CESQG would be identified as the facility to receive the credit value or receive rejection notifications, etc. and who would be the regulated entity if there were an issue with the shipment? (see question raised by EPA under section V.G.3.b "*However, EPA requests comment on whether CESQG healthcare facilities would benefit from being able to consolidate potentially creditable hazardous waste pharmaceuticals off-site, as well. Depending on comments, EPA will consider allowing a fourth transfer (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, as would also be allowed by proposed § 266.504(a)")*. For these reasons we do not believe that consolidation of potentially creditable pharmaceuticals should be adopted into the rule.
- Consolidation of pharmaceuticals could occur across state lines which may have differing requirements for CESQGs. We have experienced this problem under the current regulatory regime and it has been very confusing and frustrating for the generator, transporter and

regulator. This issue is not addressed in the regulations as outlined and must be discussed; otherwise consolidation could become very problematic or not even feasible.

Stericycle recommends that there be some minimum standards set for the proper tracking and shipment of pharmaceuticals (either for consolidation, waste destruction or reverse distribution) for CESQGs. Stericycle recommends that the EPA take the opportunity to clearly state what is required for CESQGs and what they can or cannot do if they chose not to manage their wastes under this rule. This could be accomplished by creating a specific section on CESQGs requirements in subpart P to better explain the sections that apply to them. The proposed rule currently has this information in 266.501(a) and (b), the applicability section. 266.501(a) further references other sections of Subpart P - 266.504, 266.505, and 266.507(a) and (b). Rather than cross referencing these sections, we believe it would be easier to comprehend the CESQG requirements if they were combined into a separate dedicated section under this rule. This would also be more consistent with the way that EPA is regulating generators under the Generator Improvement Rule in providing all relevant regulations in one place for generators.

WASTE DETERMINATION, CLASSIFICATION AND SEGREGATION AND OVERALL MANAGEMENT OF HAZARDOUS WASTE PHARMACEUTICALS- INCLUDING MARKING AND SHIPPING REQUIREMENTS

While we agree with the Agency that the healthcare providers may not be the best qualified to make a waste determination, the healthcare entity should still remain responsible for this very important task. Waste determination and classification is at the genesis of proper transportation and destruction of waste. If wastes are not properly identified at the facility of generation it could have serious and unintended consequences.

- Proper waste identification is essential for transportation. Improper waste identification can lead to Department of Transportation (DOT) violations and potential permit condition violations at the treatment facilities, not to mention potential safety risks, such as fires, while in transport. Transporters and destruction facilities will not want to take on such liabilities. While the Agency attempted to address the inability of healthcare facilities to make proper waste determination at the point of generation, by not requiring waste codes on the containers or on the manifest, it does not relieve the transporter of the DOT regulatory burdens (FR pg 58039 V.C.9 – Shipments of Non-Creditable Hazardous Waste Pharmaceuticals Offsite From healthcare Facilities – "*The fact that EPA is proposing to not require hazardous waste codes for shipping hazardous waste pharmaceuticals is not intended to alter or impact any Department of Transportation (DOT) requirements for the shipment of these hazardous wastes.*").
- EPA goes on to require proper management of wastes under the LDR (FR pg. 58034 – 58039 V. C. 8 - Land Disposal Restrictions for Non-Creditable Hazardous Waste Pharmaceuticals). There needs to be a compromise of sorts that allows the generator to have some lessor restrictions, but yet allows for the management of the waste downstream from the generator (transporters and treatment facilities) to ensure compliance. The way the rule is currently written it does not provide for assurances for either.
- If the EPA is going to require adherence to LDR and potential separation of materials that cannot be incinerated then there has to be some requirement for proper segregation at the point of

generation. This should be clearly identified by the EPA. As written there is ambiguity in the generators role in compliance with this requirement. If EPA intends for the generator to comply it must state that the healthcare providers would need to segregate these materials.

For the reasons stated above, Stericycle believes there still is a need for proper segregation at the source for a limited group of hazardous waste pharmaceuticals to avoid potential safety and compliance risks.

REQUIREMENTS FOR PHARMACEUTICAL REVERSE DISTRIBUTORS (PRD): TIME LINES AND RECALL MANAGEMENT, INVENTORY RECORDKEEPING AND CLOSURE

In this section Stericycle has outlined some of the comments specified in the attachment that relate to pharmaceutical reverse distributors based on our experience as a pharmaceutical reverse distributor who has also conducted numerous recalls.

- Based on Stericycle's extensive experience with recall processes we do not support the time limitation of a year on recalled products. These materials are not waste at the time that they are placed into recall. They must be evaluated according to other regulatory agencies that have authority over the recalled product (Food and Drug Administration - FDA), by the manufacturer or as directed through potential pending litigation. These materials could remain in holding for months, if not years. They are not a waste until directed to be discarded. Having to request for additional holding time and having it be at the discretion of a regional EPA director is not reasonable, especially if the holding facility has no control over the length of time the product must be maintained. At the time that the material is released, the pharmaceuticals would need to be managed under these regulations.
- Recordkeeping requirements for reverse distributors are already fairly secure. We understand that EPA would like to hold PRD accountable for more as they tend to have more consolidated waste stream and it is likely to have fewer employees to manage the wastes (unlike healthcare with a large diverse staff and retail which may have seasonal employees with less training), however some requirements are unreasonable or unclear. Under section V.G.3.a.ii *Inventory* (FR pg 58061) it states that the PRD " must keep an inventory of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that are on-site." This is not unreasonable, however in the actual regulation under §266.510(a)(9)(iii) (FR pg. 58089) it states that "A copy of its inventory for as long as the facility is subject to this subpart and. . ." It is not reasonable to require that the inventory be maintained for the life of the facility. Stericycle would recommend that the inventory be maintained for three years as is required of all other reasonable recordkeeping.
- EPA is proposing due to the generally low risk of release that the closure standards for PRD be performance based found in §265.111. We would recommend that instead of referencing to that section of regulation that the closure requirements EPA intends be moved into this section. This will remove the possibility of future changes in that section of the regulation which could become more onerous sometime in the future, since those regulations are intended for heavy industrial generators. This would be more consistent with EPA's intent to make things more

clear to generators on their responsibilities and have what is required of them all in one regulatory section.

- Time Limitations:
    - EPA requests comment on the reporting time intervals outlined in the regulations. The time limitations are overlapping and could cause added confusion:
        - 7 days for the healthcare facility to identify that the potentially creditable material was received at the reverse distributor is too short and does not account for anomalies in the shipping process. This should be extended to 21 days.
        - 15 days for the reverse distributor to report when non-creditable or nonconforming waste is sent is not reasonable if the Agency does not allow for appropriate time to evaluate materials coming in. The Agency states in the preamble on page 58063 under section V.G.3.a.vii under *Reporting* that a report must be submitted to both the healthcare facility sending the waste and the Agency. It goes on to state that the PRD must then manage the materials as hazardous waste. However, this section does not provide allowance for the 21 day evaluation period. What happens if the potentially creditable materials are identified within the 21 days that it is not creditable? The Agency must clarify that the 15 day time period starts after the 21 day evaluation period has concluded.
        - The Agency has placed a 90 day total holding time limit of the hazardous waste pharmaceuticals, however Stericycle recommends 180 days which we believe is more reasonable. Additionally, while the waste is being evaluated for credit, it should not be considered a waste yet.

MANAGEMENT OF NON-HAZARDOUS PHARMACEUTICAL DRUGS

Stericycle understands EPA's desire to keep all pharmaceuticals out of the water and for all pharmaceuticals to be managed appropriately. However, by pushing for all pharmaceuticals to be managed as hazardous waste (though we understand this is not regulatorily required) EPA is continuing to further limit the options for proper management of non-hazardous pharmaceuticals. It is important to keep in mind that approximately 90-95% of all pharmaceuticals are NOT hazardous wastes under the EPA regulations and definitions, so by recommending they be comingled is solving for 100% waste, but at what environmental and financial cost. Flexibility in managing non-hazardous waste pharmaceuticals allows for healthcare pharmaceutical waste generators to have multiple options of managing their wastes.

