Bristol-Myers Squibb Company
Corporate Environment, Health, Safety & Sustainability
P.O. Box 4755 Syracuse, NY 13221-4755 315 432-2000

November 22, 2013

Michele DiNoia
Robert C. Isner
CTDEEP
79 Elm Street
Hartford, CT 06106-5127

RE: **Comments/Suggestions - CTDEEP Pharmaceutical Universal Waste Initiative**

Dear Ms. DiNoia / Mr. Isner -

The Connecticut Department of Energy and Environmental Protection (CTDEEP; Department) has indicated its intent to develop regulations to state-list pharmaceutical waste as a Universal Waste (Pharmaceutical Universal Waste Initiative). In its October 15, 2013, letter, the CTDEEP invited Bristol-Myers Squibb to participate in a Stakeholder Group to provide input/suggestions to the Department to assist with this process.

CTDEEP specifically requested feedback and comment on five key elements of consideration for rule-making. There was also a request to highlight and discuss any other potentially- significant item that was not identified in the attachment to the letter.

Element 1 - Definition of Pharmaceuticals: In general, we support the definition of "pharmaceuticals" proposed in the attachment to the CTDEEP letter. We offer the following comments and suggestions regarding the proposed definition of "pharmaceuticals" for further clarification:

a) We agree with CTDEEP's recommended position that residues from the manufacture or production of pharmaceutical compounds should not be addressed under the state pharmaceutical Universal Waste program. Manufacturing companies have the regulatory familiarity and resources to fully-comply with the waste management provisions of the Resource Conservation and Recovery Act (RCRA).

b) The definition of "pharmaceutical" should provide clarifying language indicating that cosmetic and personal care products (e.g., contact lens disinfectants, antidandruff shampoo products, toothpaste, antiperspirants/deodorants, antiseptic skin cleaners, sunburn protectants, mouthwashes, personal hand sanitizing solutions) are excluded from the regulation. We would suggest specific exclusion language as follows: "*cosmetic and other personal care products that are regulated as both cosmetics and nonprescription drugs under the federal Food, Drug, and Cosmetic Act (Title 21 U.S.C. Chapter 9) are*

excluded".

c) Similarly, pet pesticide products (pet collars, powders, shampoos or topical applications) should be specifically excluded from the definition of "pharmaceuticals".

d) We suggest that herbal-based remedies and homeopathic drugs, products or remedies also be specifically excluded from the rule.

e) Finally, certain cleaning materials that have anti-bacterial constituents should be specifically excluded from the regulation (e.g., hard surface and toilet disinfectant cleaners).

Element 2 - Inclusion of Certain Drugs Identified in NIOSH Publication No. 2012-150:
CTDEEP has requested input as to whether certain pharmaceutical compounds that have been listed in the NIOSH Publication No. 2012-150 (Appendix A) and/or the OSHA Technical Manual (Appendix VI:2-1) should be included in CTDEEP's pharmaceutical universal waste program.

We believe that pharmaceutical compounds that have been identified in NIOSH Publication No. 2012-150 should be included in CTDEEP's definition of "pharmaceutical Universal Waste". The basis for this recommendation is as follows:

- CTDEEP has stated that one of its principal drivers for pursuing the Pharmaceutical Universal Waste Initiative is to simplify environmental compliance for several key users/stakeholders (hospitals, clinics, doctor offices, etc.). In its comments to the United States Environmental Protection Agency's (USEPA's) 2008 proposed Universal Waste Rule for pharmaceuticals, CTDEEP indicated that these users may not have adequate understanding and familiarity under RCRA to assure broad compliance. Excluding a sub-set of pharmaceutical materials from the state-level pharmaceutical Universal Waste program will create an undue level of complexity (e.g., complexity equal to or greater than what is currently realized by these key stakeholders). In order to provide the simplification/clarification desired under Pharmaceutical Universal Waste Initiative, the definitions of "pharmaceuticals" should be readily understood and universally applied. If there are complicated "carve-outs" under the program (e.g., select medicines are included in the program while select other medicines are excluded from the program), then these stakeholders would likely be equivalently unfamiliar of the detailed Universal Waste provisions as they are of the other, existing hazardous waste management requirements.

- During the November 13 stakeholder's engagement meeting, CTDEEP reported that the state is uniquely situated in that solid wastes across the state are predominantly incinerated in municipal trash-to-energy plants (state has few or no solid waste landfills). As such, the specific medicines identified in the NIOSH Publication No. 2012-150 and the OSHA Technical Manual will still receive a high degree of control if included in the Pharmaceutical Universal Waste Initiative.

- As identified in CTDEEP's Letter, it should be noted that these materials do present potential human exposure considerations. The pharmaceutical compounds listed in NIOSH Publication No. 2012-150 (Appendix A) and/or the OSHA Technical Manual (Appendix VI:2-1) are mainly oncolytics. These pharmaceuticals are most likely used only in hospital settings and are handled by individuals who are knowledgeable about the properties and characteristics of these materials. Additional human exposure considerations and safeguards which should be adopted to protect against these considerations are discussed in element "4", below.

Element 3 - Training: CTDEEP requested input as to whether additional training requirements should be proposed for either large- or small-quantity handlers of pharmaceutical Universal Waste.

Unlike other Universal Waste streams (batteries, light bulbs, pesticides, mercury-containing equipment), unused medicines potentially have a high economic value. Collecting and accumulating these materials in a centralized location increases the risk and potential for theft and diversion. We recommend that both small-quantity and large-quantity handlers of pharmaceutical Universal Waste implement a training program that includes a review of site-specific security-based provisions and safeguards.

Additionally, there are special training considerations that should be applied in situations where home-generated unused medicines are centrally collected, as follows:

a) Individuals overseeing such collection should be trained to identify what materials should not be accepted for collection (e.g., controlled substances, unless the location complies with U.S. Drug Enforcement Agency (DEA) provisions; illegal drugs; sharps; cartridges; materials that are specifically excluded under the regulation). If there are no individuals directly overseeing such collection (e.g., collection is performed using a kiosk), then signage should be provided to educate the public.

b) Additionally, the public should be informed to remove any personally sensitive information or deface the label from the medicine containers in order to maintain patient confidentiality.

Element 4 - Container Management: Under this element, CTDEEP requested input about whether containers of pharmaceutical waste should be required to be kept closed, except when pharmaceuticals are being added to or removed from the container.

We strongly support a provision requiring accumulation containers to be kept closed (except when materials are added or removed). Our basis for this recommendation is:

1) Unlike other Universal Waste streams (batteries, light bulbs, pesticides, mercury-containing equipment), unused medicines potentially have a high economic value. Collecting and accumulating these materials in a centralized location increases the risk and potential for theft and diversion. Keeping the accumulation vessel closed and secured (locked when not in use; pursuant to DEA requirements) will reduce the potential for pilfering.

2) As discussed under Element "2", above, certain pharmaceutical compounds have human exposure considerations. Due to these considerations, such compounds should be maintained in their original primary packaging materials to minimize product handling. Additionally, keeping the accumulation container closed will minimize potential for inadvertent exposure.

Additional container management items that should be considered during regulatory drafting include:

a) Due to the potential for collection/accumulation of liquid-based pharmaceutical products, any accumulation vessel/receptacle should be designed to contain leakage from liquid contents to prevent spills or releases.

b) Due to the value of unused pharmaceuticals and the increased potential for theft or diversion, a number of security-based provisions should be implemented and followed during container management. It is highly recommended that accumulation containers be locked and stored in an area that is either locked, under direct supervision, or under surveillance.

c) Accumulation vessels should be maintained in an area that is adequately ventilated (typical of commercial occupancy to minimize potential for accumulation of dusts).

Finally, there are special "container management" considerations and drivers that should be applied in situations where home-generated unused medicines are centrally collected, including:

a) Publicly available collection containers should be closed, locked and include provisions that limit the potential for theft, tampering or pilfering (e.g., accumulation container

should be designed to prevent someone from reaching into the receptacle and removing or tampering with the contents).

b) Patients should be informed to remove identifying information from their medicine containers prior to return. Providing enclosed containers will help assure patient confidentiality if adherence to removing these labels is not followed by the public.

