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Via Electronic Transmission: www.regulations.gov

U.S. Environmental Protection Agency
EPA Docket Center (EPA/DC)
1200 Pennsylvania Ave., NW
Washington, DC 20460

Re: **Docket ID No.** EPA-HQ-RCRA-2007-0932

The Healthcare Waste Institute (HWI) of the National Waste & Recycling Association (NWRA) is pleased to offer comments on the proposed revisions to the Management Standards for Hazardous Waste Pharmaceuticals (Pharmaceutical Rule) (80 FR 58014). The HWI represents manufacturers and service providers as well as other professionals in the healthcare waste management industry. Our members provide transportation and treatment of pharmaceutical wastes to the healthcare sector. The NWRA is a not-for-profit trade association representing private solid waste and recycling collection, processing and management companies.

The HWI is pleased that Environmental Protection Agency (EPA) is developing rules to manage unused or discarded hazardous pharmaceutical materials. As the draft rules indicate, there are multiple agencies and multiple divisions within agencies at the federal and state levels that play a role in the management of pharmaceuticals. Multiple regulations that often overlap or conflict with each other make the management of pharmaceuticals from dispensing to disposal extremely complex.

We have developed some general comments that apply to many sections of the rule. In addition, we have developed some specific comments that are included in the attached table.

General Comments

Hazardous waste generator rule

HWI supports the implementation of the Pharmaceutical Rule. It is on the same timeline to the proposed Hazardous Waste Generator Improvements Rule (HW rule). Should the timeline for the Pharmaceutical Rule slip or the two rules fall out of sequence, HWI is concerned that the industry could inadvertently become subject to all the requirements of the HW rule. We suggest that the two rules become effective concurrently.

Hazardous waste determination

Healthcare providers are not the most qualified to make hazardous waste determinations for the pharmaceuticals that they dispose. Yet, some determination is necessary for the appropriate management of these materials. We recommend that the EPA require manufacturers to include information to the healthcare providers on which pharmaceuticals are considered to become hazardous waste when discarded.

Hazardous Waste Pharmaceutical Management Plan

We recommend that EPA require Large Quantity Generators (LQG) and Small Quantity Generators (SQG) to develop and maintain a Hazardous Waste Pharmaceutical Management Plan (HWPMP). The HWPMP should include site-specific policies and procedures that comport with the requirements of the proposed rule.

At a minimum, the HWPMP should:

- specify container locations
- describe security measures
- describe container standards
- describe procedures for managing non-creditable hazardous waste pharmaceuticals
- describe procedures for accepting material from CESQGs
- detail communications procedures
- identify responsible personnel
- establish training and recordkeeping procedures.

We believe that requiring a site-specific plan addresses numerous issues required by the Pharmaceutical Rule without becoming too prescriptive. Additional discussion of the HWPMP is included in the attached table.

Waste codes and/or shipping names or descriptions

We believe that removing waste codes from the manifests as proposed does not reduce the regulatory burden for generators, shippers or TSDFs beyond saving physical space on the manifest itself. The generator will still need to develop the waste codes while performing waste determinations and waste compatibility, the transporters are required to have the shipping name and description per DOT regulations, and a TSDF may require the waste codes in order to comply with LDRS and air permits. EPA should consider creating a category of hazardous waste for pharmaceuticals that is truly cradle to grave, where waste determinations, waste codes, and

other regulatory mechanisms not suited for pharmaceuticals are abandoned, and a method of disposal is provided in an easy and inexpensive manner.

Conditionally Exempt Small Quantity Generator (CESQG) exemption

Exempting CESQGs creates downstream burdens on the management of the hazardous waste pharmaceuticals received from these facilities. For example, how would a reverse distributor manage its own limitation and compliance when it could receive unlimited quantities of potentially creditable hazardous waste pharmaceuticals from CESQGs? Is EPA proposing to extend the exemption for materials received from CESQGs to the downstream handlers of this material? Due to the complexities for RDs to comply with this issue, we recommend that the CESQGs operating under Subpart P be required to comply with the same notification requirements as LQG/SQGs.

Non-hazardous pharmaceuticals management

EPA includes discussion suggesting managing non-hazardous pharmaceuticals together with hazardous because quantity would not affect a facility's hazardous waste generator category. While this would not affect the generator status, the discussion fails to consider the difference in cost for managing non-hazardous versus hazardous materials. We believe the discussion of non-hazardous pharmaceuticals will be confusing to generators and the rule should clearly state that the Pharmaceutical Rule does not apply to non-hazardous pharmaceuticals. Writing the recommendation into the regulation is not necessary and could create more confusion for generators.

RCRA empty pharmaceutical packaging

We support the exemption for containers that have been fully dispensed. We are concerned about the requirement to "destroy" the containers prior to placing them in the trash. Defacing the containers would be non-invasive. However, as written in the rule, defacing the packaging is not considered acceptable. Instead EPA suggests shredding the packaging as more appropriate. We believe this could expose workers to additional hazards from trace residues becoming airborne. We suggest maintaining the exemption for the containers and revising the packaging destruction requirements so that workers are not exposed.