Adding more waste into the hazardous waste stream is in conflict with the waste minimization statement on the manifest as required under 40 CFR 262.27 "A generator who initiates a shipment of hazardous waste must certify to one of the following statements in Item 15 of the uniform hazardous waste manifest:"

- (a) "I am a large quantity generator. I have a program in place to reduce the volume and toxicity of waste generated to the degree I have determined to be economically practicable and I have selected the practicable method of treatment, storage, or

disposal currently available to me which minimizes the present and future threat to human health and the environment;" or

- (b) "I am a small quantity generator. I have made a good faith effort to minimize my waste generation and select the best waste management method that is available to me and that I can afford."

Stericycle recommends that the EPA remove the language under §266..502 (c) (FR pg 58085)"*A healthcare waste facility may choose to manage its solid waste pharmaceuticals as hazardous waste pharmaceutical under this subpart even if the solid waste pharmaceuticals do not exhibit a characteristic identified in 40 CFR part 261, subpart C and are not listed in 40 CFR part 261, subpart D."* This is an overreaching statement that is not warranted and has no legal basis to be in the regulation.

TRAINING COMPLIANCE FOR HEALTHCARE

We agree with the Agency's assessment that many healthcare providers including hospitals, clinics, doctor's offices, long term care facilities, etc are not aware of the applicability of the RCRA hazardous waste regulations to hazardous pharmaceutical waste. We would recommend that there be an extensive outreach program to ensure that all generators, especially LTCF are aware of the new requirements. The proposed rule contemplates training requirements for employees, but it is very limited in what it requires and does not require documentation or any requirement to repeat training (*FR pg. 58084-58085 §266.502(b)*). Stericycle recommends there be some basic level of training which should be required, so that employees managing these materials are aware not only of the potential hazards but also the potential need for segregation (if that is required; see section WASTE DETERMINATION, CLASSIFICATION AND SEGREGATION AND OVERALL MANAGEMENT OF HAZARDOUS WASTE PHARMACEUTICALS- INCLUDING MARKING AND SHIPPING REQUIREMENTS above for further detail on segregation). The rule should specify that health care workers that "generate, dispose of and or manage hazardous waste pharmaceuticals need training." This training should be conducted at the beginning of job function (after the rule passes and for any new hires thereafter) and, based on our experience, with the rate of turnover and the amount of change in healthcare settings, training repeated annually. Training must be documented; Stericycle feels strongly that if there is no specific documented training requirement in the rule that this regulation will not have the intended effect and that current practices will continue.

SUMMARY
We applaud the Agency in their effort to develop a solution to the important issue of hazardous pharmaceutical waste management. We appreciate the opportunity to submit comments on this important rule. We look forward to the opportunity to discuss this further with the Agency in an effort to ensure proper regulations are in place for regulated entities managing hazardous waste pharmaceuticals.

Should you have any further questions or comments please feel free to contact me at 847-943-6685 or via email at shoboy@stericycle.com.

Sincerely,

Selin Hoboy
VP of Legislative and Regulatory Affairs
Stericycle, Inc.

Enclosures
CC: Matt Marra – SVP Environmental Safety and Health, Stericycle, Inc.
Anne Germaine – Director, Healthcare Waste Institute

ATTACHMENT A

DETAILED SECTION BY SECTION REVIEW OF COMMENTS SPREADSHEET

ATTACHMENT A: STERICYCLE'S DETAILED SECTION BY SECTION REVIEW OF COMMENTS SPREADSHEET PHARMA PROPOSED RULE					
#	Section Name	FR Page#	Topic	EPA Request for Comment	Stericycle Section Specific Comment
1	V Detailed Discussion of the proposed Rule; A. What Terms are Defined in this Proposed Rule	58021	Definitions	We seek public comment on the Agency's decision to recognize dietary supplements as pharmaceuticals under this regulation. Evaluated evaluated hazardous waste pharmaceutical," "hazardous" waste pharmaceutical," "healthcare facility," "household waste pharmaceutical," "long-term care facility," "non-creditable hazardous waste pharmaceutical," "non-hazardous waste pharmaceutical," "non-pharmaceutical hazardous waste," "pharmaceutical," "pharmaceutical reverse distributor," and "potentially creditable hazardous waste pharmaceutical."	EPA identifies pharmaceuticals well, however there may be rare cases where the products or chemicals are used for two different purposes (e.g. alcohol used in the process of wound care versus cleaning instruments or surfaces; or circumstances where solvents from labs are related to diagnosis). EPA should ensure that is clear in the definition or explanation of pharmaceuticals or non-pharmaceutical hazardous waste so that the waste generated in the non-healthcare use of the materials can be properly counted towards generator status.
2	V Detailed Discussion of the proposed Rule; A. What Terms are Defined in this Proposed Rule	58021	Definitions	EPA asks for comment to identify additional types or forms of pharmaceuticals that are not adequately captured by the definition.	EPA identifies pharmaceuticals well, however there needs to be clarity around research drugs which may not have been released fully. EPA identifies that pharmaceuticals must be in their final form. We request clarity for research drugs and compound drugs or those not in their final form as to whether or not they would be considered pharmaceuticals. Based on the response, we would recommend that these be included definitions. If there are no other guidelines to require manufacturers to provide better documentation of the materials contained in these materials it will be difficult to properly characterize these materials especially when it comes to new drugs as they may have proprietary or trade secret ingredients. The Agency has neglected to consider investigational or research drugs that would have proprietary ingredients which manufacturers may not be willing to divulge during the trials. Under these circumstances the EPA needs to provide clarity on what should be done with these materials when discarded.
3	V. Detailed Discussion of the proposed Rule; A. What Terms are Defined in this Proposed Rule	58022	Definitions	We seek public comment on the Agency's decision to recognize dietary supplements as pharmaceuticals under this regulation.	While we generally support the overall definition, there may be some challenges to adding these things to the rule. Due to the limited manufacturing information on the constituents of the supplements (energy drinks/over the counter supplements etc.) it would be difficult to adequately characterize these materials as hazardous or non-hazardous. Additionally, many of these materials do not have NDC information but rather have UPC information. If there are no other guidelines to require manufacturers to provide better documentation of the materials contained in these materials it will be difficult to properly characterize these materials.
4	V. Detailed Discussion of the proposed Rule; A. What Terms are Defined in this Proposed Rule	58022	RMW/ Sharps	However, EPA is concerned about the possibility that some syringes may be disposed of in sharps containers that may contain significant amounts of undispersed pharmaceutical. EPA seeks comment on the prevalence of this situation.	Stericycle has outlined this section with four main issues in mind (a) while there may be a study regarding the exposure during autoclave venting we are unaware of any specific instance where this has caused a direct safety issue; we believe this strongly stated position is misplaced as the rational for not having pharmaceuticals managed through an autoclave; (b) more immediate disposal of sharps is safer for healthcare and waste workers and more compliant with OSHA regulations; (c) classification of sharps as regulated medical waste is appropriate for proper transportation of these waste streams; (d) majority of injectable wastes are not hazardous wastes thus placing undue risk for a nominal environmental benefit. Based on the formulary information that Stericycle has evaluated approximately 0.13% of the injectable medications are considered a hazardous waste. For these reasons, Stericycle strongly supports that there be an exemption for syringes with residue, regardless of the amount of material remaining within the syringe.
5	V. Detailed Discussion of the proposed Rule; A. What Terms are Defined in this Proposed Rule	58023	Definitions	Agency is soliciting comment on the proposed definition of "potentially creditable hazardous waste pharmaceutical" and whether the definition is broad enough to encompass the various types of hazardous waste pharmaceuticals that are shipped to reverse distributors for manufacturer's credit. . .	EPA has provided a much needed definition of potentially creditable hazardous waste pharmaceutical, however it may fall short. At what state would EPA consider this material to be non-creditable: if it was identified as not receiving credit the first time? second time? third time? Would the generator be responsible for maintaining records of the non-creditable items? We believe that these are questions and concerns regarding this definition that still need further clarity.
6	V. Detailed Discussion of the proposed Rule; A. What Terms are Defined in this Proposed Rule	58024	Definitions	The Agency is soliciting comment on the proposed definition of "healthcare facility," including whether it is appropriate to consider these compounders as healthcare facilities within the scope of this proposed rule.	EPA identifies healthcare facilities well, however there needs to be clarity on compounding drugs. If compounding drugs are included under these regulations then compounding facilities may need to be included in the definition of healthcare facility.
7	V. Detailed Discussion of the proposed Rule; B. What is the scope of this proposed rule?	58027	CESQG	. . . [LTCF]are small enough to be considered CESQGs of hazardous waste (regulated under § 261.5) and therefore not subject to part 266, subpart P (except the sewer ban).	EPA has clarified that healthcare facilities which were CESQGs prior to the passing of subpart P, they would remain under the original 261.5. However, what was not clear, and needs to be reinforced is, if a healthcare facility is an SQG or LQG currently and they drop down to a CESQG by applying subpart P, they still need to maintain compliance under Subpart P (in order to remain in that CESQG category). This would be applicable also to LTCF.
8	V. Detailed Discussion of the proposed Rule; B. What is the scope of this proposed rule?	58027	LTCF	The Agency seeks comment on whether this proposed change to consider long-term care facilities to be healthcare facilities instead of households is appropriate. We also seeking comment on the extent to which long-term care facilities will pass the cost of compliance onto its customers.	Stericycle supports the inclusion of long term care facilities in this rule as it helps to clarify the proper management of pharmaceuticals for this industry. Over the last few years there have been many questions regarding the proper management of pharmaceuticals from long term care facilities with conflicting answers.
9	V. Detailed Discussion of the proposed Rule; B. What is the scope of this proposed rule?	58027	CESQG	EPA asks for comment on whether the proposed healthcare facility standards, in addition to the sewer ban, should apply to CESQG healthcare facilities.	Stericycle supports the sewer ban.
10	V. Detailed Discussion of the proposed Rule; B. What is the scope of this proposed rule?	58027	CESQG	Although we are proposing to make this change within part 266, subpart P, we request comment on whether stakeholders would prefer this change to be made within § 261.5 instead.	Stericycle would recommend that the EPA make the change in 261.5 which would then point the generator to 266 Subpart P. This would also be more consistent with the way that EPA is regulating generators under the Generator Improvement Rule and providing all relevant regulations in one place for generators.