Element 5 - Tracking: CTDEEP is seeking input on special tracking requirements and provisions under a future Pharmaceutical Universal Waste rule. One of the key "gaps" of the USEPA's 2008 proposed Universal Waste Rule for pharmaceuticals was the lack of effective tracking requirements. As indicated previously, due to the heightened economic value of unused medicines and the potential for diversion, shipments of pharmaceutical Universal Waste should be closely monitored and tracked. A formal tracking procedure should be developed and followed for all pharmaceutical waste handlers (both small and large).

Additionally, Certificate of Destruction (COD) should be obtained at the waste disposal facility for each shipment received and managed.

Supplemental Items of Consideration:

In addition to the five elements outlined in the CTDEEP Letter, there are a number of supplemental items that should receive proper focus when drafting regulations under the Pharmaceutical Universal Waste Initiative, as follows:

1) Reverse distributors as a group are potentially significantly impacted by the CTDEEP's Pharmaceutical Universal Waste Initiative. As such, we support the suggestion made during the October 13, 2013, Stakeholder's Meeting that individuals who are principally engaged in this space be invited to participate in the Stakeholder Group.

2) There are a number of regulations and governmental agencies that should be carefully considered while framing any Pharmaceutical Universal Waste program. Key regulatory programs include:

    - DEA-controlled substance provisions and requirements.

    - Transportation-related provisions and requirements (e.g., medicines containing alcohol may be considered a Class 3, flammable liquid; some oncolytics may be classified as a 6.1 toxic material; etc.). Transportation containers (which may be the same containers used for collection) must consider appropriate DOT

provisions/requirements.

3) Even though alternate disposal methodologies (e.g., landfilling) are understood to be limited in Connecticut, the regulations should stipulate the incineration of pharmaceutical Universal Waste. We suggest that the upcoming rule allow the flexibility to incinerate these materials in the following facilities: (a) municipal trash-to-energy incinerators; (b) medical/biomedical waste incinerators; and/or (c) hazardous waste incinerators.

4) As mentioned several times in our response, due to the economic value of these materials and heightened potential for diversion, security provisions are critically important. These measures become further amplified in situations where collection containers would be publicly accessible (e.g., collection of home-generated unused medicines). As such, regulations developed under this initiative should account for this fact and include provisions/mechanisms for assuring the safety of the State's pharmaceutical supply chain.

Bristol-Myers Squibb appreciates the opportunity to provide input and support to the CTDEEP in framing regulations under the Pharmaceutical Universal Waste Initiative. If you have any questions or require any additional information, please do not hesitate to contact me directly at 315-432-4851.

Sincerely,

Bristol-Myers Squibb Company

Douglas Morrison
Director, Environmental Policy & Strategy

CHA CONNECTICUT HOSPITAL ASSOCIATION

December 3, 2013

Michele DiNoia
Connecticut Department of Energy and Environmental Protection
Waste Engineering and Enforcement Division
Bureau of Materials Management and Compliance Assurance
79 Elm Street
Hartford, CT 06106-5127

Dear Ms. DiNoia:

The Connecticut Department of Energy and Environmental Protection (DEEP) has outlined a process to address hazardous pharmaceutical waste through state regulation. The Connecticut Hospital Association (CHA) appreciates the opportunity to work with DEEP and other stakeholders on the important issues relating disposal and management of pharmaceuticals.

DEEP has announced a focus on five key areas to be considered in their draft regulations: (1) definitions; (2) scope and effect of NIOSH publication 2012-150; (3) training; (4) container management; and (5) tracking. DEEP has asked for input as to other possible focus areas that DEEP should consider when drafting proposed regulations. CHA respectfully requests that draft regulations would need to include consideration of the following areas.

Regulations should be:

1. Evidence-based. It is critical that any regulatory undertaking be based on facts and science, not perception. This includes an accurate assessment of waste water treatment issues, all sources of contamination, and specifically the role people play in the drug ingestion and excretion cycle. Specifically, it is critical to learn what percentage of drugs that may contaminate the water supply come from people, at home or in residential care, ingesting and excreting drugs (as opposed to facilities wasting unused drugs).

2. Informed by existing laws and federal guidance. While the proposed 2008 Environmental Protection Agency (EPA) rules were not adopted, there are still federal rules and guidance in those areas, both relative to waste and pharmaceutical definitions. EPA has also announced that more regulations are likely to be proposed soon. Any state regulation should be aligned with, and clarify not confuse, the existing obligations.

3. Weigh the challenges of implementation. There are myriad types of facilities and businesses that will be affected by any regulation in this area. Regulations need to be workable and balanced.

We look forward to our continued collaboration on this issue.

Sincerely,

Diane Mase
Assistant Vice President

Carl Schiessl
Director, Regulatory Advocacy

DM:mb
By e-mail

CVMA
Connecticut Veterinary Medical Association
enhancing the quality of human and animal life

November 22, 2013

Michele DiNoia
Senior Sanitary Engineer
Waste Engineering and Enforcement Division
Bureau of Materials Management and Compliance Assurance
Department of Energy and Environmental Protection
79 Elm Street
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Dear Ms. DiNoia:

Thank you for allowing the Connecticut Veterinary Medical Association (CVMA) the opportunity to participate in the State-list hazardous pharmaceutical waste as a universal waste working group. The CVMA represents the majority of Connecticut veterinarians. Our organization, and its members, strive to be good stewards of the environment who comply with all state regulations. The CVMA applauds the Department of Energy and Environmental Protection's leadership in the safe disposal of pharmaceutical waste.
The veterinary profession is a minimal contributor of hazardous pharmaceutical waste due to tight inventory control, transferring unused pharmaceuticals back to distributors, and voluntary best management practices for pharmaceutical disposal (https://www.avma.org/KB/Policies/Pages/Best-Management-Practices-for-Pharmaceutical-Disposal.aspx). Under current Resource Conservation and Recovery Act categories, most veterinary facilities would be classified as Conditionally Exempt Small Quantity Generators.

The CVMA has two specific comments in response to the key issues which DEEP is requesting comment. First, the CVMA supports the definition of pharmaceutical universal waste as "A pharmaceutical that is a hazardous waste as defined in 40 CFR 261.3, and containers (e.g., bottles, vials, IV bags, tubes of ointment/gels/creams, ampules, etc.) which have held any hazardous pharmaceutical waste and which would be classified as hazardous waste under 40 CFR 261.7." Second, as such minimal contributors of hazardous pharmaceutical waste, we feel that veterinary facilities, and all Conditionally Exempt Small Quantity Generators, should not be required to have additional training.

Thank you again for this opportunity to communicate with the DEEP on this important environmental issue. We look forward to working with you and the Department.

Respectfully,

Christopher Gargamelli, DVM
Immediate Past-President, CVM
Co-chair, CVMA Government Affairs Committee

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November 22, 2013

Via email to Michele.DiNoia@ct.gov
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Bureau of Materials Management and Compliance Assurance
Department of Energy and Environmental Protection
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Hartford, CT 06106

RE: Response to Request for Stakeholder Input on Key Issues Regarding Connecticut Department of Energy & Environmental Protection's Proposal to State-list Hazardous Pharmaceutical Waste as a Universal Waste

Dear Ms. DiNoia:

CVS Pharmacy ("CVS") is submitting these comments in response to the Connecticut Department of Energy and Environmental Protection's ("DEEP") November 5, 2013 request for stakeholder input on key issues regarding DEEP's upcoming proposal to state-list hazardous pharmaceutical waste as a universal waste ("Key Issues Document").