Inclusion of HMIWI incinerators

EPA discusses the use of hazardous waste and municipal waste combustors but fails to include Hospital Medical and Infectious Waste Incinerators (HMIWI) for management of home generated pharmaceutical wastes and DEA controlled substances that become hazardous pharmaceutical waste. Such facilities operate under more restrictive standards than municipal waste combustors, and healthcare providers already have vendor relationships in place with access to HMIWI facilities. HWI believes that these facilities, in consideration of applicable permitting requirements, should be included throughout the rule as an option for the disposal of Hazardous Pharmaceutical Waste.

Sewering issue

HWI fully supports efforts to reduce discharging hazardous pharmaceutical waste that might find its way into ground and surface water through sewage discharge. However, an outright ban on sewer discharge removes the local wastewater treatment facility's ability to decide the best course of action for specific discharge requests such as for controlled substances including hazardous wastes. Further, an outright ban on sewer discharge removes any option to consider future technologies that could render hazardous pharmaceutical waste inert or harmless.

Again while supporting the effort and intent, an outright ban on sewer discharge results in an ever increasing amount of pharmaceuticals that require incineration, and with the number of permitted incinerators declining in number this poses an additional burden on these units. It also requires trucking the pharmaceutical waste over long distances which increases both security and environmental risks.

As a result we recommend that EPA instead require that "in the absence of specific approval from the local wastewater treatment agency or POTW to allow for such discharge, EPA prohibits the discharge of pharmaceutical waste to the sewer."

Conclusion

The HWI appreciates EPA's consideration of these recommendations. Should you have any questions, please call me at 202-364-3724 or e-mail at agermain@wasterecycling.org.

Very truly yours,

Anne Germain, P.E., BCEE
Director of Waste & Recycling Technology

Row #	Section Name	FR Page#	Topic	EPA Request for Comment	HWI Comments or issues
1	IV. Background; D. EPA's Office of Inspector General Report	58020-58021	Identify new RX	EPA does not address the OIG's first two recommendations as part of this proposed rulemaking; however, in Section VII of this preamble, we solicit comment on our ongoing efforts to identify additional pharmaceuticals as hazardous wastes.	HWI suggests that the EPA look at NIOSH Table 1 (antineoplastics) and would recommend that the EPA work with the FDA and manufacturers to be able to come up with plan on how they could work together to identify what would be considered hazardous wastes.
2	V. Detailed Discussion of the proposed Rule; A. What Terms are Defined in this Proposed Rule	58021	Definitions	We see comment on the following definitions: "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."	HWI suggests that EPA clarify applicability of this rule to materials that could be both a product and a pharmaceutical under the term "non-pharmaceutical hazardous waste." For example, we suggest clarifying items that could be used both as a pharmaceutical and as a disinfect such as alcohol. In addition, we suggest adding the following defintion, "Wholesale drug distributors: Any person whose primary function is to purchase pharmaceuticals from manufacturers and sell and physically distribute them to pharmacies, hospitals, and other healthcare and retail customers. They may also engage in reverse distribution to service customers but it is not a primary business function." We recommend Wholesale drug distributors be permitted, but not required, to participate in 266 subpart P except for the reverse distribution section of their facility, should they have one.
3		58022	Definitions	We seek public comment on the Agency's decision to recognize dietary supplements as pharmaceuticals under this regulation.	HWI supports the inclusion of dietary supplements under this regulation.
4		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 undispensed pharmaceutical. EPA seeks comment on the prevalence of this situation.	See detailed section below that is discussed in the Healthcare section regarding residues.
5		58022	Definitions	The Agency also solicits information on whether any dietary supplements currently on the market meet or potentially could meet RCRA's definition of a hazardous waste.	HWI supports the inclusion of dietary supplements and believes that some current supplements will meet the definition of hazardous waste. HWI recommends that EPA work with supplement manufacturers to be able to identify what would be considered hazardous wastes based TCLP data for selenium and chromium and alcohol content.
6		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.	The definition of "potentially creditable hazardous waste pharmaceutical" should be expanded to include generics because some do have a credit policy. We also advocate for removal of the one year limit, since large pharmacy and healthcare corporations often negotiate more favorable terms for receiving credit. Further, we request that EPA provide language on consequences and penalties of sending non-creditable materials multiple times (exceeding three). Last, EPA should clarify in the rule the distinction between what is waste like and items that are potentially creditable similar to what was included in outreach presentations conducted by EPA.
7		58023	Credit	Finally, the Agency is seeking comment on additional situations where it is well known that a returned pharmaceutical will or will not receive manufacturer's credit.	Other situations where drugs might be returned for credit include experimental drugs. These drugs are not likely to be creditable but may have some return requirement associated with the trial. Otherwise, they might be managed or destroyed as Subpart P hazarouds waste.
8		58024	Definitions	EPA has decided to include "coroners" within the definition of healthcare facility, although the Agency solicits comment on including coroners within the definition of healthcare facility.	HWI supports the inclusion of coroners in the definition of healthcare facility. We suggest that the rule treat coroners that encounter household hazardous waste the same as is described for LTCF.
9		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.	HWI supports the proposed definition of healthcare facility including compounders.
10		58024	Definitions	EPA requests public comment on the proposed definition of long-term care facility, and the inclusion of assisted living facilities, skilled nursing facilities and other LTCFs that administer their residents' pharmaceuticals as an integral part of their services within the definition of "healthcare facility."	HWI suggests that residential short term treatment facilities should be included (including in-house rehab facilities) in the definition of LTCF as they could potentially have hazardous waste pharmaceuticals being used to treat their patients.