ATTACHMENT A: STERICYCLE'S DETAILED SECTION BY SECTION REVIEW OF COMMENTS SPREADSHEET PHARMA PROPOSED RULE					
#	Section Name	FR Page#	Topic	EPA Request for Comment	Stericycle Section Specific Comment
11	V. Detailed Discussion of the proposed Rule; B. What is the scope of this proposed rule?	58028	CESQG	Agency is proposing to make this recommendation a requirement for collected household waste pharmaceuticals in §266.506. The Agency seeks comment on changing this recommendation to a requirement for pharmaceutical collection programs.	Stericycle supports the position that pharmaceuticals collected at household pharmaceutical collection and take-back events and collected in DEA authorized collection receptacles should continue to be excluded from regulation as household hazardous waste. Stericycle also recommends that the EPA clarify and confirm that these materials will remain exempt from hazardous waste regulations. Additionally, Stericycle recommends that options for the proper disposal of household collection event or DEA authorized collection receptacles remain open to any facility which is properly permitted and allowed to accept and manage this type of waste. This should include Hospital Medical Infectious Waste Incinerators (HMIWI) that are properly permitted to accept such wastes (please see accompanying letter for further details on HMIWI). We recommend that the limitation on the type of facility be removed and rather the regulations specify "a facility which is properly permitted to accept this type of waste may do so". Requiring hazardous waste incineration has a potential environmental impact of having to transport wastes long distances to the few available hazardous waste incinerators and will drive up the cost of these collection events, which are often already limited in funding.
12	V. Detailed Discussion of the proposed Rule; B. What is the scope of this proposed rule?	58028	DEA Controlled Substances	. . . the Agency is proposing to conditionally exempt from RCRA regulatory requirements those pharmaceuticals that are both a RCRA hazardous waste and a DEA controlled substance, provided the hazardous waste pharmaceuticals that are also DEA controlled substances are combusted at a permitted or interim status hazardous waste incinerator, or a permitted municipal solid waste incinerator.	While Stericycle agrees with the conditional exemption for the RCRA requirements for pharmaceuticals that are both RCRA hazardous waste and DEA controlled substances, we would request that the EPA also allow the use of HMIWI incinerators for the proper incineration of these pharmaceutical wastes (please see accompanying letter for further details). Restricting the use of other alternative treatment could cause additional environmental harm (transporting long distances) and be more costly . Often these materials are already in vials or syringes that are considered sharps.
13	V. Detailed Discussion of the proposed Rule; B. What is the scope of this proposed rule?	58029	RMW/ Sharps	In addition, as discussed in Section V.E.3.c of this preamble, EPA is proposing to conditionally exclude the residues of hazardous waste pharmaceuticals remaining in fully dispensed syringes from RCRA regulation.	Stericycle has outlined this section with four main issues in mind (a) while there may be a study regarding the exposure during autoclave venting we are unaware of any specific instance where this has caused a direct safety issue; we believe this strongly stated position is misplaced as the rational for not having pharmaceuticals managed through an autoclave; (b) more immediate disposal of sharps is safer for healthcare and waste workers and more compliant with OSHA regulations; (c) classification of sharps as regulated medical waste is appropriate for proper transportation of these waste streams; (d) majority of injectable wastes are not hazardous wastes thus placing undue risk for a nominal environmental benefit. For these reasons, Stericycle strongly supports that there be an exemption for syringes with residue, regardless of the amount of material remaining within the syringe.
14	V. Detailed Discussion of the proposed Rule; B. What is the scope of this proposed rule?	58029	RX Waste Mgmt.	However, a healthcare facility may choose to manage its solid and hazardous waste pharmaceuticals together (as hazardous waste pharmaceuticals) under these new proposed regulations. Because all healthcare facilities operating under this subpart are regulated in the same way regardless of quantity of pharmaceutical hazardous waste generated, managing non-hazardous waste pharmaceuticals as hazardous waste under this subpart would not affect the facility's hazardous waste generator	Stericycle understands EPA's desire to keep all pharmaceuticals out of the water and for all pharmaceuticals to be managed appropriately. However, by pushing for all pharmaceuticals to be managed as hazardous waste (though we understand this is not regulatorily required) EPA is continuing to further limit the options for proper management of non-hazardous pharmaceuticals. It is important to keep in mind that approximately 90-95% of all pharmaceuticals are NOT hazardous wastes under the EPA regulations and definitions, so by recommending they be comingled is solving for 100% waste, but at what environmental and financial cost. Flexibility in managing non-hazardous waste pharmaceuticals allow for healthcare pharmaceutical waste generators to have multiple options of managing their wastes. Adding more waste into the hazardous waste stream is in conflict with the waste minimization statement on the manifest as required under 40 CFR 262.27 "A generator who initiates a shipment of hazardous waste must certify to one of the following statements in Item 15 of the uniform hazardous waste manifest:" o (a) "I am a large quantity generator. I have a program in place to reduce the volume and toxicity of waste generated to the degree I have determined to be economically practicable and I have selected the practicable method of treatment, storage, or disposal currently available to me which minimizes the present and future threat to human health and the environment;" or o (b) "I am a small quantity generator. I have made a good faith effort to minimize my waste generation and select the best waste management method that is available to me and that I can afford." Stericycle recommends that the EPA remove the language under §266..502 (c) (FR pg. 58085)"A healthcare waste facility may choose to manage its solid waste pharmaceuticals as hazardous waste pharmaceutical under this subpart even if the solid waste pharmaceuticals do not exhibit a characteristic identified in 40 CFR part 261, subpart C and are not listed in 40 CFR part 261, subpart D." This is an overreaching statement that is not warranted and has no legal basis to be in the regulation.
15	V. Detailed Discussion of the Proposed Rule; C. What are the proposed standards for healthcare facilities that manage non-creditable waste pharmaceuticals?	58031	RX Waste Mgmt.	Alternatively, if a healthcare facility determines that it is a CESQG,65 but does not want to keep track of the amount of hazardous waste generated and whether it is above or below the CESQG threshold limit, it can choose to operate under this proposed rule.	Stericycle recommends that the EPA take the opportunity to clearly state what is required for CESQGs and what they can or cannot do if they chose not to manage their wastes under this rule. This could be accomplished by creating a specific section on CESQGs requirements in subpart P to better explain the sections that apply to them. The proposed rule currently has this information in 266.501(a) and (b), the applicability section. 266.501(a) further references other sections of Subpart P - 266.504, 266.505, and 266.507(a) and (b). Rather than cross referencing these sections, we believe it would be easier to comprehend the CESQG requirements if they were combined into a separate dedicated section under this rule. This would also be more consistent with the way that EPA is regulating generators under the Generator Improvement Rule and providing all relevant regulations in one place for generators.
16	V. Detailed Discussion of the Proposed Rule; C. What are the proposed standards for healthcare facilities that manage non-creditable waste pharmaceuticals?	58032	Training	Agency is seeking comment regarding the appropriateness of these personnel training requirements and if these requirements 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.	Stericycle appreciates that the EPA has included training requirements, but the requirements fall short in ensuring compliance with all requirements. Training is critical to ensure that generators understand how to comply with these requirements. There should be greater clarity around the staff that needs training for example nursing staff, pharmacists, medication providers, environmental services staff, etc. The rule should specify that health care workers that "generate, dispose of and or manage hazardous waste pharmaceuticals need training." We also recommend that there be clarification that the training should include information about proper segregation, such that generators understand the need to separate specific drugs identified under the LDR requirements. This training should be conducted at the beginning of job function (after the rule passes and for any new hires thereafter) and, based on our experience, with the rate of turnover and the amount of change in the healthcare settings, training repeated annually. Training must be documented; Stericycle feels strongly that if there is no specific documented training requirement in the rule that this regulation will not have the intended effect and that current practices will continue.