As a nationwide retail pharmacy chain, CVS appreciates the efforts of DEEP to streamline management requirements for generators of pharmaceutical hazardous wastes. CVS believes that a proposed rule to state-list hazardous pharmaceutical waste as a universal waste offers an excellent alternative to Connecticut's current program for regulating hazardous pharmaceutical waste. CVS's Connecticut operations include 148 retail pharmacy stores and 15 MinuteClinics. CVS employs more than 4,100 employees in Connecticut, including 492 pharmacists and 42 nurse practitioners. In 2012, CVS's Connecticut stores filled over 17,000,000 prescriptions. While developing these comments, CVS sought input from various other national retail chains with pharmacies in Connecticut. Although these comments represent CVS's perspective, CVS believes that these other retailers share many of the views that CVS has expressed in this letter.

Although CVS understands and appreciates the state's interest in reform efforts at the state level, CVS urges DEEP to first look to follow the U.S. Environmental Protection Agency's ongoing pharmaceutical regulatory reform efforts to the greatest extent possible, especially since such reform seeks to address the state's concerns regarding pharmaceutical reverse distribution and is intended to do so at a national level. These interstate shipments trigger special legal considerations best addressed on the federal level. The U.S. EPA has stated its intent to issue a proposed rule in the

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Spring of 2014. The status of U.S. EPA's current efforts on the proposed rule can be found at the following link: http://www.epa.gov/wastes/hazard/generation/pharmaceuticals.htm. Because the issue of pharmaceutical reverse distribution is a national issue, the establishment of uniform management standards across the states would greatly improve consistency and implementation by national chains like CVS. CVS encourages DEEP to continue to work closely with stakeholders during the development of the proposed rule.

CVS's specific comments to the Key Issues Document are provided in the following paragraphs.

I. Definitions

A. Definition of "Pharmaceutical"

CVS generally supports DEEP's preliminary definition of "pharmaceutical." However, CVS believes that "pharmaceuticals" should be defined to specifically include over-the-counter drugs and prescription drugs. This will help to avoid any confusion within the regulated community regarding whether certain prescription or over-the-counter drug products are considered pharmaceuticals. To allow for further clarification, DEEP should also specifically clarify that nicotine replacement therapy is included in the definition of "pharmaceutical." In addition, CVS supports DEEP's decision to include a provision that specifies which drug products are not intended to be included in the definition of pharmaceutical. However, CVS believes that residues resulting from the manufacture, production, or distribution of pharmaceuticals should also be considered a pharmaceutical.

B. Definition of "Pharmaceutical Universal Waste"

DEEP proposes to define "pharmaceutical universal waste" to include containers (e.g., bottles, vials, IV bags, tubes of ointment/gels/creams, ampules, etc.) which have held any hazardous pharmaceutical waste and which would be classified as hazardous under 40 CFR 261.7. CVS believes that DEEP should not define "pharmaceutical universal waste" to include containers. Instead, DEEP should define this term to include the *hazardous pharmaceutical waste residues* that remain in containers that are not "RCRA-empty." This would allow DEEP's rule to be consistent with the principles set forth in the U.S. Environmental Protection Agency's ("EPA") November 4, 2011 guidance entitled "Containers that Once Held P-Listed Pharmaceuticals." (see Appendix A). According to this guidance and 40 C.F.R. 261.33, only the hazardous pharmaceutical waste residue is regulated as hazardous waste and not the container itself. However, from a practical standpoint, CVS

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understands that many retailers will manage both the containers and hazardous pharmaceutical waste residues as universal wastes.

Next, it is CVS's understanding that Connecticut takes the position that pharmaceuticals that are returned to manufacturers for possible credit via reverse distribution are considered a waste "at the point that they are determined to be unwanted or unusable by the generating facility." See DEEP's Comments on EPA's Proposed Amendment to the Universal Waste Rule at 4, available at Docket ID No. EPA-HQ-RCRA-2007-0932. CVS urges DEEP to reconsider this position. DEEP should also consider any new federal provisions regarding interstate reverse distribution. CVS believes that the term "pharmaceutical universal waste" should not include, and should specifically exempt, items that are returned to a manufacturer with a reasonable expectation of credit through a reverse distributor. Indeed, items that are returned to a manufacturer via reverse distribution have not yet been discarded, and therefore should not be considered a "waste" under DEEP's universal waste rule or hazardous waste regulations.

II. Inclusion of Drugs from NIOSH Publication No. 2012-150

DEEP seeks comment on whether oncology drugs from Appendix A of NIOSH Publication No. 2012-150 and Appendix VI: 2-1 of the OSHA Technical Manual should be managed as universal wastes. CVS believes that this issue is better suited for comment by hospitals and clinics who typically distribute and store these items. However, as described in greater detail in Section VI of these comments, CVS believes that all generators should have the discretion to over-manage non-RCRA hazardous drugs as pharmaceutical universal waste without the drugs being classified as such.

III. Training

DEEP requests comment on whether additional training should be required for large quantity handlers ("LQH") of pharmaceutical universal waste, small quantity handlers ("SQH") of pharmaceutical universal waste, or both. DEEP is also seeking comment on the type(s) of training that should be required. As a threshold matter, CVS supports DEEP's category thresholds for SQHs and LQHs of pharmaceutical universal wastes. DEEP proposes to define LQH as one who handles more than 5,000 kilograms of total universal wastes at one time and SQH as one who handles 5,000 kilograms or less of total universal wastes at one time. CVS supports DEEP's decision not to base these thresholds on the amount of RCRA P-listed hazardous waste that is generated.

In rulemaking comments filed with EPA, DEEP pointed out that "waste pharmaceuticals present environmental risks that are comparable with other currently-listed universal wastes, such as cancelled pesticides and mercury-contain devices." See

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DEEP Comments at 9. DEEP also stated that a different threshold for pharmaceutical universal waste would "make inspections and enforcement of the Universal Waste Rule more difficult, by complicating the handler status determination process." Id. at 10. CVS agrees with these observations and urges DEEP to maintain the universal handler waste thresholds as proposed.

With respect to training, the pharmaceutical waste category should be added to DEEP's existing training requirements for universal waste handlers. CVS believes that additional training beyond the current universal waste handler training would be unduly burdensome on many small, independent, local pharmacies and, therefore, should not be required.

IV. Container Management

DEEP requests comments on whether containers of hazardous pharmaceutical waste should be required to be kept closed, except when pharmaceuticals are being added to or removed from the container. In its comments to EPA, DEEP stated that it believed containers of pharmaceutical universal wastes should be required to be kept closed. DEEP stated three reasons for this belief: (1) there will be many instances where waste pharmaceuticals will not be in their original packaging; (2) even for those pharmaceuticals that may be in their original packaging, if they are in liquid, or aerosol/inhaler form, or in the form of auto-injectors, they present an immediate possibility of release; and (3) requiring waste pharmaceuticals to be kept in closed containers would provide an increased level of security for such pharmaceuticals, and help prevent pilfering and abuse. See DEEP Comments at 10-11.

DEEP's concern about waste pharmaceuticals not being in their original packaging is reasonable. However, it is common practice for some generators to place hazardous pharmaceutical waste that is not in its original packaging (e.g., loose pills or liquids) in individual plastic bags or stock bottles before placing them into a secondary container. CVS believes that the individual bags and stock bottles are the primary containers, and the larger container that holds these smaller "containers" is the secondary container. CVS believes that requiring secondary containers of pharmaceutical waste to be kept closed will cause undue burden. The primary containers should be kept closed and the secondary container should be allowed to remain open to make it easier for employees to manage the pharmaceutical waste at the point of generation. Therefore, CVS believes that any "closed at all times" container requirement should be limited to the primary container that holds the pharmaceutical waste (e.g., amber vials, stock bottles, original manufacturer packaging, etc.).

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CVS believes that the primary container adequately addresses DEEP's concerns about the possibility of release from liquids and pharmaceuticals not being in their original containers. With respect to DEEP's concerns about security, DEEP should be mindful of various internal protocols that many pharmacies already have in place to prevent pilfering and abuse.