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11		58025	Definitions	Specifically, EPA asks for comment on whether the definition of "pharmaceutical reverse distributor" captures the universe of facilities acting as reverse distributors for pharmaceuticals. In addition, the Agency asks for comment regarding the intersection of DEA and EPA's definitions.	We agree that the definition of pharmaceutical reverse distributor captures the universe of these facilities. We are concerned that it would be very difficult for a forward distributor to participate in subpart P for the reverse distibution portion of their operation without including the rest of their operation. We also advocate that wholesale drug distributors share more characteristics with healthcare facilities and reverse distributors than with manufacturers. They typically stock between 30,000 and 60,000 pharmaceutical products and generally do not have detailed knowledge of the formulations of these products in terms of alcohol content, mercury and m-cresol preservatives, and other key RCRA factors, and they typically do not employ sophisticated industrial hygienists, safety officers, or others conversant with the RCRA regulations. We therefore encourage EPA to include them as healthcare facilities in subpart P. With respect to their reverse distribution component, we do not believe the majority would meet the current definition of a large quantity generator and encourage EPA not to apply this standard to drug wholesalers with respect to their reverse distribution function. Since returns are normally managed through company-owned vehicles rather than common carrier, we also do not believe the advance notice of shipment would be required. Typically pharmacies must request return authorization prior to returning products, many of which may still be indated and have active shelf life available.
12	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).	If LTCF are currently CESQGs, we believe they should continue to be CESQGs and they should also be subject to Subpart P. We suggest that CESQG/VSQG should fall under this rule. Further, HWI suggests that the status of LQG, SQG and CESQG could be made more clear. For example, if an entity were a CESQG before this rule, then they would remain so under the applicability of 266.501. Also, a LQG/SQG healthcare facility should use Subpart P in order to obtain the CESQG exemption. EPA should clarify whether a current CESQG (VSQG) who is under the 261.5 can send material to a reverse distributor. If so, would it count as a hazardous waste before it gets sent to the RD?
13	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.	HWI supports the inclusion of LTCFs as healthcare facilities.
14		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.	HWI recommends that CESQGs be considered healthcare facilities. Because CESQGs can send material back to RDs, yet are not be subject to the reporting requirements (i.e. 7 day advance notice) or possess EPA identification numbers, non-creditable pharmaceutical waste received by RDs would be difficult to track and report to EPA. We believe that unless CESQGs are included in this subpart, there is greater likelihood that the waste will go into the RMW or to the solid waste stream.
15		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.	We request that EPA include CESQGs under subpart P.
16		58028	CESQG	Agency is proposing to require for collected household waste pharmaceuticals be incinerated in §266.506.53 The Agency seeks comment on changing this recommendation to a requirement for pharmaceutical collection programs.	HWI recommends that EPA considers the following language: "The Agency recommends that collected household waste pharmaceuticals be incinerated at either a permitted hazardous waste incinerator, a Hospital Medical Infectious Waste Incinerator "HMIWI", or a large or small municipal waste combustor". In addition, we recommend removing the term feasibility from the referenced memo as it has not been defined and could be interpreted too broadly. Further, access to one or more of the identified incinerator options is universally available through a myriad of licensed collectors and transporters nationwide.
17		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 .	Since the DEA letter was released last year, many hospitals have assumed that these pharmaceuticals are not part of the DEA inventoried controlled substances and can be managed however they want to up to and including sewering. Therefore, we support the requirment for the clarification that these pharmaceuticals would need to be incinerated. Similar to our comment above, the proposed rule should include HMIWI facilities when they discuss hazardous waste incinerators and municipal waste combustors. In addition, we reiterate our comment regarding HMIWI incinerators