ATTACHMENT A: STERICYCLE'S DETAILED SECTION BY SECTION REVIEW OF COMMENTS SPREADSHEET PHARMA PROPOSED RULE					
#	Section Name	FR Page#	Topic	EPA Request for Comment	Stericycle Section Specific Comment
17	V. Detailed Discussion of the Proposed Rule; C. What are the proposed standards for healthcare facilities that manage non-creditable waste pharmaceuticals?	58033	Storage	. . . hazardous waste pharmaceuticals are not subject to the 90- or 180-day requirements. EPA solicits public comment on its decision to not require hazardous waste pharmaceutical-specific central and satellite accumulation area requirements.	Stericycle supports this decision to not require accumulation areas. However this decision may make it more difficult for generators to track the 1 year time limit, if they do not have specific documented locations of containers. Stericycle recommends that there be some inventory of containers so that tracking them for the year requirement is feasible to ensure compliance.
18	V. Detailed Discussion of the Proposed Rule; C. What are the proposed standards for healthcare facilities that manage non-creditable waste pharmaceuticals?	58033	Containers	However, the Agency solicits comment as to whether other types of waste management units are also used by healthcare facilities to accumulate and store hazardous waste pharmaceuticals and whether EPA should establish technical standards for other types of waste management units.	Stericycle recommends EPA clarifies what they mean as a waste management unit, such as tanks. If the agency is suggesting that there are no large or bulk containers being used for the management of hazardous pharmaceutical wastes, which is generally true then these provisions would apply. We would suggest that there would be better definition of what is a "container" for the purpose of this rule which could change the implication for waste management units.
19	V. Detailed Discussion of the Proposed Rule; C. What are the proposed standards for healthcare facilities that manage non-creditable waste pharmaceuticals?	58034	Containers	. . . appropriateness of the proposed container management standards. In addition, the EPA is soliciting comment on the proposed requirement for ensuring that the hazardous waste pharmaceuticals contained in collection containers remain secure.	Stericycle supports EPA's outline of appropriate containers to be used for hazardous waste pharmaceuticals and agrees that these collection containers should remain secure.
20	V. Detailed Discussion of the Proposed Rule; C. What are the proposed standards for healthcare facilities that manage non-creditable waste pharmaceuticals?	58034	Containers	Agency is soliciting comment on the appropriateness of the proposed general labeling requirement.	Stericycle feels that the EPA labeling should provide the same leeway as is provided under 262.34, which states " 'hazardous waste' or with other words that identify the contents of the containers." Currently there are different marking schemes that ultimately communicate the same information (for example "Hazardous Pharmaceutical Waste" or "Hazardous Compatible Pharmaceutical Waste").
21	V. Detailed Discussion of the Proposed Rule; C. What are the proposed standards for healthcare facilities that manage non-creditable waste pharmaceuticals?	58034	Containers	The Agency also requests comment on security concerns regarding having the word "pharmaceutical" marked on the containers.	Stericycle responded during the 2009 proposal that there may be more potential for diversion if the labels stated it was a pharmaceutical waste. Since that time we have gained considerable experience with programs in healthcare facilities. Experience has shown that this poses no greater threat than if it were not labeled as pharmaceuticals and it does provide clarity for healthcare workers as to where to place these wastes. Stericycle supports labeling as pharmaceuticals.
22	V. Detailed Discussion of the Proposed Rule; C. What are the proposed standards for healthcare facilities that manage non-creditable waste pharmaceuticals?	58035	Training	In order to comply with the LDRs, healthcare facilities will need to segregate these wastes from the organic pharmaceutical hazardous wastes so that they can be properly treated by the TSDF.	While the EPA did not request specific comment in this section, Stericycle believes this is yet another section of the proposed rule that further supports the need for proper documented training for generators.
23	V. Detailed Discussion of the Proposed Rule; C. What are the proposed standards for healthcare facilities that manage non-creditable waste pharmaceuticals?	58035	RX Waste Mgmt.	Agency seeks comment on whether it is necessary to incorporate into the regulations a requirement to segregate these wastes and whether additional labeling requirements are necessary to identify the hazardous waste pharmaceuticals that are not suitable for incineration.	The key to proper waste management is regulatory clarity and applicability. Stericycle supports proper segregation at the source to avoid potential safety and compliance risks. This must include proper labeling and container requirements for these waste streams. Often the transporter will not have the ability to identify materials in the container to properly sort on site prior to transporting to a TSDF (i.e. individual pills in containers). Therefore requiring labeling to properly identify the hazardous waste pharmaceuticals not suitable for incineration or other management is essential. At a minimum there should be proper labeling and waste code identification for the waste prior to leaving the generator and corresponding information should be identified on the manifest. This section further supports the need for proper documented training for generators.