V. Tracking

DEEP is seeking comment on the types of documents that should be used for tracking shipments of pharmaceutical universal waste between handlers and from handlers to disposal facilities. DEEP is also seeking comment on what specific information should be required in such tracking documents. CVS encourages appropriate recordkeeping of hazardous pharmaceutical wastes by entities that take these wastes from pharmacies and other healthcare entities and providers. However, CVS believes this documentation should include a simple bill of lading or other tracking document for in-state shipments. No itemized logs should be required.

With respect to out of state shipments, a hazardous waste manifest should be used for waste shipments to out of state incinerators or out of state treatment, storage, or disposal facilities. The "additional information" section of the hazardous waste manifest should state that the hazardous pharmaceutical waste is considered universal waste per DEEP's regulations. This will allow the hazardous pharmaceutical waste to be managed as universal waste in Connecticut even where it is being shipped to a state that may not recognize DEEP's universal waste rule. CVS believes that hazardous pharmaceutical waste should not lose its universal waste status in Connecticut just because it is sent out-of-state for treatment, storage, or disposal.

VI. Other Key Issues That Should Be Considered

A. Over-Management of Non-RCRA Pharmaceutical Waste

CVS believes that pharmacies and other pharmaceutical universal waste generators should have the option of managing pharmaceutical universal waste and non-RCRA pharmaceutical wastes on-site prior to transport and disposal as either universal waste or as hazardous waste, without losing the ability to classify qualifying waste items as universal waste upon transport. In some situations, where generators have several different types of waste streams to manage in a space-constrained setting (e.g., RCRA hazardous waste, non-RCRA waste, and pharmaceutical universal waste), the need for efficiency and simplicity dictates that a program developed to manage such wastes be designed to achieve compliance with the most stringent management standards applicable to those waste streams. Typically, the most stringent management standards are those that apply to RCRA hazardous wastes.

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Therefore, implementing a program that results in "over-management" of pharmaceutical universal waste and non-RCRA pharmaceutical wastes as hazardous waste should be permissible and should not foreclose the generator's ability to classify qualifying waste streams as pharmaceutical universal waste upon transport. In such cases, the generator or its agent would segregate waste items by classification upon transport for purposes of calculating and documenting the amount of hazardous waste (vs. pharmaceutical universal wastes or non-RCRA pharmaceutical waste) that has been generated. Accordingly, CVS believes that the proposed rule should include a provision that clarifies that pharmaceutical universal waste and non-RCRA pharmaceuticals can be over-managed as hazardous waste prior to transport without being classified as such.

B. Security

CVS agrees that security is an important consideration when managing pharmaceuticals. CVS encourages DEEP to consider these elements, such as privacy and diversion, during the development of the universal pharmaceutical waste management requirements. CVS urges DEEP to continue coordinating with other affected agencies such as the State Board of Pharmacy and DEA while developing management requirements that include security concerns. This would prevent DEEP from developing regulations that are inconsistent with the intent of DEA or the State Board of Pharmacy regulations.

Conclusion

CVS appreciates the opportunity to present our views on the Key Issues Document and looks forward to working with DEEP on these issues. Please feel free to contact me at (401) 770-7457 or Wendy.Brant@CVSCaremark.com with any questions. Thank you for your consideration of these comments.

Sincerely,

Wendy Brant

Wendy Brant,
Senior Manager, Corporate Environmental
CVS Caremark

APPENDIX A

U.S. Environmental Protection Agency
Containers that Once Held P-Listed Pharmaceuticals
(November 4, 2011)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
SOLID WASTE AND EMERGENCY
RESPONSE

NOV 4 2011

MEMORANDUM

SUBJECT: Containers that Once Held P-listed Pharmaceuticals

FROM: Suzanne Rudzinksi, Director
Office or Resource Conservation and Recovery

TO: RCRA Division Directors, EPA Regions 1-10

Issue

We have received numerous inquiries regarding the regulatory status of containers that once held pharmaceuticals that are on the "P-list" of commercial chemical products (CCPs) in 40 CFR 261.33(e). Most inquiries are regarding pill bottles that have held warfarin (brand names Coumadin and Jantoven; P001 at concentrations greater than 0.3%). But others have been about the packaging that held nicotine (P075) gum and patches and physostigmine (P204) ampoules. These inquiries are often about the original packaging for the P-listed pharmaceuticals – such as pill bottles, vials, blister packs, wrappers, etc. But they often extend to those containers that are used in healthcare facilities to deliver pharmaceuticals to patients – such as paper cups.

The inquiries have focused on the containers that held P-listed CCPs listed in 261.33(e) because P-listed CCPs are considered acute hazardous wastes when discarded. When a generator generates or accumulates more than 1 kg acute hazardous waste per month, the acute hazardous waste is subject to the large quantity generator (LQG) regulations of 40 CFR 262.34(a) (along with all applicable regulations in 40 CFR Parts 262 through 266, 268, 270 and 124, and notification requirements of section 3010 of RCRA). These generators have expressed concern that they are becoming LQGs, at least episodically, based on managing containers that have been fully dispensed and typically have very small amounts of residues in them which may not even be visually detectable.

Applicable Regulations

The regulatory status of CCP residues remaining in a container are specifically addressed in 40 CFR 261.33:

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

According to 40 CFR 261.7(b)(3) there are three ways that a container that held an acute hazardous waste can be considered "empty":

> "A container or an inner liner removed from a container that has held an acute hazardous waste listed in §§261.31 or 261.33(e) is empty if: . . .
>
> (i) The container or inner liner has been triple rinsed using a solvent capable of removing the commercial chemical product or manufacturing chemical intermediate;
>
> (ii) The container or inner liner has been cleaned by another method that has been shown in the scientific literature, or by tests conducted by the generator, to achieve equivalent removal; or
>
> (iii) In the case of a container, the inner liner that prevented contact of the commercial chemical product or manufacturing chemical intermediate with the container, has been removed."

Therefore, if the container that held the P-listed pharmaceutical is not triple rinsed, or cleaned by another method that has been demonstrated to achieve equivalent removal, or had the inner liner removed, the container is not considered "RCRA empty," even though the pharmaceutical may be fully dispensed. If the container is not "RCRA empty," then the *residues* are regulated as acute hazardous waste.

Three Approaches to the Issue that Generators Can Use

1. Count only the weight of the residue toward generator status

As the regulatory language makes clear, it is only the *residue* in the non-RCRA-empty container that is considered a P-listed hazardous waste; the container itself is not a hazardous waste. Accordingly, it is only the weight of the *residue* in the container that needs to be counted toward generator status; the weight of the *container* does not need to be counted toward generator status (see November 1983 Q&A; November 25, 1980, 45 FR 78527; and December 23, 1993 memo from Shapiro to Peter Joseph).

A major retail pharmacy that has raised this issue with EPA has provided some limited testing data. This generator has indicated that after all the pills have been dispensed from a 100-count bottle of 10-mg Coumadin pills, the bottle (without a cap) weighs approximately 10 grams. At 10 grams/bottle, the generator has calculated that 100 such bottles weigh 1000 g (or 1 kg/2.2 lbs), and if the pharmacy generates >1 kg/month, it would be an LQG for the month. However, the generator has also indicated that the same fully dispensed 100-count bottle of 10-mg Coumadin contains approximately 1 mg of residue (sometimes slightly higher or lower amounts) when all the pills have been dispensed. When only the 1 mg of *residue* is counted toward generator status, then it would take the combined residues from >1 million dispensed bottles to reach LQG quantities of >1 kg/month.

Becky Wehrman of SmartER Community Assistance has also provided some limited testing data. In this case, single-dose packaging was tested for several P-listed chemicals and the most residue that was detected was 35.8 µg (or 0.0358 mg).

It is important to note that it is hard to generalize these results to all containers that held pharmaceuticals. The data provided were for a few types of containers/packaging for a few of the most common doses of P-listed pharmaceuticals. Certainly not every generator will know the exact weight of residue in each container. However, using conservative approximations for similar situations of visually empty

containers, it is fair to say that it would take the combined residues from many thousands of containers before a generator would exceed the LQG quantities of 1 kg/month acute hazardous waste. For example, if a container had 100 mg of residue, it would take the combined residues from more than 10,000 containers to exceed 1 kg/month of acute hazardous waste.