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18		58029	RMW/ Sharps	EPA notes that autoclaving is not an acceptable method of treating hazardous wastes that are also medical waste.	HWI supports EPA's position that autoclaving is not acceptable for treating hazardous wastes that are medical wastes.
19		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.	HWI supports EPA's proposal that residue in syringes should NOT be counted in this rule, regardless of the amount contained within the syringe. Instead, syringes should be considered as part of the regular regulated medical waste stream because there is not enough substance to risk the potential healthcare and waste worker safety and exposure. The amount of residual material is so small that the environmental benefits are not worth the additional effort to segregate this material.
20		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	EPA should clarify that the non-hazardous waste pharmaceuticals are NOT required to go a hazardous waste facility so that it is clear that generators have options. There can be significant costs associated with treating all pharmaceuticals as hazardous waste both from a treatment aspect as well as from a transportation aspect. These costs have not been adequately evaluated by the EPA. Should generators follow EPA's recommendations, many solid waste pharmaceuticals will needlessly be transported across the country to the few facilities that can manage hazardous waste pharmaceuticals. With significant budgetary issues faced by healthcare facilities, these costs should not be underestimated. HWI recommends removing the suggestion from the regulations under 266.502(c) (FR pg 58085) "A healthcare facility may choose to manage its solid waste pharmaceuticals 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."
21	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.	EPA is proposing to require that a healthcare facility that does not qualify as a CESQG to submit a one-time notification as a "healthcare facility" to the appropriate EPA Regional Administrator. Healthcare facilities subject to 40 CFR part 266, subpart P will have to submit notification even if the healthcare facility has previously obtained an EPA identification number.	As stated above, HWI recommends that CESQGs be considered healthcare facilities. Because CESQGs can send material back to RDs, yet are not be subject to the reporting requirements (i.e. 7 day advance notice) or possess EPA identification numbers, non-creditable pharmaceutical waste received by RDs would be difficult to track and report to EPA. We believe that unless CESQGs are included in this subpart, there is greater likelihood that the waste will go into the RMW.
22		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.	As stated above, HWI recommends that CESQGs be considered healthcare facilities. Because CESQGs can send material back to RDs, yet are not be subject to the reporting requirements (i.e. 7 day advance notice) or possess EPA identification numbers, non-creditable pharmaceutical waste received by RDs would be difficult to track and report to EPA. We believe that unless CESQGs are included in this subpart, there is greater likelihood that the waste will go into the RMW.
23	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.	The rulemaking should clearly identify who needs to be trained. HWI recommends that the following personnel should be rquired to be trained: medication administration personnel, pharmacists and assistants, doctors, nurses, and personnel in environmental services departments. Further, the training should be function specific to each position and records documenting training should be required to be maintained. Training should address how staff is "disposing" of the waste by clarifying that disposal means putting the waste in the "proper" container - which requires "segregation" to be part of the training. Training should be conducted at the beginning of job function and annually thereafter with documentation being maintained for 3 years. This training should be outlined in their hazardous waste pharmaceutical management plan as recommended.
24		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.	Without satellite or central accumulation areas (SAA or CAA) and with allowance for collection to occur over a period of 1-year, there is potential for containers to be misplaced, lost, or mismanaged. In order to address this, we recommend that EPA require a Hazardous Waste Pharmaceutical Management Plan . This plan should include policies and procedures to ensure compliance. At a minimum, the plan should specify container locations, security, container standards, managing non-creditable hazardous waste pharmaceuticals, and training.

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25		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.	Without satellite or central accumulation areas (SAA or CAA) and with allowance for collection to occur over a period of 1-year, there is potential for containers to be misplaced, lost, or mismanaged. In order to address this, we recommend that EPA require a Hazardous Waste Pharmaceutical Management Plan. This plan should include policies and procedures to ensure compliance. At a minimum, the plan should specify container locations, security, container standards, managing non-creditable hazardous waste pharmaceuticals, and training.
26		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.	Without satellite or central accumulation areas (SAA or CAA) and with allowance for collection to occur over a period of 1-year, there is potential for containers to be misplaced, lost, or mismanaged. In order to address this, we recommend that EPA require a Hazardous Waste Pharmaceutical Management Plan . This plan should include policies and procedures to ensure compliance. At a minimum, the plan should specify container locations, security, container standards, managing non-creditable hazardous waste pharmaceuticals, and training.
27		58034	Containers	Agency is soliciting comment on the appropriateness of the proposed general labeling requirement.	It is impossible to comply with both the LDR and DOT manifest restrictions without waste codes. We are concerned that TSDFs would either 1) reject the load or 2) charge an astronomical fee because the burden is now placed on the end user to inspect and make a determination when the generator is in a better position to make that determination. TSDF will not accept containers without a profile of the material. Therefore, at a minimum, waste codes should be on the manifest for sending the waste to the final TSDF. This is especially key for the wastes that are identified to be segregated to LDRs and for DOT. This waste code process should be laid out in the Hazardous Waste Pharmaceutical Management Plan which has policies and procedures to meet this requirement and provides the needed profile for the TSDF as it is not likely that TSDFs will accept it without a profile.
28		58034	Containers	The Agency also requests comment on security concerns regarding having the word “pharmaceutical” marked on the containers.	HWI does not believe that this is an issue. Current practices include labeling containers with pharmaceuticals. This has not resulted in any problems.
29		58034	Storage	proposed accumulation time limit of one year in order to allow healthcare facilities to generate enough non-creditable hazardous waste pharmaceuticals for cost-effective shipment,	HWI supports the extended time limit if the Hazardous Waste Pharmaceutical Management Plan described above is required.
30		58034	Storage	on the proposed mechanism to request a time extension.	We recommend that EPA require facilities to have a Hazardous Waste Pharmaceutical Management Plan which include requirements for container management. Additionally, Reverse Distributors should be allowed to manage potentially creditable hazardous waste pharmaceutical (PCHWP) returns in accordance with Manufacturer’s policy. The PCHWP should have no time restrictions or requirements placed on something that is considered still in circulation. Reverse distributors guidelines for credit should fall under the same requirements Wholesalers and Manufactures are given for distribution. EPA should allow Reverse Distributors to work with manufacturer's policies & procedures for properly managing PCHWP for returned credit.
31		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.	Further segregation of organic pharmaceutical hazardous wastes supports the need for additional documented training which should be detailed in the Hazardous Waste Pharmaceutical Management Plan developed by the generator. Further, we recommend the Agency specify minimum training requirements according to job classifications.
32		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.	Further segregation of organic pharmaceutical hazardous wastes supports the need for additional documented training which should be detailed in the Hazardous Waste Pharmaceutical Management Plan developed by the generator. Further, we recommend the Agency specify minimum training requirements according to job classifications.