ATTACHMENT A: STERICYCLE'S DETAILED SECTION BY SECTION REVIEW OF COMMENTS SPREADSHEET PHARMA PROPOSED RULE					
#	Section Name	FR Page#	Topic	EPA Request for Comment	Stericycle Section Specific Comment
24	V. Detailed Discussion of the Proposed Rule; C. What are the proposed standards for healthcare facilities that manage non-creditable waste pharmaceuticals?	58038	RX Waste Mgmt.	As mentioned earlier, because this proposed rule does not require that healthcare facilities label their waste with the hazardous waste codes, the TSDF must always analyze the incinerator ash for these seven constituents—lindane, chloroform, m-cresol, dichlorodifluoro methane, trichloromonofluoromethane, phenacetin, and phenol—according to their waste analysis plan, as they could possibly be present in any shipment of organic hazardous waste pharmaceuticals.	As Stericycle commented, proper labeling of the waste materials, including waste codes prior to transportation and treatment at a TSDF is important. TSDF treatment facilities require profiles to ensure their compliance with their permit conditions. Therefore requiring labeling to properly identify the hazardous waste pharmaceuticals not suitable for incineration or other management is essential. At a minimum there should be proper labeling and waste code identification for the waste prior to leaving the generator and corresponding information should be identified on the manifest. This section further supports the need for proper documented training for generators.
25	V. Detailed Discussion of the Proposed Rule; C. What are the proposed standards for healthcare facilities that manage non-creditable waste pharmaceuticals?	58039	RX Waste Mgmt.	b. Incineration of mercury-containing hazardous waste pharmaceuticals (*entire section referenced)*	As Stericycle commented, proper labeling of the waste materials, including waste codes prior to transportation and treatment at a TSDF is important. TSDF treatment facilities require profiles to ensure their compliance with their permit conditions. Therefore requiring labeling to properly identify the hazardous waste pharmaceuticals not suitable for incineration or other management is essential. At a minimum there should be proper labeling and waste code identification for the waste prior to leaving the generator and corresponding information should be identified on the manifest. This section further supports the need for proper documented training for generators.
26	V. Detailed Discussion of the Proposed Rule; C. What are the proposed standards for healthcare facilities that manage non-creditable waste pharmaceuticals?	58041	Reporting and Records	. . . proposed recordkeeping requirements for healthcare facilities managing their non-creditable hazardous waste pharmaceuticals in accordance with the standards proposed in this document.	Stericycle supports the proper recordkeeping as outlined in this section and would recommend that documented training as well as the tracking of waste being shipped (7 day requirement and any discrepancies) also be included under the recordkeeping section for the same required time period.
27	V. Detailed Discussion of the Proposed Rule; C. What are the proposed standards for healthcare facilities that manage non-creditable waste pharmaceuticals?	58042	CESQG	The Agency solicits comment on this new provision under this subpart, including whether any additional conditions should be imposed. In recommending any additional conditions, the Agency requests that commenters provide their rationale for the additional condition(s), as well as why such additional condition(s) would not pose an undue burden on healthcare facilities that are CESQGs. In addition, the Agency solicits comment on whether it might be appropriate to allow facilities, other than those meeting the proposed definition of a healthcare facility, to accept hazardous waste pharmaceuticals from an off-site CESQG (e.g., a military medical logistics facility).	• Consolidation of non-creditable pharmaceutical wastes at a consolidation location could have its advantages for the CESQG, however it presents challenges to the receiving facility. The EPA states that the CESQG does not have to mark the material with what is inside and they are not required to manifest it or provide any shipping description information or follow any specific packaging requirements, yet the receiving facility must maintain records of the shipment for 3 years. What would the receiving facility keep record of? Additionally, EPA states in sections throughout that they are concerned about security of material and diversion. Even though we do not believe diversion issues are really within EPA's purview necessarily, these untracked shipments of pharmaceuticals are fraught with potential for diversion. This is equally true of potentially creditable waste being shipped to a reverse distributor. • Consolidation of potentially creditable pharmaceuticals at remote consolidation location could have its advantages for CESQGs, however as stated above this also presents challenges to the receiving facility to maintain compliance. There needs to be minimum requirements set so that the receiving facility understand and can track that material that is intended to be shipped for creditable hazardous waste to a potential reverse distributor. For these reasons we do not believe that consolidation of potentially creditable pharmaceuticals should be consolidated. (Please see attached letter for further information) • Consolidation of pharmaceuticals could occur across state lines which may have differing requirements for CESQGs. We have experienced this problem under current regulatory regime and it has been very confusing and frustrating for the generator, transporter and regulator. This issue is not addressed in the regulations as outlined and must be discussed, otherwise consolidation could become very problematic for all involved. Stericycle recommends that there be some minimum standards set for the proper tracking and shipment of pharmaceuticals (either for consolidation, waste destruction or reverse distribution) for CESQGs. We recommend that the Agency consider the packaging, labeling and marking standards as proposed in section 266.508(a)9(1)(i)-(iii) be required for CESQGs as well.
28	V. Detailed Discussion of the Proposed Rule; E. What are other proposed novel prohibitions, exemptions and other unique management requirements for hazardous waste pharmaceuticals?	58048	No Sewering	EPA requests comment on whether there are additional technologies that would be appropriate to include for the destruction of hazardous waste pharmaceuticals that are also controlled substances.	While Stericycle agrees with the conditional exemption for the RCRA requirements for pharmaceuticals that are both RCRA hazardous waste and DEA controlled substances, we would request that the EPA also allow the use of HMIWI incinerators for the proper incineration of these pharmaceutical wastes (please see accompanying letter for further details). Restricting the use of other alternative treatment could cause additional environmental harm (transporting long distances) and be more costly . There could be technologies in the future so the EPA should consider language that allows for approval of other alternative technologies to remain flexible. Often these materials are already in vials or syringes that are considered sharps.
29	V. Detailed Discussion of the Proposed Rule; E. What are other proposed novel prohibitions, exemptions and other unique management requirements for hazardous waste pharmaceuticals?	58049	No Sewering	EPA believes that the DEA tracking and shipping requirements are sufficient to act in lieu of the RCRA hazardous waste manifest and hazardous waste transporter requirements. EPA requests comment on this assessment.	Stericycle agrees that the DEA tracking and shipping documents provide sufficient information and would support that they be used for this limited waste stream.