In some cases, we anticipate that this interpretation will mean that some healthcare facilities that have been counting the weight of the container and therefore managing their hazardous waste in accordance with the LQG standards, will now be able to manage their hazardous waste in accordance with the CESQG standards of 40 CFR 261.5. In such instances, we are concerned that the containers, which could be discarded in the municipal wastestream, could be diverted from the municipal wastestream and used for illicit purposes, such as packaging counterfeit pharmaceuticals. In order to prevent diversion, abuse, and identity theft of the containers and other packaging, CESQGs that discard containers that formerly held any pharmaceutical should destroy the containers prior to placing them in the trash (i.e., by crushing the container in a trash compactor, and/or removing or defacing the labels).

In other cases, however, a healthcare facility may generate other acute hazardous wastes in a month that, combined with the P-listed container residues, would cause the facility to exceed the 1 kg monthly threshold. In such cases, all the acute hazardous wastes - including the pharmaceutical residues inside the non-RCRA-empty containers - would have to be managed in accordance with the LQG regulations. Among other requirements, the hazardous waste must be manifested to an interim status or permitted hazardous waste treatment, storage or disposal facility. The manifest only needs to reflect the weight of the hazardous waste; it does not need to include the weight of the containers. However, if only the total weight is known (i.e., weight of the hazardous waste residues plus the weight of the container), the total weight may be included on the manifest instead. Transporters typically charge on the basis of the total weight transported over a specified distance and; therefore, may choose to include the total weight of the shipment on the manifest (see March 4, 2005, 70 FR 10791; November 25, 1980, 45 FR 78527; and November 1983 Q&A). Weights that are listed on the manifest are often used by generators and inspectors to make estimations of generator status. If only the weight of the residues in a container is counted toward generator status, but the total weight is listed on the manifest, there could be some confusion about a generator's actual generator status. We recommend that when non-RCRA-empty containers are manifested, the generator/transporter use Box 14 of the manifest (Special Handling Instructions and Additional Information) to indicate that although the total weight is included on the manifest, the weight of the containers was not included in determining its generator status.

2. Demonstrate an equivalent removal method to render containers RCRA empty

Generators have been reluctant to use triple-rinsing to render their containers "RCRA empty" for several reasons. First, if a container that once held P-listed pharmaceuticals is triple-rinsed to render the container "RCRA empty," the rinsate would be considered P-listed hazardous waste due to the mixture rule (see 40 CFR 261.3(a)(2)(iv)), unless the P-listed CCP is listed for ignitability, corrosivity or reactivity and the rinsate does not exhibit the characteristic for which the P-listed chemical was listed (see 40 CFR 261.3(g)(1)). Second, although the container would be considered "RCRA empty" after triple rinsing, in most cases a generator would generate considerably more P-listed hazardous waste than it started out with. Finally, EPA strongly discourages the drain disposal of rinsate that is hazardous waste.

As a result, generators have been interested in demonstrating that the containers are "RCRA empty" in accordance with 261.7(b)(3)(ii), which allows a container that held an acute hazardous waste to be

considered "RCRA empty" if it has been cleaned by a method (other than triple rinsing) "that has been shown in the scientific literature, or by tests conducted by the generator, to achieve equivalent removal."

To our knowledge, there are no references in the scientific literature demonstrating an equivalent removal method to triple rinsing. In the absence of scientific literature, a generator would need test data to show that it has achieved an equivalent removal method. EPA has said in a memo dated July 28, 1993:

> "EPA requires no formal approval process if an alternative cleaning method is used to empty the container, and no variance is necessary under the federal regulations when using alternative cleaning methods pursuant to 40 CFR 261.7(b)(3)(ii). We would suggest that if you do use an alternative cleaning method, you document the method used and keep this record as part of your facility's operating record."

Therefore, in such cases, it would be up to the generator's implementing agency (i.e., the State or Region) to review a generator's data to make case-by-case decisions about whether the generator has achieved an equivalent removal method. The implementing agency could review data either at the generator's request, or during an inspection.

Finally, recently, generators have inquired whether a method such as "bag beating" would be an equivalent removal method to triple rinsing containers and other packaging that once held pharmaceuticals. This question stems from a May 20, 1985 memo, in which EPA stated that "beating the bags after emptying can be an alternative to triple rinsing," because paper bags cannot be triple rinsed. To our knowledge, containers and packaging that once held pharmaceuticals are, however, made of materials that, unlike paper bags, can be triple rinsed. Therefore, "bag beating" is an equivalent removal method to triple rinsing only for paper bags and not for other types of containers.

3. Show that warfarin concentration in the residue is below P-listed concentrations

The last approach only applies to pharmaceutical containers that once held the p-listed pharmaceutical warfarin (brand names Coumadin and Jantoven). Most of the inquiries we receive regarding pharmaceutical containers are about the P-listed pharmaceutical warfarin (brand names Coumadin and Jantoven). The P- & U-listings for warfarin are unusual in that they are concentration-based. Warfarin (and its salts) at a concentration of $> 0.3\%$ is listed as P001 in 40 CFR 261.33(e), while warfarin & salts at a concentration of $\leq 0.3\%$ is listed as U248 in 40 CFR 261.33(f). If the concentration of warfarin in the residue is ≤ 0.3 %, then the residue would meet the U248 listing, not the P001 listing. U-listed hazardous wastes are not acute hazardous wastes and are not subject to the 1 kg/month threshold.

We do not have, nor have we received, data regarding the concentration of warfarin in the residue remaining in fully dispensed containers of warfarin. Generators have indicated that some doses of warfarin pills contain concentrations high enough to meet the P-listing. But if a generator conducted analysis on the warfarin residues remaining in a fully dispensed container and the concentration of the residues is $\leq 0.3\%$ warfarin, then the residues would not meet the listing description for the P-listed waste, even if the pills originally in the container did meet the listing description. Instead, the residues remaining in the container would be regulated as U248 hazardous waste.

In order to determine the concentration of warfarin in the residue of fully dispensed Coumadin containers, one would need to conduct the following calculation:

$$\frac{\text{weight of the warfarin in the residue}}{\text{total weight of the residue remaining in the container}} \times 100 = \text{warfarin concentration of the residue (expressed as a percent)}$$

Additional Information

Please note that this letter discusses only the federal hazardous waste regulations. States that are authorized to implement the RCRA program may have regulations that are different than the federal regulations provided they are not less stringent than the federal program. Please consult your state regulatory requirements in addition to this memo. If you have any questions about the federal hazardous waste regulations discussed in this memo, please contact Kristin Fitzgerald at (703) 308-8286 or Fitzgerald.Kristin@epa.gov.

cc: RCRA Enforcement Managers, EPA Regions 1-10
RCRA Interpretive Network (RIN)
Dania Rodriguez, ASTSWMO