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33		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.	It is impossible to comply with both the LDR and DOT manifest restrictions without waste codes. We are concerned that TSDFs would either 1) reject the load or 2) charge an astronomical fee because the burden is now placed on the end user to inspect and make a determination when the generator is in a better position to make that determination. TSDF will not accept containers without a profile of the material. Therefore, at a minimum, waste codes should be on the manifest for sending the waste to the final TSDF. This is especially key for the wastes that are identified to be segregated to LDRs and for DOT. This waste code process should be laid out in the Hazardous Waste Pharmaceutical Management Plan which has policies and procedures to meet this requirement and provides the needed profile for the TSDF as it is not likely that TSDFs will accept it without a profile.
34		58039	RX Waste Mgmt.	b. Incineration of mercury-containing hazardous waste pharmaceuticals - this section is very technical and has a lot of information that is related to the treatment facilities themselves. It is difficult to understand and the relevance. The main issue is if there is no coding required how would the treatment facility know and understand they are getting this material??	It is impossible to comply with both the LDR and DOT manifest restrictions without waste codes. We are concerned that TSDFs would either 1) reject the load or 2) charge an astronomical fee because the burden is now placed on the end user to inspect and make a determination when the generator is in a better position to make that determination. TSDF will not accept containers without a profile of the material. Therefore, at a minimum, waste codes should be on the manifest for sending the waste to the final TSDF. This is especially key for the wastes that are identified to be segregated to LDRs and for DOT. This waste code process should be laid out in the Hazardous Waste Pharmaceutical Management Plan which has policies and procedures to meet this requirement and provides the needed profile for the TSDF as it is not likely that TSDFs will accept it without a profile.
35		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	HWI recommends that the 3 year time period should be from the end of generation rather than from the time the determination is made.
36		58041 - #15	LTCF	extent to which long- term care facilities keep an inventory of the pharmaceuticals that individuals self-administer, as this would facilitate the collection of the hazardous waste pharmaceuticals for proper disposal. regarding this requirement, and specifically requests comment on the various approaches that long-term care facilities use, or could use in collecting hazardous waste pharmaceuticals from individuals that self-administer their pharmaceuticals.	HWI recommends that HMIWI be permitted for the section related to the DEA. Such facilities operate under more restrictive standards than municipal waste combustors, and healthcare providers already have vendor relationships in place with access to HMIWI facilities.

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37		58042 - #15	CESQG	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).	This issue raises questions about personnel transporting hazardous waste pharmaceuticals from a CESQG facility to the point of consolidation. Would there be any restrictions on this with respect to transportation or personnel that would manage it? For example, would anyone be permitted to do it (i.e. a front office clerk or nurse)? In addition, if there is no tracking, material could easily be diverted for improper use. Even transporting empty containers could wind up being diverted. This provision is problematic for the following reasons: The CHF needs to "maintain records" of what it receives from off-site, but without specifying what those records need to reflect, this requirement is not meaningful. Without the information included in a hazardous waste manifest, such as EPA Waste Codes and weights, the CHF would have trouble: • communicating to its employees the hazards contained in the CESQG pharmaceutical waste • know its own generator status (SQG or LQG) If the CESQG transports the hazardous waste without a hazardous waste manifest, how does a First Responder know the proper exposure risks when they respond to an incident? Many pharmaceutical wastes are flammable, some are oxidizers, some are corrosives. These are distinct transportation Hazard Classes and cannot be combined in the same container. Such materials should not be transported without proper shipping papers. The CHF is essentially becoming a hazardous pharmaceutical waste TSDF without any incremental EPA regulatory oversight beyond what is required as a generator. Is there any Quality Control required of the CHF to verify what it receives from the CESQG? Is there any incremental reporting to the EPA? We recommend that LQGs that intend to receive materials from CESQGs, they should include policies and procedures in their Hazardous Waste Pharmaceutical Management Plan.
38	V. Detailed Discussion of the Proposed Rule; D. How does this proposed rule address healthcare facilities that accumulate potentially creditable hazardous waste pharmaceuticals prior to shipment to pharmaceutical reverse distributors?	58044	Potentially creditable waste mgmt.	Comment on its proposal not to require specific accumulation, container management or labeling standards for potentially creditable hazardous waste pharmaceuticals that will be transported to a reverse distributor, including no specific labeling standards for containers holding potentially creditable hazardous waste pharmaceuticals on-site prior to shipment off-site.	Without standards for labelling and managemetn, there is a significant potential for mismanagement. We recommend that EPA require a Hazardous Waste Pharmaceutical Management Plan that would have policies and procedures to help ensure that these requirement are met; should include: container locations, security, container standards, managing non-creditable hazardous waste pharmaceuticals, training etc. The reason for this is that if there is no more standards for SAA or CAA - combined with the 1 year collection, there is a potential for containers to be misplaced, stockpiled, mismanaged, and possibly diverted.

