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December 4, 2015

Online Submittal Only

U. S. Environmental Protection Agency
Office of Resource Conservation and Recovery (MC: 5304P)
1200 Pennsylvania Ave., NW
Washington, DC 20460

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

The Oklahoma Department of Environmental Quality (DEQ) respectfully submits the following comments for EPA's proposed "Management Standards for Hazardous Waste Pharmaceuticals" published September 25, 2015 at 80 FR 58014 – 58092. Our comments will be directed toward three areas:

- comments on the text of the proposed rule;
- comments on one of the specific requests for comment; and
- a suggestion for an alternative regulatory framework for managing pharmaceutical wastes.

DEQ fully supports EPA's effort with this proposed rulemaking to address the very unique regulatory challenges associated with hazardous waste pharmaceuticals (HWPs), and we believe this proposed rulemaking does much to bring some common sense management standards to this wastestream. The RCRA regulatory structure that has been in place since 1980 was designed to address the environmental issues of the day – improper management of hazardous wastes generated in fairly large quantities at industrial facilities. The basic structure is largely unchanged and it was never well-suited for HWPs which are generated in fairly small quantities at many, widely-varied facilities by people who are trained medical professionals, not hazardous waste experts. The number of EPA memos and guidance documents issued over the years to clarify how HWPs fit into the RCRA regulatory framework attest to the difficulty of trying to, figuratively, fit a square peg into a round hole. We know many years of effort went into this proposed rulemaking and we appreciate EPA recognizing the need to devise a regulatory structure for this unique wastestream.

Comments on the Proposed Rule Text

266.500 – Definitions [Page 58083]

Pharmaceutical – While we understand the reasoning for including pharmaceutical residues, personal protective equipment (PPE), and clean-up material from spills within the definition of "pharmaceutical," these examples of pharmaceuticals do not fit within the overall structure of the definition or what one would conceptualize as a pharmaceutical. The first portion of the proposed definition clearly and unambiguously identifies a pharmaceutical as something with a

specific purpose – in short, to treat disease in humans or animals. To clarify what constitutes a pharmaceutical, the definition further states that pharmaceuticals include dietary supplements, prescription drugs, and over-the-counter drugs – each of which may be ingested, injected, or applied to the skin. These items are what the general public and healthcare workers would consider a pharmaceutical.

PPE and clean-up material are neither intended to treat disease nor can they be ingested, injected, or applied to the skin. Including these items within the definition of pharmaceutical implies there may be cases where they could be managed under Subpart P even though they would have no creditable value and could only be disposed as waste. Furthermore, with respect to PPE, the vast majority of pharmaceutical cleanups in a healthcare setting would leave little to no pharmaceutical residual on the PPE. Requiring these to be managed as a pharmaceutical will greatly increase costs for healthcare facilities with no measurable environmental benefit.

We recommend removing pharmaceutical residues, personal protective equipment, and clean-up material from the definition of "pharmaceutical" and, if it is deemed necessary, include additional language in the final rule that clearly states these materials must be managed as a hazardous waste if they are listed or exhibit a characteristic.

Pharmaceutical reverse distributor – The definition includes the term "forward distributor," a term also used in the preamble. The final rule should define "forward distributor."

266.501 – Applicability [Page 58084]
We believe further clarification regarding the applicability of the Part 266 standards to hospice and home health organizations is needed. Many hospices provide in-home care for patients (as do home health organizations by design). The nurses with those organizations will often bring medications to the home to administer to the patient. If a nurse during an in-home visit generates a HWP, it is not clear who is the generator of that waste. Is it exempt from regulation under the household waste exclusion or is it subject to regulation because the hospice or home health organization is considered the generator?

266.501(a) and (b) are contradictory. The text of 266.501(a) definitively excludes CESQG healthcare facilities from the provisions of Subpart P (except for 266.504, 266.505, and 266.507(a) and (b)), while the text of 266.501(b) offers CESQG healthcare facilities the option to manage their HWPs under all of Subpart P.

We believe the CESQG rules of 261.5 should identify the options available to CESQG healthcare facilities: either manage HWPs under 261.5 plus 266.504, 266.505, and 266.507(a) and (b) or fully under Subpart P. This revision would eliminate the need for 266.501(a) and (b).

We also believe the Applicability should be the first rule in Subpart P, before the definitions. This allows the reader to determine if Subpart P applies to his facility before reviewing any of its requirements.