To: Michele DiNoia November 18, 2013

From: Gregory McKenna

Response to key issues from a independent community pharmacy standpoint,

1) The EPA definition for a Pharmaceutical is a fairly rigorous, as it includes prescription medications and Over-the-Counter (OTC) medications, which recently has become an increasing category with the proliferation of Rx to OTC conversions in the marketplace as manufacturers are attempting to get more products directly in front of the consumer, and the pharmacy benefit managers attempt to lower their costs, by not covering the OTC product. This will add to the burden on the pharmacy as it is another source of universal waste. I believe the definition of pharmaceutical is complete, but the definition of Pharmaceutical Universal Waste should be amended to: A pharmaceutical that has exceeded the manufacturer suggested expiration date, and is not able to be included in the Reverse Distributor process, is a hazardous waste as defined in 40 CFR 261.3.
2) I do not see an expansion of pharmaceuticals to be treated as hazardous waste, and as such would include the Medications listed from the NIOSH Publication No. 2012-150, and classifying these medications as Universal Pharmaceutical waste, but do so in concert with the long standing practice of a Reverse Distributor, which is an integral component to the viability of a pharmacy. Historically, the Reverse distributor mechanism function allowed for pharmacies to carry a product that needs to be dispensed with timely accessibility of appropriate medication therapy. The Reverse distributor created the mechanism for the manufacturer to reimburse the pharmacy for making the product readily accessible in the marketplace, which was always funded on the back end. This is a key difference between the HealthCare machine versus almost any other commodity based manufactured products- the client who is sick and does not have the luxury of waiting for the distribution pathway, to provide the medication. As by example, would anyone expect mail-order only delivery of antibiotics, pain medications, or new blood pressure therapy, the examples are endless. The manufacturer is taking part in the disposal of the product thru the Reverse Distributor. But, with the Use of a Reverse Distributor the medication is being handle so that it does not get thrown in the trash.
   There are medications on the NIOSH list that are returnable via a Reverse Distributor. Since these drugs do have a Hazardous component to them, any medication that is not processed first thru a Reverse distributor, thus being place in Universal Pharmacy Waste category should have a more stringent container rule to protect the handler, and employees within the generators facility in case of spill. The medications that are not within their regular container should be identified on a form placed on the outside of the waste container with the name of product, quantity, and date of disposal. This also aids the generator in determining storage time. The form does not have to be extremely technical in determination of waste codes, because they fall into the universal waste stream, but a reactive or flammable medication should be stored in separate containers, still considered universal pharmacy waste. Training is integral. The other issue we have to discuss is the destruction and disposal of Schedule 2-5 controlled drugs, since prior to disposition the medication needs to be accounted for with various agencies, and then rendered irretrievable for use.
3) Training to pharmacy staff should take place within 3 months of hire, but in-house training programs should be allowed. The state should have the requirement to provide multiple training sites and times throughout the year to create Train-the-trainer programs. This would solve some important issues since the DEEP would 1) create defined educational and thus operational goals, 2) make the disposal of Universal Waste more affordable to the small generators, and 3) keep more medication out of the trash. But prior to having the

enforcement, the DEEP should clearly define the rules, and publish them. I would also like to see DEEP provide a web based training program that would collect data showing date of training and proficiency of concepts, possibly providing a certificate for individual certifying acknowledgement, attendance, and understanding of concepts for the healthcare provider.

4) The pharmacies within which I manage utilize the Kendall 3-gallon Pharmacy closed container system for the individual tablets that are: 1) broken tablet/capsule from stock bottle, or 2) tablet/capsule that have dropped on the floor. When the container is full, we render these medications irretrievable usually through addition of bleach, then we seal the Container with duct tape and place in trash, since our trash is incinerated. Normally in a one year period this would amount or something less than 2 pounds. I could envision this type of Pharmaceutical Waste to be handled under the Universal Waste Rules, because if this type of container is used it would certainly eliminate tablets thrown in trash or worst yet the public water system.

   The biggest amount of universal waste comes from the normal process that has occurred in pharmacies over the last 32 years that I have been in practice, which is the monthly review of current inventory that is taken off the shelf, both in the pharmacy and front store, so as not to dispense or sell expired medication. Once taken off the shelf, these are stored in a separate area away from viable product. These soon to be outdated and or outdated medications are all ready packaged in the containers from the manufacturer, so at this juncture I do not see why the soon to be expired product should be placed in a closed lid container, as it all ready is, and their is no danger of leakage. I would be remiss not to address The other waste stream that should be acknowledged is used bulk pharmaceutical bottles, which are by definition "empty". The problem is space, and financial reimbursement, since pharmacy reimbursement is at its lowest level in history, and this would pose another non-reimbursable expense.

I believe the only time Universal Pharmacy waste should have mandated closed container, is when the pharmaceutical now resides outside the original pharmaceutical manufacturer container, as all pharmaceuticals are shipped, and stored on pharmacy shelves in appropriately closed containers . If the pharmaceutical waste exists outside its original container, I.e. Intravenous solution with an additive, then the closed container should match the product that it stores, making an allowance for a potential spill. But, the rule has to be cognizant of the tremendous financial burdens being placed on pharmacies.

5) The use of Reverse distributors already provide a listing of medications and approximate quantities the pharmacies are shipping via the transporter. I do not see the use of having to store other shipping documents greater than what happens already.

6) The biggest issue that I see, which arose in our initial conversation focuses on the potential definition of expired pharmaceuticals as universal waste, when in fact the pharmacy utilizing the manufacturer standards has made the decision not to sell the product to the typical end consumer (individual client) but instead is selling it back to the manufacturer thru the Reverse Distributor. Currently, the manufacturer, and the pharmacy benefit managers retain the largest profit margins in the system, and to discontinue their financial input to the system would be unjust. Generic Pharmaceutical manufacturers as well as the brand manufacturers should be required to reimburse the pharmacies for their products. I also believe the manufacturers should be responsible for the cost of the disposal of the bulk empty pharmaceutical bottles.

November 5th, 2013

Robert C. Isner, Director
Waste Engineering and Enforcement Division
Bureau of Materials Management and
Compliance Assurance
Connecticut Department of Energy and Environmental Protection
79 Elm Street, Hartford, CT 06106-5127

Dear Mr. Isner:

I am responding to your request for comments regarding the proposed development of a state universal waste rule to include waste pharmaceuticals. These comments are on behalf of PharmEcology Services, WM Healthcare Solutions, Inc., a Waste Management company. We understand the issues surrounding pharmaceutical waste compliance, especially with respect to hazardous waste generator status as it applies to P-listed drugs. Since Connecticut continues to manage epinephrine, nitroglycerin, and phentermine as P-listed hazardous waste, most if not all hospitals in Connecticut may have notified as Large Quantity Generators of hazardous waste under the current regulations. Enabling generators to manage these drugs under universal waste rules would remove the need to document their weight monthly and to include these weights when calculating generator status, and we support this initiative.

While this letter will address primarily the items noted in a letter I received via email on October 29th, 2013, I have previously provided a response to the EPA's proposed Universal Waste Rule, published on December 2nd, 2008, from PharmEcology Associates, a company with which I was previously affiliated.

1. Definitions
    a. Pharmaceutical
        i. The proposed definition includes "any chemical product…" We respectfully request that for the purpose of this rule-making, the definition should specify that the pharmaceutical has been formulated by the manufacturer or other party into a final dosage form, which includes diluents, excipients, and other non-active ingredients, and the definition should specifically exclude pharmaceutical grade bulk chemicals from management under this rule. To the pharmaceutical industry, especially manufacturers, pharmaceuticals exist initially in their pure chemical form. PharmEcology Services does not agree that these bulk chemicals should be managed as universal waste during the manufacturing process or as these are formulated into finished dosage forms such as tablets, capsules, oral liquids, ointments, injectables, etc. In their

pure form these chemicals exhibit much more serious safety and disposal risks and should be managed under full RCRA regulations.

We agree that sharps, spill clean-up materials, and the other items noted as being excluded are appropriate for exclusion.

b. Pharmaceutical Universal Waste
    i. We would recommend the following slight modification to the definition: "A pharmaceutical that is a hazardous waste as defined in 40 CFR 261.3, and containers (e.g. bottles, vials, IV bags, tubes of ointment/gels/creams, ampules, etc.) *which have held any hazardous pharmaceutical waste and which are not considered to be "RCRA-empty" as defined in 40 CFR 261.7 Residues of Hazardous Wastes in Empty Containers.*

2. Inclusion of drugs from NIOSH Publication No. 2012-150:
    a. PharmEcology Services has long recognized the fact that RCRA hazardous waste listings (P and U) have not kept up with drug development. We developed a PharmE Hazardous® category to include those drugs which we believed, in our professional judgment as pharmacists, should be managed as hazardous waste. At one time, we included all the drugs listed on the NIOSH Alert 2012 and the Appendix of the OSHA Technical Manual. As the healthcare industry has begun moving not only towards compliance with RCRA but also towards the best management practice of discontinuing drain disposal of most other drugs, we have adjusted our PharmE Hazardous® category to include the following: chemotherapy drugs (as identified in the American Hospital Formulary Service), EPA regulated pesticides formulated as drug products (e.g. permethrin), iodine-containing products (e.g. Isovue used in Radiology), multi-mineral preparations containing selenium and chromium when a TCLP is not available, and pressurized aerosols in addition to those with ignitable propellants (to comply with DOT shipping regulations).