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39	V. Detailed Discussion of the Proposed Rule; E. What are other proposed novel prohibitions, exemptions and other unique management requirements for hazardous waste pharmaceuticals?	58045	No Sewering	established under 40 CFR 403.5(b)(1), which is under the Clean Water Act (CWA) regulations. The Agency seeks comment on whether it would be helpful to incorporate in 40 CFR 261.4(a)(1)(ii), a cross-reference to the CWA regulations prohibiting the sewering of liquid ignitable hazardous wastes.	HWI fully supports efforts to reduce discharging pharmaceutical waste that might find its way into ground and surface water through sewage discharge. However, an outright ban on sewer discharge removes the local wastewater treatment facility's ability to decide the best course of action for specific discharge requests. Further, an outright ban on sewer discharge removes any option to consider future technologies that could render pharmaceutical waste inert or harmless. Again while supporting the effort and intent, an outright ban on sewer discharge results in an ever increasing amount of pharmaceuticals that require incineration, and with the number of permitted incinerators declining in number this poses an additional burden on these units. It also requires trucking the pharmaceutical waste over long distances which increases both security and environmental risks. As a result we recommend that EPA instead require that "in the absence of specific approval from the local wastewater treatment agency or POTW to allow for such discharge, EPA prohibits the discharge of pharmaceutical waste to the sewer."
40		58046	No Sewering	ban the sewer disposal of hazardous waste pharmaceuticals at all healthcare facilities, including healthcare facilities that are CESQGs that generate such wastes. As part of its solicitation of comments, the Agency especially requests comment on the risk-risk tradeoffs inherent in prohibiting sewer disposal, which extends the life cycle of pharmaceutical waste, resulting in additional opportunities for diversion and increasing the possibility of inadvertent exposures for certain workers (and possibly even patients or visitors) as a tradeoff for a reduction in aquatic risks. EPA also solicits comment on whether the ban on sewer disposal should be limited to those healthcare facilities that are currently LQGs and SQGs, and not extended to CESQGs.	HWI fully supports efforts to reduce discharging pharmaceutical waste that might find its way into ground and surface water through sewage discharge. However, an outright ban on sewer discharge removes the local wastewater treatment facility's ability to decide the best course of action for specific discharge requests. Further, an outright ban on sewer discharge removes any option to consider future technologies that could render pharmaceutical waste inert or harmless. Again while supporting the effort and intent, an outright ban on sewer discharge results in an ever increasing amount of pharmaceuticals that require incineration, and with the number of permitted incinerators declining in number this poses an additional burden on these units. It also requires trucking the pharmaceutical waste over long distances which increases both security and environmental risks. As a result we recommend that EPA instead require that "in the absence of specific approval from the local wastewater treatment agency or POTW to allow for such discharge, EPA prohibits the discharge of pharmaceutical waste to the sewer."
41		58048	No Sewering	EPA requests comment on whether these are, indeed, the only pharmaceuticals in common usage that are regulated both as DEA controlled substances, and when discarded, RCRA hazardous waste.	To the best of the knowledge of the committee members, these are the only commonly used controlled substances that are also hazardous waste pharmaceuticals.
42		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. U	We recommend that EPA make allowance for development of new technologies which may meet DEA standards.
43		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.	HWI supports utilizing DEA tracking and shipping requirements in lieu of manifest and transporter requirements.
44		58049	No Sewering	request comment on whether to allow the sewering of the pharmaceutical wastage for the five hazardous wastes that are also controlled substances.	DEA does not consider sewering as meeting the "non-retrievable" standards for controlled substances.
45		58051	Household waste	The Agency solicits comments on all these provisions.(home generated waste and collection programs) must still be incinerated	HWI recommends that EPA considers the following language: "The Agency recommends that collected household waste pharmaceuticals be incinerated at either a permitted hazardous waste incinerator, a Hospital Medical Infectious Waste Incinerator "HMIWI", or a large or small municipal waste combustor". In addition, we recommend removing the term feasibility from the referenced memo as it has not been defined and could be interpreted too broadly. Further, access to one or more of the identified incinerator options is universally available through a myriad of licensed collectors and transporters nationwide.
46		58052	Residue	(1)blister packs, and delivery devices) and dispensing bottles and vials; (2) dispensed syringes; and (3) other containers, including delivery devices.	We believe the requirement to destroy RCRA containers to be outside EPA's authority. Further, without any size limit, this requirement could become extremely onerous. However, we suggest that EPA require discussion of diversion of these containers in the healthcare facility's Hazardous Waste Pharmaceutical Management Plan .