ATTACHMENT A: STERICYCLE'S DETAILED SECTION BY SECTION REVIEW OF COMMENTS SPREADSHEET PHARMA PROPOSED RULE					
#	Section Name	FR Page#	Topic	EPA Request for Comment	Stericycle Section Specific Comment
30	V. Detailed Discussion of the Proposed Rule; E. What are other proposed novel prohibitions, exemptions and other unique management requirements for hazardous waste pharmaceuticals?	58050	No Sewering	. . . we are proposing as an acceptable method of disposal of the long-term care facility's hazardous waste pharmaceuticals would be to place them in a DEA collection receptacle, even if they are not controlled substances.	This section of the regulation is not feasible. Take back kiosks for controlled substances are intended to be used by end users and not the DEA registrants. We do not think this is a workable solution and would recommend that they follow the same conditions required under the CESQG requirements if they are a CESQG.
31	V. Detailed Discussion of the Proposed Rule; E. What are other proposed novel prohibitions, exemptions and other unique management requirements for hazardous waste pharmaceuticals?	58051	Household waste	The Agency solicits comments on all these provisions.(home generated waste and collection programs) must still be incinerated	Stericycle supports the position that pharmaceuticals collected at household pharmaceutical collection and take-back events and collected in DEA authorized collection receptacles should continue to be excluded from regulation as household hazardous waste. Stericycle recommends that the EPA clarify and confirm that these materials will remain exempt from hazardous waste regulations. Additionally, Stericycle recommends that options for the proper disposal of household collection event or DEA authorized collection receptacles remain open to any facility which is properly permitted and allowed to accept and manage this type of waste. This should include Hospital Medical Infectious Waste Incinerators (HMIWI) that are properly permitted to accept such wastes (please see accompanying letter for further details on HMIWI). We recommend that the limitation on the type of facility be removed and rather the regulations specify "a facility which is properly permitted to accept this type of waste may do so". Requiring hazardous waste incineration has a potential environmental impact of having to transport wastes long distances to the few available hazardous waste incinerators and will drive up the cost of these collection events, which are often already limited in funding.
32	V. Detailed Discussion of the Proposed Rule; E. What are other proposed novel prohibitions, exemptions and other unique management requirements for hazardous waste pharmaceuticals?	58055	Residue	. . .to whether "RCRA empty" pharmaceutical containers that are the original pharmaceutical packages should be destroyed prior to placing them in the trash.	While we understand the concern for security, this section is very limiting and narrow. The majority of pharmaceutical waste packaging that is disposed of is from non-hazardous pharmaceuticals, which this rule does not regulate and will not be able to reduce potential diversion of these containers. The way that this is described in the preamble, it does not seem to allow for the ability for the healthcare facility to chose an option to securely send this waste off site for ultimate destruction. Stericycle strongly suggests that EPA remove this requirement altogether. However, should the EPA continue with this unreasonable requirement, Stericycle suggests that the EPA provide language that requires the generator to destroy the packaging prior to placing them into the regular municipal trash or to have an alternative secure disposal option. The EPA should define the term "destroy" to ensure healthcare facilities have a clear understanding on how to maintain compliance with this requirement.
33	V. Detailed Discussion of the Proposed Rule; E. What are other proposed novel prohibitions, exemptions and other unique management requirements for hazardous waste pharmaceuticals?	58056	RMW/ Sharps	EPA is concerned that the residues remaining in the syringes could be aerosolized during autoclaving and inadvertently expose workers to the aerosolized hazardous waste residues, posing risks (via pulmonary exposure) to those present during venting of the autoclave. Research suggests that autoclaving may even increase the toxicity of certain drugs.135 EPA seeks comment on the extent of risks associated with autoclaving hazardous waste residues leftover in syringes and whether it is necessary to place a limit on the volume of residue or the volume of the syringe to which this conditional exemption would apply or whether any other conditions would be appropriate	Stericycle has outlined this section with four main issues in mind (a) while there may be a study regarding the exposure during autoclave venting we are unaware of any specific instance where this has caused a direct safety issue; we believe this strongly stated position is misplaced as the rational for not having pharmaceuticals managed through an autoclave; (b) more immediate disposal of sharps is safer for healthcare and waste workers and more compliant with OSHA regulations; (c) classification of sharps as regulated medical waste is appropriate for proper transportation of these waste streams; (d) majority of injectable wastes are not hazardous wastes thus placing undue risk for a nominal environmental benefit. Based on the formulary information that Stericycle has evaluated approximately .13% of the injectable medications are considered a hazardous waste. For these reasons, Stericycle strongly supports that there be an exemption for syringes with residue, regardless of the amount of material remaining within the syringe.
34	V. Detailed Discussion of the Proposed Rule; E. What are other proposed novel prohibitions, exemptions and other unique management requirements for hazardous waste pharmaceuticals?	58056	Residue	Other Deliver Devices: EPA seeks comment on whether these proposed provisions address stakeholder concerns, while protecting human health and the environment. Related to IV bags, tubing, creams/gels and aerosols. . .	Stericycle feels that the EPA definition of RCRA empty was clear and most in the healthcare industry were already accustomed to this idea. This will now potentially cause more waste to be placed unnecessarily into the hazardous waste stream. For example, currently many IV bags that are mostly empty or that would have met the definition of empty are from chemotherapy treatments and are managed through the medical waste incineration process as often times they also have sharps. EPA stated that they felt that bags were cut to be dispensed for drain disposal. It has not been Stericycle's experience with generators that this is a practice commonly used by the healthcare industry with chemotherapy wastes. They are typically fully used and then placed into the trace chemotherapy yellow containers for HMIWI incineration or sent back to the pharmacy. This is actually already part of many state medical waste regulations which require medical waste incineration of this material. We would strongly recommend that this process which is already working be maintained, or that there be a separation for the IV bags which would meet the definition of empty.
35	V. Detailed Discussion of the Proposed Rule; F. What re the proposed standards for shipping hazardous waste pharmaceuticals?	58056	Shipping	EPA requests comment on this proposed approach for manifesting non- creditable hazardous waste pharmaceuticals from a healthcare facility.	Proper waste identification is essential for transportation. Improper waste identification can lead to Department of Transportation (DOT) violations and potential permit condition violations at the treatment facilities, not to mention potential safety risks such as fires while in transport. Transporters and destruction facilities will not want to take on such liabilities. While the Agency attempted to address the inability of healthcare facilities to make proper waste determination at the point of generation by not requiring waste codes on the containers or on the manifest, it does not relieve the transporter of the DOT regulatory burdens (FR pg. 58039 V.C.9 – Shipments of Non-Creditable Hazardous Waste Pharmaceuticals Offsite From healthcare Facilities – "The fact that EPA is proposing to not require hazardous waste codes for shipping hazardous waste pharmaceuticals is not intended to alter or impact any Department of Transportation (DOT) requirements for the shipment of these hazardous wastes."). Stericycle supports proper segregation at the source to avoid potential safety and compliance risks.