266.502, 266.503, 266.504, and 266.510 [Pages 58084, 58086, 58087, and 58088]
We generally support the container management standards of these rules, except as identified in following discussions. However, because facilities that may generate HWPs typically do so in small quantities at many locations within the facility, the preamble of the final rule should suggest (but not require) central accumulation areas for collection of waste pharmaceuticals to facilitate compliance.

266.502(a)(1)(i) and (ii) – Notification [Page 58084]
These proposed rules, together, state that LQG healthcare facilities could have up to two years (until the next biennial reporting cycle) to notify they are operating under Subpart P while other healthcare facilities have only 60 days from the effective date of the final rule to notify. Because re-notification is a fairly straightforward process that takes little time, it is not clear why LQG healthcare facilities should receive up to two years to notify, and therefore remain "under the radar," while smaller entities have only 60 days. We recommend the final rule provide a 60-day period for all healthcare facilities to notify or re-notify.

266.502(c) – Hazardous Waste Determination [Page 58085]
The parenthetical "(i.e., it exhibits a characteristic identified in 40 CFR part 261, subpart C or is listed in 40 CFR part 261, subpart D)" is unnecessary as this is already captured by the definition of "hazardous waste pharmaceutical."

We believe the last sentence stating healthcare facilities may manage their non-hazardous pharmaceuticals under the Subpart P requirements is unnecessary and should be removed. While we believe this is a prudent measure so healthcare workers do not need to be concerned with hazardous waste determinations, requirements for management of non-hazardous pharmaceuticals may differ across states. Including such a statement in the rule, even though it ultimately has no regulatory effect, may conflict with a state requirement and be construed as an EPA endorsement of its management standards over those of a state. If EPA's purpose for this provision is only informational, then it should be discussed in the preamble of the final rule but not included as regulatory text.

266.502(e) and 266.510(c)(4)(i) – Container Labeling [Pages 58085 and 58090]
Labeling HWP containers to clearly identify the contents is a prudent measure to help ensure HWPs are managed correctly. Since both LQG and SQG healthcare facilities are already required to label their containers of non-pharmaceutical hazardous wastes, this labeling requirement should be familiar to them and not present an additional burden. However, we believe EPA should be more flexible in its labeling requirement rather than prescribing precise text for the label. Many violations are written due to labels not having the exact text required by a rule even though the label clearly identifies what is in the container. The final rule should offer flexibility, such as "mark each container with the phrase 'Hazardous Waste Pharmaceuticals' or similar language that clearly identifies the contents of the container."

266.502(f)(3)(i) – Accumulation Time Extension Requests [Page 58085]
We believe "90 days" should be "one year."

266.502(h)(4) – Returned Shipments of HWPs [Page 58085]
Based on the construction and text of paragraphs (h)(1) through (h)(4), we believe (h)(4) could be interpreted in a way that negates the 90-day period a healthcare facility is authorized to retain a returned shipment of HWPs. According to the text of paragraph (h), while returned pharmaceuticals may be accumulated on-site for an additional 90 days, the healthcare facility must complete four actions ***upon receipt*** of a returned shipment of HWPs. These are:

- sign the manifest used to return the HWPs to the healthcare facility [(h)(1)(i) or (ii)];
- provide the transporter a copy of the manifest [(h)(2)];
- within 30 days, send a copy of the manifest to the facility that rejected the waste [(h)(3)]; and
- transport, or offer for transport, the returned shipment [(h)(4)].

The first two bullets do not specify a timeframe, so it is clear these actions are to be performed "upon receipt" of the shipment. The third bullet gives the healthcare facility 30 days to perform the action, rather than having to complete it "upon receipt" of the shipment. The fourth bullet does not specify a timeframe; therefore, the construction of paragraph (h)(4) implies that the returned shipment must be transported off-site "upon receipt" by the healthcare facility – an impossible task. We do not believe this is EPA's intent, and believe (h)(4) should be revised to clarify that the healthcare facility has to ship the HWPs to an alternate facility within the 90-day period authorized by paragraph (h).