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47		58055	Residue	to whether "RCRA empty" pharmaceutical containers that are the original pharmaceutical packages should be destroyed prior to placing them in the trash.	Because empty containers do not pose an environment risk, HWI does not believe this falls under EPA's authority nor that EPA should regulate them. Further, we believe that it is unrealistic to expect healthcare providers to spend the time to destroy them. Lastly, destroying these containers could result in exposing the generator's personnel to residue resulting in OSHA and NIOSH issues.
48		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	HWI is unaware of any evidence of this type of exposure. We request that EPA provide any published data and documentation about this risk exposure. We suggest that any limitations be enacted by OSHA or NIOSH who have jurisdiction over the safety and exposure of employees. HWI supports EPA's proposal that residue in syringes should NOT be counted in this rule. Instead, syringes should be considered as part of the regular regulated medical waste stream because there is not enough substance to risk the potential healthcare and waste worker safety and exposure. The amount of residual material is so small that the environmental benefits are not worth the additional effort to segregate this material.
49		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 ivbags, tubing, creams/gels and aerosols	We strongly recommend that EPA retain the current definition of "empty" for U-listed 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 incinerated at a regulated medical waste facility. Operationally, all chemotherapy IV bags and tubing would need to be managed as hazardous waste as the proposed rule is written as it is too difficult to train nurses to manage a few drugs in this manner and others as trace chemotherapy. 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 incineration at a regulated medical waste facility. We believe the current definition of empty for other potential IV hazardous waste is sufficient as these occur very infrequently if at all. We are also very concerned about the proposed requirements to manage all "trace contaminated" gowns, gloves, pad, etc. as hazardous waste. These also are managed as trace chemotherapy waste and incinerated at a regulated medical waste facility in most cases. We again encourage EPA to offer this option as an alternative to hazardous waste management to reduce costs while maintaining environmental protection. We are not aware of any facilities emptying partially used IV bags of chemo into the sewer. Based on our members' experience, these materials are placed in the hazardous waste containers.
50	V. Detailed Discussion of the Proposed Rule; F. What are 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.	Waste codes should be on the manifest for sending the waste to the final TSDF. This is especially key for the wastes that are identified to be segregated to LDRs and for DOT. This waste code process should be laid out in the Hazardous Waste Pharmaceutical Management Plan .
51		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.	Waste codes should be on the manifest for sending the waste to the final TSDF. This is especially key for the wastes that are identified to be segregated to LDRs and for DOT. This waste code process should be laid out in the Hazardous Waste Pharmaceutical Management Plan .
52		58058	Shipping	EPA asks for comment on whether the proposed tracking system and controls are sufficient to protect human health and the environment. (this is related to the tracking of the shipments with notifications and with something that is trackable)	We agree that the proposed tracking mechanisms provided by common or private carriers are sufficient to protect human health and the environment.
53		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	HWI suggests that 21 days is more reasonable for our members to be able to comply with this requirement.

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54		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.	As stated above on Line 12, if CESQGs are exempt from the rule, it will be difficult for reverse distributors to comply with this requirement.
55	V. Detailed Discussion of the Proposed Rule; G. What are the proposed standards for pharmaceutical reverse distributors?	58059	RD Operations	pharmaceutical reverse distributor retains the potentially creditable hazardous waste pharmaceutical on-site until it is credit eligible. EPA requests comment on how often this happens and how long the potentially creditable hazardous waste pharmaceuticals are kept on-site at reverse distributors to await changes in manufacturers' return goods policies.	Reverse Distributors should be allowed to manage potentially creditable hazardous waste pharmaceutical (PCHWP) returns in accordance with Manufacturer's policy. The PCHWP should have no time restrictions or requirements placed on something that is considered still in circulation. Reverse distributors guidelines for credit should fall under the same requirements Wholesalers and Manufactures are given for distribution. EPA should allow Reverse Distributors to work with manufacturer's policies & procedures for properly managing PCHWP for returned credit.
56		58060	RD Operations	EPA requests comment on whether the processes described previously are representative of the pharmaceutical reverse distribution process.	The agency should consider that some RDs are TSDFs.
57		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.	HWI supports the inclusion of the regulatory standard directly.
58		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)	HWI recommends utilizing a time frame of 3 years in order to be consistent with other time frames in the rule. As written this requirement is overly burdensome.
59		58062	RD Operations	PA requests comment on the 90-day timeframe and whether this timeframe is sufficient, or whether an alternative timeframe should be allowed.	HWI suggests that 180 days is more reasonable for our members to be able to comply with this requirement. Not all RDs will be LQG and thus having smaller shipments which will be much more costly on a 90 day basis. As EPA states generally speaking this waste stream is a low risk and therefore remaining on site for 180 should not be an increased risk.
60		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.	HWI supports the requirement to inventory potentially creditable hazardouse waste pharmaceuticals upon arrival. However, in order to comply with this rule, CESQGs must be subject to the rule or they would not be able to submit their pharmaceuticals to reverse distributors. See comment in Line 12.
61		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.	HWI strongly recommends that time limits should not be imposed in the case of recalls or litigation. Any material subject to recalls or litigation should not even be considered waste until the final disposition of the material is determined. In the past, our members have been required by the FDA to retain some pharmaceuticals for years. Nonetheless, we recommend that EPA require records related to recalls and litigation to be available for review by appropriate authorities and to be maintained for the required period of time based on the activity. It is unreasonable for EPA to require individual time extensions because compliance would be burdensome and potentially subject the industry to conflicting regulatory and legal requirements.
62		58063	RD Operations	Closure requirement under vi.	These closure requirements are excessive and would be cost prohibitive for small reverse distributors.
63		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	HWI suggests that 15 days **after processing** is more reasonable for our members to be able to comply with this requirement.