ATTACHMENT A: STERICYCLE'S DETAILED SECTION BY SECTION REVIEW OF COMMENTS SPREADSHEET PHARMA PROPOSED RULE					
#	Section Name	FR Page#	Topic	EPA Request for Comment	Stericycle Section Specific Comment
36	V. Detailed Discussion of the Proposed Rule; F. What re the proposed standards for shipping hazardous waste pharmaceuticals?	58057	Shipping	EPA requests comment regarding the proposed manifest and transportation requirements for non-creditable hazardous waste pharmaceuticals from healthcare facilities and evaluated hazardous waste pharmaceuticals from pharmaceutical reverse distributors.	EPA notes in the preamble that potentially creditable hazardous waste pharmaceuticals pose a low risk during shipment due to their form, packaging, and small quantities. Thus, a spill or release causing a negative environmental impact would be unlikely. However, even after making this assessment, EPA requires the healthcare facility or reverse distributer that is shipping potentially creditable hazardous waste pharmaceuticals to follow extraneous steps. These steps include notifying the receiving facility of the intent to ship, complying with pre-transportation requirements of 266.508(a)(1)(i)-(v) (DOT packaging, labeling, marking, placarding, and shipping paper requirements). Also, the receiving facility must provide confirmation of delivery, and the shipper must contact the receiving facility if they haven't received confirmation in 7 days. Stericycle understands the EPA's interest in requiring these steps to ensure the security and confirmation of receipt of shipments of pharmaceutical wastes, we don't understand why the EPA would not be equally concerned with the shipments allowed under the proposed rule from a CESQG to another healthcare facility that is an authorized consolidation point for CESQG wastes. These shipments between a CESQG and an authorized consolidation point would represent substantially more volume than the material sent back to a reverse distributor as potentially creditable, and yet the EPA is proposing no pre-notification of shipment, or confirmation of receipt by the CESQG consolidation point. Stericycle believes it would be important to keep the requirements similar for these two shipment processes.
37	V. Detailed Discussion of the Proposed Rule; F. What re the proposed standards for shipping hazardous waste pharmaceuticals?	58059	Shipping	the Agency requests comment on whether any additional requirements, such as reporting to the implementing agency, are necessary in such cases.; this is in regards to shipments not arriving within 7 days	Stericycle does not agree that there should be a requirement to report to the implementing agency within 7 days. This time frame is too short. Notification should only occur if a shipment is truly lost in shipment and that the time frame is not key here. This is consistent with other regulatory requirements, such as those for DEA controlled substances. Stericycle suggests that the EPA remove the time frame requirement but rather reporting be required if the shipment is not recovered.
38	V. Detailed Discussion of the Proposed Rule; F. What re the proposed standards for shipping hazardous waste pharmaceuticals?	58059	Shipping	The Agency 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 7 calendar days and the steps must be taken to locate the shipment.	Stericycle does not agree that there should be a requirement to report to the implementing agency within 7 days. This time frame is too short. Notification should only occur if a shipment is truly lost in shipment and that the time frame is not key here. This is consistent with other regulatory requirements, such as those for DEA controlled substances. Stericycle suggests that the EPA remove the time frame requirement but rather reporting be required if the shipment is not recovered.
39	V. Detailed Discussion of the Proposed Rule; G. What are the Proposed Standards for Pharmaceutical Reverse Distributors?	58061	RD Operations	However, the Agency requests comment as to whether we should include the regulatory standard directly in 40 CFR part 266, subpart P, instead of providing a cross-reference to the standard in 40 CFR part 265 in an effort to make the rules easier to follow and comply with.	Stericycle fully supports that all sections be included in 40 CFR 266 Subpart P so that everything is in one place. This would be consistent with the efforts in the generator rule.
40	V. Detailed Discussion of the Proposed Rule; G. What are the Proposed Standards for Pharmaceutical Reverse Distributors?	58062	RD Operations	Maintaining inventory on site: However, EPA requests comment on whether this practice is already commonly followed. (in the regulation it states copy of inventory for the life of the facility so long as it is subject to this subpart)	Stericycle agrees and supports that maintaining an inventory is reasonable and follows current practice. However we feel that maintaining the inventory for the life of the facility so long as it is subject to this subpart is unreasonable and unnecessary and would request that these documents be consistent with the way LDR's and manifests are maintained for 3 years. We feel this is more closely aligned with the LQG generator rules.
41	V. Detailed Discussion of the Proposed Rule; G. What are the Proposed Standards for Pharmaceutical Reverse Distributors?	58062	RD Operations	EPA is proposing a similar requirement for pharmaceutical reverse distributors: they must prevent unknowing entry, and minimize the possibility for the unauthorized entry into the portion of the facility where potentially creditable and evaluated hazardous waste pharmaceuticals are kept (e.g., a receiving area and accumulation area).	Stericycle supports this initiative and it is something that is consistent with the way reverse distributors operate, especially those with DEA registrations. However, this is likely to be an issue for other storage/consolidation areas for CESQG and this requirement should be the same for those types of facilities which don't have any inventory and could have greater opportunity for mismanagement or diversion.
42	V. Detailed Discussion of the Proposed Rule; G. What are the Proposed Standards for Pharmaceutical Reverse Distributors?	58062	RD Operations	EPA requests comment on the 90-day timeframe and whether this timeframe is sufficient, or whether an alternative timeframe should be allowed.	Stericycle would accept the 90 day time limit but, we would suggest that the EPA consider a 180 day option.
43	V. Detailed Discussion of the Proposed Rule; G. What are the Proposed Standards for Pharmaceutical Reverse Distributors?	58062	RD Operations	We anticipate that most pharmaceutical reverse distributors would use the inventory system to verify the 90-calendar day timeframe rather than using an additional requirement of labeling containers with dates for verification, but we request comment on this issue. We also request comment on whether EPA needs to specify a method of documenting that 90 calendar days is not exceeded.	Stericycle supports the idea that there should be alternative ways to identifying the container coming into the facility to labeling each container and would suggest that this remain open for operators to chose.

ATTACHMENT A: STERICYCLE'S DETAILED SECTION BY SECTION REVIEW OF COMMENTS SPREADSHEET PHARMA PROPOSED RULE					
#	Section Name	FR Page#	Topic	EPA Request for Comment	Stericycle Section Specific Comment
44	V. Detailed Discussion of the Proposed Rule; G. What are the Proposed Standards for Pharmaceutical Reverse Distributors?	58063	RD Operations	EPA is proposing to allow the EPA Regional Administrator to grant a time extension at their discretion on a case-by-case basis. EPA requests comment on whether it is necessary to place a limit on the length of time for which an extension may be granted. - this is in regards to the potential of a litigation or recall - I don't' think we should have to ask for an extension with a recall	Based on Stericycle's extensive experience with recall process, we do not support that there should be a limit on the products being held due to recall. These pharmaceuticals are usually under extensive review and potentially litigation. Often there are regulatory requirements placed on the manufacturer(s) by the FDA and they need to hold those products as the decision to discard these products have not been made. This will get very confusing and would place an increased burden on the reverse distributors to have to report and request continuation of time for a product to be held due to a recall. These materials are not considered waste due to the nature of the circumstances and should not be regulated under these rules, until such time that the recall time frame has been lifted by the FDA or litigation releases the products. At that time, the pharmaceuticals would need to be managed under these regulations.
45	V. Detailed Discussion of the Proposed Rule; G. What are the Proposed Standards for Pharmaceutical Reverse Distributors?	58063	RD Operations	Closure requirement under vi.	Stericycle supports closure conditions, but it should be clear what that means (if cross referencing to 265.111 as identified in the preamble as it does not cross reference in the actual regulatory citation). EPA should state the requirement specifically in the regulation under 266 rather than referencing to other regulations in other sections since it was intended to make this section sector specific. This would also ensure that if that section changes in the future due to other regulatory conditions that it doesn't impact PRDs. Lastly, the main burden of closure plan approval typically falls on the state regulatory agencies and this issue needs to remain specific to PRD.
46	V. Detailed Discussion of the Proposed Rule; G. What are the Proposed Standards for Pharmaceutical Reverse Distributors?	58063	RD Operations	We request comment on whether EPA's understanding regarding this type of situation is representative. - this is in regards to reporting when non-creditable or nonconforming waste is sent to a PRD - there is also a requirement to send a report to EPA within 15 days and the PRD must manage the waste and pass on the costs	EPA has provided a much needed definition of potentially creditable hazardous waste pharmaceutical, however it may fall short. At what state would EPA consider this material to be non-creditable if it was identified as not receiving credit the first time? Second time? Third time? Would the generator be responsible of maintaining records of the non-creditable items? Finally, the reporting time frame should mirror the evaluation period of 21 days. Multiple dating schemes will lead to confusion in operations.
47	V. Detailed Discussion of the Proposed Rule; G. What are the Proposed Standards for Pharmaceutical Reverse Distributors?	58063	Reporting and Records	viii. *Recordkeeping- entire section*	Recordkeeping requirements for reverse distributors are already fairly secure. We understand that EPA would like to hold PRD accountable for more as they tend to have more consolidated waste stream and it is likely to have fewer employees to manage the wastes (unlike healthcare with a large diverse staff and retail which may have seasonal employees with less training), however some requirements are unreasonable or unclear. Under section V.G.3.a.ii Inventory (FR pg. 58061) it states that the PRD " must keep an inventory of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that are on-site." This is not unreasonable, however in the actual regulation under §266.510(a)(9)(iii) (FR pg. 58089) it states that "A copy of its inventory for as long as the facility is subject to this subpart and. . ." It is not reasonable to require that the inventory be maintained for the life of the facility. Stericycle would recommend that the inventory be maintained for three years as is required of all other reasonable recordkeeping.
48	V. Detailed Discussion of the Proposed Rule; G. What are the Proposed Standards for Pharmaceutical Reverse Distributors?	58064	Potentially creditable waste mgmt.	However, EPA requests comment on whether CESQG healthcare facilities would benefit from being able to consolidate potentially creditable hazardous waste pharmaceuticals off-site, as well.	Stericycle commented on this issue in line 29 and in the attached letter extensively. We believe if there are no minimum requirements for CESQGs then it will make the management of these wastes potentially more confusing and more susceptible to diversion.
49	V. Detailed Discussion of the Proposed Rule; G. What are the Proposed Standards for Pharmaceutical Reverse Distributors?	58065	Training	The Agency requests comment on whether the training standards are appropriate for the specific reverse distributor personnel.	Stericycle supports the training criteria as outlined in the preamble and regulations for reverse distributors.
50	V. Detailed Discussion of the Proposed Rule; G. What are the Proposed Standards for Pharmaceutical Reverse Distributors?	58065	Reporting and Records	but we request comment regarding this requirement and whether it is necessary to specify a method for how a pharmaceutical reverse distributor must verify that the 90-day maximum accumulation time is not exceeded.	Stericycle supports the fact that EPA lets the reverse distributor determine how to verify that they are within the 90 (or greater) day limit which allows for greater flexibility.
51	V. Detailed Discussion of the Proposed Rule; G. What are the Proposed Standards for Pharmaceutical Reverse Distributors?	58066	Storage	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.	Stericycle supports that so long as materials are in their original packaging and are in good condition the closure requirement should not be mandated regardless of material.