266.502(h)(4)(i)(2)(ii)(A) and (B) – Exception Reports [Pages 58085-58086]
We do not believe (h)(4)(i)(2)(ii)(A) and (B) are needed. Paragraphs (h)(4)(i)(2)(i)(A) and (B) already require an exception report to be submitted if a signed manifest has not been received by the generator from the designated TSDF within 60 days of the waste being accepted by the initial transporter. Even if non-creditable HWPs are rejected by the designated TSDF and transferred to an alternate facility, the generator will still be required to file an exception report if he has not received a signed manifest within 60 days of the waste being accepted by the initial transporter. We believe (h)(4)(i)(2) should be rewritten to simply state an exception report is required if a manifest signed by a TSDF has not been received by the healthcare facility within 60 days of the waste being accepted by the initial transporter.

266.502(k) – Response to Releases [Page 58086]
We believe a release of creditable HWPs should also be subject to these containment and cleanup requirements, unless the rule is intended to imply that all releases of creditable HWPs render them non-creditable. Some creditable HWPs (e.g. tablets or capsules) may remain creditable after they have been cleaned up while others (e.g. liquids or gels), would likely be non-creditable after a release. To rectify this concern, the rule should require any release of HWPs to be cleaned up. Once the cleanup has occurred, then, for any creditable HWPs that were cleaned up, the healthcare facility must ascertain whether or not they remain creditable and handle them accordingly.

266.503(a) – Hazardous Waste Determination [Page 58086]
The parenthetical "(i.e., it [is] listed in 40 CFR part 261, subpart D or exhibits a characteristic identified in 40 CFR part 261, subpart C)" is unnecessary as this is already captured by the definition of "hazardous waste pharmaceutical."

We believe the last sentence stating healthcare facilities may manage their potentially creditable solid waste pharmaceuticals under the Subpart P requirements is unnecessary and should be removed. While we believe this is a prudent measure so healthcare workers do not need to be concerned with hazardous waste determinations, requirements for management of non-hazardous pharmaceuticals may differ across states. Including such a statement in the rule, even though it ultimately has no regulatory effect, may conflict with a state requirement and be construed as an EPA endorsement of its management standards over those of a state. If EPA's purpose for this provision is only informational, it should discussed in the preamble of the final rule but not included as regulatory text.

266.504 – CESQG Healthcare Facilities [Page 58087]
We fully support each of the three options for HWP management by CESQG healthcare facilities; however, nothing in the proposed rule requires a method for these facilities to ensure their HWPs are received at a designated facility. We recommend a requirement for tracking documents (manifest, shipping papers, bills of lading, etc.) or some other method to definitively ensure the HWPs make it to a facility authorized by the rule.

266.505 – Sewer Disposal Prohibition [Page 58087]
Due to many well-documented studies of pharmaceuticals in the environment because wastewater treatment systems are not designed to adequately treat wastewater to remove pharmaceuticals, DEQ supports banning sewer disposal of non-household exempt HWPs, including HWPs generated at CESQG healthcare facilities. However, we believe the rule, as written, has two flaws.

First, there is no prohibition from disposal of HWPs into septic systems. We believe this prohibition should be included because septic system disposal results in an almost-immediate release to the environment through the lateral line field with little to no treatment.

Secondly, we believe the second sentence could be interpreted that EPA is exerting RCRA authority over domestic sewage if it contains HWPs – an area that has been exclusively under Clean Water Act jurisdiction since the first RCRA regulations were promulgated in 1980. This sentence states that the domestic sewage exclusion in 261.4(a)(1)(ii) does not apply to HWPs. This could suggest that if HWPs are found in domestic sewage, the entire mixture, including the domestic sewage component, could be subject to RCRA. By extension, RCRA jurisdiction could then be exerted over wastewater treatment plants that receive sewage containing HWPs. We do not believe this is EPA's intent. To rectify this concern, we believe 266.205 only needs to definitively ban sewer and septic disposal of all non-household exempt HWPs. With such an unambiguous rule, further clarification is unnecessary.

266.506 – Deferral to DEA for Controlled Substances [Page 58087]
In principle, we support EPA deferring to the Drug Enforcement Administration's (DEA) destruction and disposal requirements for HWPs that are also controlled substances to avoid dual regulatory requirements; however, we question EPA's authority to do so. RCRA explicitly requires hazardous wastes to be disposed at facilities with RCRA permits. If a DEA-approved incinerator does not have a RCRA permit, RCRA is clear the incinerator cannot accept hazardous wastes, including HWPs.