    We have deliberately re-classified endocrine disruptors such as estrogenic compounds into the non-hazardous category with the expectation that these will be treated by incineration at either a waste-to-energy plant or a regulated medical waste incinerator. Because Connecticut already prohibits drain disposal of pharmaceuticals, this concept could suffice thereby saving considerable expense to the healthcare facility while protecting the environment by not allowing drain disposal.

3. Training:
    a. Healthcare facilities are still working very hard to train their employees how to segregate pharmaceutical waste based on the RCRA regulations. We believe training on universal pharmaceutical waste is even more important to clarify what the Universal Waste Rule is and how it applies to waste

pharmaceuticals at the state level. For example, many pharmacists believe that the term "universal" applies to all drugs and that they must therefore manage all drugs under the universal waste rule, thereby shipping all pharmaceutical waste to a hazardous waste incinerator at an increased cost. At least a core team of individuals at a facility needs to understand that "universal waste" is a subset of hazardous waste, and also includes lamps, batteries, pesticides, and mercury-containing devices. With this understanding, facilities can make better decisions as to how to manage this waste stream and whether or not to segregate items accordingly.

4. Container Management
    a. We believe that since the items collected in the Universal Waste containers are essentially the same as the items collected in a RCRA container, the containers of hazardous pharmaceutical waste managed under Universal Waste rules should be kept closed when not in active use.

5. Tracking:
    a. One of our primary concerns about the Universal Waste Rule proposed by the EPA was the loss of the six-part Uniform Hazardous Waste Manifest. We maintain that unlike other items currently managed under the Universal Waste Rule, many discarded pharmaceuticals still have value on the black market and a more robust system of tracking and tracing this waste stream is needed. In our comments to EPA regarding the federal proposed UWR for pharmaceuticals, we proposed that waste pharmaceuticals be managed under UWR rules within the healthcare facility but then are tracked on the Uniform Hazardous Waste Manifest. Since this waste stream will need to be manifested when leaving the State of Connecticut, we propose the Uniform Hazardous Waste Manifest be used at the point of generation. This is also consistent with how the State of Michigan, which also manages RCRA pharmaceutical waste, manages their Liquid Industrial Waste, which includes universal pharmaceutical waste.

       We expanded on these concerns in our response to the EPA Docket regarding the proposed addition of RCRA pharmaceutical waste to the Universal Waste Rule, dated December 2, 2008. I've included our response in a prior communication.

6. Additional Key Issues:
    a. Eligible entities: We encourage CT DEEP to restrict the applicability of this proposed Universal Waste Rule to healthcare and related entities, including drug wholesalers, pharmacies, and other provider organizations. We propose that pharmaceutical manufacturers and reverse distributors continue to manage waste pharmaceuticals under the current RCRA regulations, given the nature of their businesses and the volumes of waste typically generated either through the manufacturing process or the reverse distribution process.

b. Full waste categorization of the potential universal waste: The final disposition of this potential universal waste stream will be a fully permitted RCRA facility. Therefore hazardous waste profiles will continue to be required by the vendor and waste categorization will need to be performed by the generator to enable segregation, if desired, and appropriate profile generation.

c. Registration of Universal Waste Handlers: Require transport and consolidation vendors to register with the State of Connecticut in some form. The State of Florida, one of the other two states to add pharmaceuticals to their UWR, finally had to require universal waste handlers of pharmaceuticals to become reverse distributors with full DEA registration to avoid unvetted haulers from taking position of dangerous drugs and possibly consolidating them, thereby exposing employees to OSHA hazards as well as diversion opportunities.

d. Consider contacting the Michigan Dept. of Environmental Quality and the Florida Dept. of Environmental Protection to learn more about their experiences with implementing the universal waste rule for pharmaceuticals.

PharmEcology Services has had experience working with both the Florida DEP and Michigan DEQ universal waste rules and is pleased to participate in the current stakeholder group. Please let us know if you have any additional questions or concerns to which we can respond at this time.

Sincerely yours,

Charlotte A. Smith, R. Ph., M.S.
Senior Regulatory Advisor
PharmEcology Services
WM Healthcare Solutions, Inc.

Connie Greene

Facility Licensing and Investigations Section

November 20, 2013

Pharmaceutical Waste as a Universal Waste

1. Comment on whether the proposed definition of “pharmaceutical” should be amended and how such definition should be amended?

The pharmaceutical waste definition should include sharp items in the home setting; since many patients are educated and trained to self administer Lovenox (Anticoagulant) and / or use insulin injections in the home setting. If this process is not monitored and/ or regulated it could lead to environmental hazards and inappropriate use of needles in the community.

Many patients are discharged from the hospital and nursing homes with infectious diseases such as Methicillin Resistant Staphylococcus (MRSA) and Vancomycin-Resistant Enterococci (VRE). Although families are educated on the utilization of protective equipment during care to prevent the spread of infection. Often, families in the home setting have no idea of what to do with the infected protective equipment. The result is they dispose hazardous materials in the trash. This process places families and the public at risk for infection. The definition should also include: digital thermometers, blood pressure cuffs and other medical devices used for medical treatment, because of the potential spread of infection.

2. Should oncology drugs that are toxic and present exposure hazards be managed as universal waste?

Oncology medications oral and intravenous are toxic and should not be managed as universal waste as they present exposure hazards .Chemotherapy medications administered orally require the user to wash their hands and wear gloves during administration of the drug to prevent toxic exposure. Patients are instructed for disposition to take their un-used medications back to the pharmacy for proper disposal to ensure environmental protection. Intravenous chemotherapy medications are disposed in a controlled hospital setting to prevent public exposure to toxin. Families and health care professionals, who store and dispense the cytotoxic medications, must have an emergency plan in the event of a spill or exposure. Chemotherapy medication should not be considered a form of universal waste, because of the potential environmental risk.

3. Should additional training be required for quantity handlers of universal pharmaceutical waste of 5000 kilograms or less?

The amount of pharmaceutical waste does not matter. However, what is important is the type of waste and the education the handler receives to safely perform their duties. The training should include step by step directions regarding disposal of various types of waste products without releasing toxins into the environment and how to prevent self exposure. To ensure compliance, training should include a universal manual that specifies: the type of waste product, tracking, monitoring and Quality Assessment measure.

4. Should pharmaceutical waste containers be required to be kept closed?

Yes, it appears to be expensive on the supply chain but in the end it will preserve the environment and ensure the public safety. I believe, most people want to save the environment from toxins and will realize that the benefit out way the cost.

5. What type of document that should be used to track shipments of universal waste pharmaceuticals between handlers to handlers and to disposal facilities?

Long term care facilities use a log to track infectious disease. A written log or a facility generated spread sheet should be use to track: the type of universal pharmaceutical waste , the date and time of the exchange between handler to handler, the amount of waste and any accidents that occurred during the delivery process. Waste facilities should be educated regarding the use of the tool and monitoring staff compliance.

6. Are there any other key issues that should be considered at this time for preliminary draft of regulations?

To prevent employee abuse, there needs to be a system or mechanism to track employees who transport pharmaceutical agents to disposal facilities. For example, Fentanyl (pain reliever patch applied transdermal) can be abused by patients and healthcare providers when disposed of in the trash.

The group needs to consider that many of vials of Pertussin and Hepatitis B vaccines contain Mercury. Mercury can have a significant effect on the environment if not disposed of appropriately.