ATTACHMENT A: STERICYCLE'S DETAILED SECTION BY SECTION REVIEW OF COMMENTS SPREADSHEET PHARMA PROPOSED RULE					
#	Section Name	FR Page#	Topic	EPA Request for Comment	Stericycle Section Specific Comment
52	V. Detailed Discussion of the Proposed Rule; G. What are the Proposed Standards for Pharmaceutical Reverse Distributors?	58066	RD Operations	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. However, if EPA is mistaken in this understanding and commenters indicate they would like to be able to use tanks, containment buildings, or drip pads, EPA would consider including in this proposal the LQG standards for accumulation in these units.	Stericycle supports that there should not be a need to include accumulation units such as tanks, containment buildings or drip pads.
53	V. Detailed Discussion of the Proposed Rule; G. What are the Proposed Standards for Pharmaceutical Reverse Distributors?	58066	RD Operations	EPA requests comments on whether its current understanding is correct and whether the 40 CFR part 265, subparts AA, BB, and CC RCRA air emission standards should be applied to pharmaceutical reverse distributors.	Stericycle agrees that the 40 CFR part 265, subparts AA, BB, and CC RCRA air emission standards should NOT be applied to pharmaceutical reverse distributors.
54	VI. Implementation and Enforcement A. Healthcare Facilities	58068	General	to determine whether a healthcare facility is a subject to 40 CFR part 266, subpart P, or a CESQG regulated under § 261.5, a healthcare facility must count all the hazardous waste – pharmaceutical and non-pharmaceutical – it generates in a calendar month. In	Stericycle comments that there is a need for the EPA to clarify how the Subpart P and CESQG applicability intersect. EPA needs to provide better clarity about the applicability of the rule before the generator applies it. This will be key in the generator determining their generator status before applying the rule.
55	VI. Implementation and Enforcement A. Healthcare Facilities	58068	General	in addition, if a healthcare facility does not want to keep track of the amount of hazardous waste it generates to ensure it does not exceed the CESQG quantity limits, it could choose to operate under this proposed rule. If it chooses to operate under this proposed rule, however, a healthcare facility must comply with all the requirements of this subpart for the management of its hazardous waste pharmaceuticals.	Stericycle comments that there is a need for the EPA to clarify how the Subpart P and CESQG applicability intersect. EPA needs to provide better clarity about the applicability of the rule before the generator applies it. This will be key in the generator determining their generator status before applying the rule.

ATTACHMENT B

COMPARISON OF REGULATORY LIMITS FOR INCINERATOR LIMITS

ATTACHMENT B: COMPARISON OF REGULATORY LIMITS FOR INCINERATOR LIMITS

HMIWI	= Hospital, Medical, Infectious Waste Incinerator (permit specific - aprox 20 tons/day)
MWC	= Municipal Waste Combustor (Large over 250Tons/day; small 35-250 Tons/day)
HWC	= Hazardous Waste Combustor (permit specific)

Limits may vary by incinerator type and state regulations or permit conditions; limits shown are for federal limits only

Subpart (40 CFR Part 60 unless otherwise noted)	Ce		Cb	BBBB	BBBB	40 CFR Part 63, Subpart EEE
Type of Combustion/Incineration	HMIWI		MWC	MWC	MWC	HWC
Unit Type	Large, Commercial		Large	Small/Class I	Small/Class II	Incinerators
New or Existing	Existing		Existing	Existing	Existing	Existing
Date/Status (Proposed, Final)	1997 Final	2009 Final	2000 Final	2000 Final	2000 Final	2005 Final/2008 Amendment
Pollutant, units						
Particulate, grains/dscf	**0.015**	**0.011**	**0.011**	**0.012**	**0.031**	**0.013**
Nitrogen Oxides, ppmv	**250**	**140**	**165-250***	**170-380***	**170-380***	**NA**
Carbon Monoxide, ppmv	**40**	**11**	**50-250***	**50-250***	**50-250***	**100**
Sulfur Dioxide, ppmv	**55**	**9.0**	**29**	**31**	**77**	**NA**
Hydrogen Chloride, ppmv	**100**	**6.6**	**29.0**	**31**	**250**	**32.0**
Cadmium, milligrams/dscm	**0.16**	**0.0092**	**0.035**	**0.040**	**0.10**	**0.230****
Lead, milligrams/dscm	**1.2**	**0.036**	**0.400**	**0.490**	**1.6**	
Mercury, milligrams/dscm	**0.55**	**0.018**	**0.050**	**0.080**	**0.080**	**0.130**
Total Dioxins/Furans, nanograms/dscm	**125**	**9.3**	**30-35**	**30-60**	**125**	**NA**
TEQ Dioxins/Furans, nanograms/dscm	**2.3**	**0.054**	**NA**	**NA**	**NA**	**0.20-0.40**

Subpart (40 CFR Part 60 unless otherwise noted)	Ec		Eb	AAAA	AAAA	40 CFR Part 63, Subpart EEE
Type of Combustion/Incineration	HMIWI		MWC	MWC	MWC	HWC
Unit Type	Large, Commercial		Large	Small/Class I	Small/Class II	Incinerators
New or Existing	New		New	New	New	New
Date/Status (Proposed, Final)	1997 Final	2009 Final	2000 Final	2000 Final	2000 Final	2005 Final/2008 Amendment
Pollutant, units						
Particulate, grains/dscf	**0.015**	**0.0080**	**0.009**	**0.010**	**0.010**	**0.0016**
Nitrogen Oxides, ppmv	**250**	**140**	**150**	**150**	**500**	**NA**
Carbon Monoxide, ppmv	**40**	**11**	**50-150***	**50-200***	**50-200***	**100**
Sulfur Dioxide, ppmv	**55**	**8.1**	**30**	**30**	**30**	**NA**
Hydrogen Chloride, ppmv	**15**	**5.1**	**25**	**25**	**25**	**21**
Cadmium, milligrams/dscm	**0.04**	**0.00013**	**0.010**	**0.020**	**0.020**	**0.010****
Lead, milligrams/dscm	**0.07**	**0.00069**	**0.140**	**0.20**	**0.20**	
Mercury, milligrams/dscm	**0.55**	**0.0013**	**0.050**	**0.080**	**0.080**	**0.0081**
Total Dioxins/Furans, nanograms/dscm	**25**	**9.3**	**13**	**13**	**13**	**NA**
TEQ Dioxins/Furans, nanograms/dscm	**0.6**	**0.035**	**NA**	**NA**	**NA**	**0.11-0.20**

NOTES:

*Standards for municipal waste depends on incinerator type; ranges are shown.

**Lead and Cadmium combined limit (Semivols).