While we question EPA's authority for this aspect of the rule, EPA has touched on a possible regulatory framework for management of all pharmaceuticals. We believe DEA (or similar) combustion requirements could be the framework for a conditional exclusion so that pharmaceuticals as a category could be exempt from the definition of hazardous waste provided they are being combusted. This may also help prevent releases of non-hazardous pharmaceuticals to the environment. This framework will be discussed further in the third section of these comments.

266.507 – HWP Residue Management in Containers [Page 58087]
We support EPA's proposed rules for management of HWP residues as a common-sense method to deal with these very small quantities of HWPs. EPA's historical guidance on this topic, while sound from a regulatory standpoint, has clearly demonstrated that RCRA is not well-designed for handling pharmaceutical residues.

In 266.507(c), the phrase "if the residues are listed in 40 CFR part 261, subpart D or exhibit a characteristic identified in 40 CFR part 261, subpart C" is unnecessary as this is already captured by the definition of "hazardous waste pharmaceutical."

266.508(a)(1)(v) and (2) – Shipping Papers [Page 58078-58088]
We question if 266.508(a)(1)(v) is necessary in light of the manifest requirement of 266.508(a)(2). The hazardous waste manifest is intended to meet the hazardous materials shipping papers requirement of 49 CFR 172; therefore, we believe (a)(1)(v) is unnecessary in light of the hazardous waste manifest requirements of paragraph (2).

266.509 – Shipping HWPs to Reverse Distributors [Page 58088]
We believe this rule should include both a provision requiring some form of shipping paper to document that potentially creditable HWPs were received at the designated facility, and an exception reporting requirement if the healthcare facility has not received a signed copy of that shipping paper within the seven days discussed in 266.509(c). It appears EPA intended for shipping papers to be required because the recordkeeping requirements for reverse distributors in 266.510(a)(9) require them to maintain copies of shipping papers/bills of lading for potentially creditable HWPs received.

266.510(c)(7) – Returned Shipments of HWPs [Page 58091]
Based on the construction and text of paragraphs (c)(7)(i) through (iv), we believe (c)(7) could be interpreted in a way that negates the 90-day period a reverse distributor is authorized to retain

a returned shipment of evaluated HWPs. According to the text of paragraph (c)(7), while returned pharmaceuticals may be accumulated on-site for an additional 90 days, the reverse distributor must complete four actions ***upon receipt*** of a returned shipment of evaluated HWPs. These are:

- sign the manifest used to return the evaluated HWPs to the reverse distributor [(c)(7)(i)(A) or (B)];
- provide the transporter a copy of the manifest [(c)(7)(ii)];
- within 30 days, send a copy of the manifest to the facility that rejected the waste [(c)(7)(iii)]; and
- transport, or offer for transport, the returned shipment of evaluated HWPs [(c)(7)(iv)].

The first two bullets do not specify a timeframe, so it is clear these actions are to be performed "upon receipt" of the shipment. The third bullet gives the reverse distributor 30 days to perform the action, rather than having to complete it "upon receipt" of the shipment. The fourth bullet does not specify a timeframe; therefore, the construction of paragraph (c)(7)(iv) implies that the returned shipment must be transported back off-site "upon receipt" by the reverse distributor – an impossible task. We do not believe this is EPA's intent, and believe (c)(7)(iv) should be revised to clarify that the reverse distributor has to ship the HWPs to an alternate facility within the 90-day period authorized by paragraph (c)(7).

Specific Requests for Comment

The preamble to the proposed rule included approximately 60 specific requests for comment and our responses to many of those are already addressed above. However, in section VIII.E, EPA is seeking specific comment on the following regarding the P075 listing – nicotine and salts:

- all possible approaches to amending the acute hazardous waste listing for nicotine and salts;
- should other low-concentration, nicotine-containing smoking cessation products (e.g. inhalers or nasal sprays) be exempt from P075; and
- should e-cigarettes and nicotine-containing e-liquids for e-cigarettes be included within the scope of the definition of pharmaceutical.

We believe smoking cessation products such as nicotine patches, gums, lozenges, inhalers, nasal sprays, e-cigarettes, e-liquids, etc. should not be regulated as acutely hazardous wastes when discarded. As noted in the preamble, EPA originally listed nicotine as acutely hazardous waste because of its use as a pesticide. Since nicotine-containing smoking cessation products were just coming to market at that time and the apparent purpose of the listing was to regulate nicotine as a pesticide, EPA had no reason to evaluate the impact of the listing on smoking cessation products or entities who sold them. With the explosion of nicotine-containing smoking cessation products over the years, one result has been a tremendous increase in the number of commercial businesses who must notify as large quantity generators solely due to generating waste smoking cessation products when they may generate little other hazardous waste. We have always felt this was an unnecessary regulatory burden on these entities because of huge costs of compliance as a large quantity generator with little environmental benefit. We believe EPA should revise the

P075 listing to clarify EPA's original intent – that it applies only to nicotine when used as a pesticide. Smoking cessation products, then, would be hazardous wastes only if they exhibit a hazardous characteristic.