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64		58063	Reporting and Records	We request comment on whether additional recordkeeping is necessary to document cases when shipments of potentially creditable hazardous waste pharmaceuticals do not reach their intended destination within 7 calendar days. - this is also the section where it talks about maintaining the inventory so long as the facility is under these regulations; most of the other recordkeeping requirements refer to a three year maintenance	Per the previous section, HWI suggests that 14 days is more reasonable for our members to be able to comply with this requirement.
65		58064	Reporting and Records	EPA has chosen to propose 21 calendar days to ensure that the pharmaceutical reverse distributor has a long enough of time to make the evaluation, yet a short enough time to ensure that potentially creditable hazardous waste pharmaceuticals do not linger awaiting evaluation. The Agency requests comment on this timeframe and whether it should be shortened or lengthened. We also want to emphasize that the 21 calendar days for evaluating the potentially creditable hazardous pharmaceuticals counts as part of the total 90 calendar days that the hazardous waste pharmaceuticals are allowed to accumulate on-site.	HWI recommends that no specific timeframe be set for the processing of potentially creditable hazardous waste pharmaceuticals due to varbiables beyond the control of the reverse distributor, such as the requirement for return authorization from the manufacturer which can take weeks or even months. It is our recommendation that a 180 day time period begin at the time the returns become evaluated hazardous waste pharmaceuticals. This timeframe allows for adequate accumulation of volume for smaller reverse distributors to keep transport costs reasonable.
66		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.	CESQGs may benefit from consolidating this material. Per our previous comments, it is important for the LQGs to be able to adequately document the material to the RDs. To do this, we recommend that LQGs be required to have a Hazardous Waste Pharmaceutical Management Plan .
67		58065	Potentially creditable waste mgmt.	EPA requests comment as to whether the three-transfer and 90-day limits are appropriate and whether more or fewer transfers are necessary for verification of manufacturer's credit.	HWI recommends that 90 days after processing is appropriate for shipping of potentailly creditable hazardous waste pharmaceutcials to another reverse distributor or manufacturer and 180 days after processing is more reasonable for transport of evaluated hazardous waste pharmaceuticals for our members to be able to comply with this requirement.
68		58065	Training	The Agency requests comment on whether the training standards are appropriate for the specific reverse distributor personnel.	HWI supports trainning standards for specific reverse distributor personnel.
69		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.	HWI does not believe it is necessary to specify how records are maintained, simply that they should be. However, the method should ensure that they do not exceed the 180 days
70		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.	HWI agrees with EPA that subparts AA, BB and CC should not apply to pharmaceutical reverse distributors.
71		58067	Reporting and Records	EPA believes that these recordkeeping requirements are appropriate for pharmaceutical reverse distributors, many of whom are currently LQGs, but requests comment on this requirement.	HWI recommends that consistent with the rest of the rule, recordkeeping should be maintained for 3 years, not life of facility.
72	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	HWI recommends that CESQGs be subject to this rule.
73		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.	HWI recommends that CESQGs be subject to this rule.

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74	VI. Implementation and Enforcement; B. Pharmaceutical Reverse Distributors	58068	General	Even pharmaceutical reverse distributors that are currently CESQGs will be regulated under 40 CFR part 266, subpart P for the management of their hazardous waste pharmaceuticals.	HWI recommends that CESQGs be subject to this rule.
75	VII. Request for Comment on EPA's Efforts to Identify Additional Pharmaceutical Hazardous Wastes	58071	Identify new RX	Thus, before deciding on a possible proposal to list additional pharmaceuticals as hazardous wastes, we request comment on the September 2011 final report, and solicit information regarding additional potentially hazardous pharmaceuticals. W	HWI suggests that EPA consider including NIOSH Table 1 (antineoplastics). Further, we recommend that EPA work with the FDA and manufacturers to determine what is hazardous and not burden the generators with this.
76	XII. Statutory and Executive Order Reviews	58078	General	Agency does not anticipate will cause significant hardship on pharmaceutical reverse distributors that are small entities. However, the Agency requests comment on the cost impacts on small entity pharmaceutical reverse distributors that process creditable hazardous waste pharmaceuticals.	The requirements for recordkeeping of advance notice of shipment, receipt of shipment, notification should shipment not be received, and notification to hospital and EPA of the receipt of non-creditable hazardous waste pharmaceuticals will be a significant burden on small reverse distributors. Since drug diversion is an admirable but not a core regulatory concern of EPA, we recommend that reverse distributors generating below a specific threshold could be relieved of these reporting requirements.