Alternate Regulatory Framework for Pharmaceutical Wastes

As previously noted, DEQ applauds EPA's effort to develop proposed rules for management of HWPs that takes into consideration the unique aspects associated with this waste stream. If these proposed rules are finalized in much the same form as proposed, we believe a significant amount of regulatory relief will result for healthcare facilities; however, since this approach only targets HWPs, it will not significantly alleviate the well-documented issues of pharmaceuticals in the environment. We believe an alternative regulatory approach could provide even greater reduction in the amounts of pharmaceuticals in the environment.

In April 2013, the Association of State and Territorial Solid Waste Management Officials published a Position Paper outlining an alternative regulatory framework for HWPs.[1] In summary, the Paper recommends pharmaceuticals, as a category, be excluded from the definition of hazardous waste if they meet certain management standards and are disposed by incineration. DEQ supports this concept.

When the hazardous waste regulations were first promulgated in 1980, approximately 31 pharmaceutical compounds were identified in the P- and U-lists of hazardous wastes, including nicotine, lindane, and warfarin which were listed due to their use as pesticides, not as pharmaceuticals. In the 35 years since, no additional pharmaceutical compounds have been listed even though an estimated 900 new drugs have been developed during the period. The lack of new listings is largely due to the arduous process EPA must follow to create new listings – a process not amenable to a compound-by-compound review when pharmaceuticals are being developed at such a rapid pace. It would be prohibitively costly and nearly impossible for EPA to evaluate every pharmaceutical currently on the market and new ones as they are developed to determine if they should be added to the P- or U-lists. This is a large reason DEQ believes a new regulatory framework for pharmaceutical wastes must be developed. Interestingly, some pharmaceuticals, such as carmustine, dactinomycin, and oxytocin, have been identified by other federal agencies as meeting EPA's criteria for acutely hazardous.

The RCRA regulatory structure is also not well-suited for the sector-based approach for pharmaceutical management. Section IV.B.1 of the preamble presents an excellent discussion of the difficulties with regulating pharmaceuticals under RCRA. Hazardous waste regulations were designed from the outset for industrial settings where a few, relatively large quantities of hazardous wastes are generated at a few locations within a facility and managed primarily in tanks or 55-gallon drums. At large healthcare facilities such as hospitals, pharmaceuticals are generated in relatively small quantities, in many forms, at unpredictable times, in multiple

[1] As of the date of these comments, the Position Paper can be reviewed at http://www.astswmo.org/files/policies/Hazardous_Waste/2013-04-Pharmaceutical_Waste_Position_Paper-Board_Approved.pdf.

locations within the facility, by a wide range of individuals whose education, training, and experience is centered toward patient care, not waste management. We believe a single management standard that would apply to all pharmaceuticals would facilitate compliance and significantly reduce the amount of pharmaceuticals making their way into the environment.

The approach suggested by the Position Paper is to conditionally exclude all pharmaceuticals from the definition of hazardous waste provided they are managed in ways to minimize the risk of releases to the environment and are destroyed through incineration. By implementing such an approach, there will be no need for updated listings and waste pharmaceuticals will be destroyed, preventing diversion for illicit purposes or inadvertent releases to the environment. A conditional exclusion may have the added benefit of encouraging entities such as neighborhood pharmacies or household hazardous waste collection centers to participate in pharmaceutical take-back programs for their customers if they know they will not be subject to arduous hazardous waste regulatory requirements. All of these will enhance environmental protection by greatly reducing the amount of pharmaceuticals reaching the environment. We strongly encourage EPA to evaluate the ASTSWMO position paper and work with Congress and the states to bring a more holistic approach to pharmaceutical waste management. DEQ would be happy to work closely with EPA on such a project.

If you have any questions about these comments, please do not hesitate to contact Jon Roberts of my staff at (405) 702-5153.

Sincerely,

Kelly Dixon, Director
Land Protection Division
Department of Environmental Quality