The definition of Pharmaceutical agent should also include respiratory inhaler medications as a chemical agent.

Stericycle®
Specialty Waste

November 26, 2013

Michele DiNoia
Robert C. Isner
CT DEEP
79 Elm Street
Hartford, CT 06106-5127

RE: **Comments/Suggestions-CTDEEP Pharmaceutical Universal Waste**

Dear Ms. DiNoia and Mr. Isner

CT DEEP requested input on five key issues and comment on whether there were other key issues that should be considered by the stakeholder group. Stericycle provides the following comments for your consideration:

1) **Definitions:**

"This definition does not include sharps or other infectious or biohazardous waste, ..."

The definition of pharmaceutical excludes all sharps which includes syringes "regardless whether a hypodermic needle is attached thereto". We recommend that the definition of "sharps" not include uncontaminated syringes CGS §22a209-15(a)"Infectious waste" includes used sharp. The recommendation to not include uncontaminated sharps provides the ability to manage pharmaceuticals in syringes such as auto-injectors, leur locks etc. Since no needle is attached and these devices are protected from body fluids by use, design, and valves, they pose no infection risk. This will allow a larger quantity of partial medications to be managed as Universal Pharmaceutical Waste (UPW).

To support this CGS §22a209-15(a) Definitions excludes hazardous waste from the definition of biomedical waste and we recommend that the DEEP allow non-hazardous pharmaceutical wastes to be managed as Universal Pharmaceutical Waste.

CGS §22a209-15(a) Definitions

""Biomedical waste" means untreated solid waste...but excluding (1) any solid waste which is a hazardous waste pursuant to Section 22a-115 of the General Statutes or a radioactive material..."

2) **Inclusion of drugs from NIOSH Publication No. 2012-150:**

We agree that the NIOSH list of Antineoplastic and Other Hazardous Drugs in Healthcare Settings should be included in the definition of pharmaceuticals that are hazardous waste and may be managed as UPW.

We recommend that a formulary characterization be performed on all medications stocked. The reason for the characterization report would be to ensure incompatible medications are separated appropriately. Additionally, when medications are added to the formulary or inventory, the characterization report would be required to be updated. Since chemotherapy medications have a higher danger risk for handling additional precautions should be written in for the handling of chemo waste. Since P-listed waste would be handled very differently under these new UPW rules, we recommend that a "call out" be included regarding the handling of P-listed waste.

DEEP stated: " The Food and Drug Administration ("FDA") approved about fifty (50) new oncology drugs alone since 2008." Are the 50 new oncology drugs included on the NIOSH list? Additionally as new oncology medications will continue to be developed faster than the regulations can be amended we recommend that all chemotherapeutic drugs be managed as UPW until it can be demonstrated that they do not pose a substantial risk to humans or the environment.

3) **Training:**

We recommend that training be required for handling of UPW Pharmaceutical waste. We recommend the training requirements be General Awareness and Function Specific. Different types of handlers should customize the training to their specific needs. We recommend, at a minimum, that training be the same as for DOT which requires training within 90 days of hire and every 3 years after the initial training. This would allow easier tracking as well as allow for DOT and UPW training to be concurrent.

The key stake holders may consider more frequent training, such as yearly, given that many new drugs enter the market each year.

4) **Container Management:**

We do not recommend that containers need to be kept closed when not being used. We recommend that, if the lids are allowed to be kept open, then liquids or items that can leak be placed into another individual sealed container so as to prevent spills. Florida has addressed this topic in the UPW regulations.

62-730.186 Universal Pharmaceutical Waste. (7)

(b) A handler shall clearly label those containers and tanks accumulating waste pharmaceuticals with the phrase "universal pharmaceutical waste" or "universal waste pharmaceuticals," and keep records of what is going into each container sufficient to allow safe handling and proper disposal of the universal pharmaceutical waste.

(c) A handler may conduct the following activities as long as the innermost container of each individual pharmaceutical remains intact and closed, or if the innermost container is placed into another individual sealed container:

We do recommend that containers must be under the generators' control at all times and stored in such a manner that prevents unauthorized access.

There will be many references to security and locking containers. From a practical standpoint there are many situations where this securement or locking mechanism is not possible or practical. Specifically operating rooms and Emergency rooms become virtually impossible to utilize locking containers while maintaining usability. This does not prevent security by observation and access control. Our recommendation is to place the burden of security on the generator by using the means necessary to prevent unauthorized access and diversion.

5) **Tracking:**

We recommend shipping papers be required to allow for the tracking of the waste to its final destruction and include documentation of final destruction. The shipping papers would be required to be maintained for three years with the generator receiving the original signed document from the destruction facility similar to a hazardous waste manifest.

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Specialty Waste

6) DEEP is seeking comment on whether there are other key issues that should be considered at this time for our preliminary draft of the regulations.

We recommend the notification of UPW transporters who could be allowed the ability to manage UPW waste through use of a transportation facility similar to a transfer station or reverse distributor.

Also, we recommend the handling of controlled substances be addressed as part of this process which would meet both DEA and EPA requirements.

Thank you for the opportunity to participate in this process. Stericycle believes in the stakeholder process and looks forward to continued communication with the department through this very important undertaking. For further questions regarding our comments or additional correspondence please contact me at (770) 891-2531 or TMcCaustland@Stericycle.com and you may also reach Gerry Van Domelen Senior Manager, Rx Waste Compliance Service, SteriVantage, & Specialty Waste at (651) 248-9343 GVandomelen@Stericycle.com.

T.J. M^{c} Caustland

Environmental Safety & Health Manager - East Region

5158 Ashley Drive

Covington, Georgia 30014

UCONN | HEALTH CENTER

November 22, 2013

Michele DiNoia
Waste Engineering and Enforcement Division
Bureau of Materials Management and Compliance Assurance
Department of Energy and Environmental Protection
79 Elm Street
Hartford, CT 06106-5127

Dear Ms. DiNoia,

Thank you for allowing me to participate in the Stakeholders Group Regarding Connecticut's Proposal to State-list Pharmaceutical Waste as Universal Waste. Please find comments on the key issues below. These comments are based on conversations I've had with key personnel knowledgeable about the pharmaceutical and hazardous waste as well as the impact of a state-initiated universal waste listing.

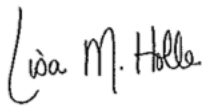
1) **Definitions.** Overall the definitions proposed for "pharmaceutical" and "pharmaceutical universal waste" are appropriate. Amending current definitions could lead to confusion and other definitions specified in this section (eg, sharps, biohazardous waste) currently fall under other regulations (including EPA and state). Additionally, one pharmaceutical waste stream should provide an efficient and safe means of collection and still meet the OSHA and employee's right to know laws.
   Of note, although we agree with definition, the exclusion of sharps in this definition does pose additional hazards to healthcare staff because of the stricter disposal methodology, and to patients by requiring extra bin in patient care rooms, with very limited environmental benefit. Additionally, in the future, consideration of inclusion of personal protective equipment contaminated with hazardous pharmaceuticals (eg, chemotherapy gowns, gloves) in definition of "pharmaceutical" should be addressed.
2) **Inclusion of drugs from NIOSH Publication No. 2012-150.** Agree that drugs from Appendix A of NIOSH publication No. 2012-150 and Appendix VI:2-1 of the OSHA Technical Manual (or updated versions of these documents) should be managed as universal waste. Classifying all chemotherapy as pharmaceutical universal waste is appropriate because it eliminates confusion and automatically includes the newly introduced compounds as they come to market. This simplifies and standardizes the process, which historically tend to be the most successful.
3) **Training.** Training should be required for both small and large handlers of universal waste. It provides the employer with the ability to convey the hazards associated with the waste stream as well as re-enforce the appropriate response in the event of an exposure or adverse event. Additionally, training creates a sense of ownership, and input from trainees can be valuable for improving

processes or future training. Certain workplace standards (eg, OSHA, the Joint Commission) may also need to be met and are subject to change, which creates a challenge for developing a curriculum that is manageable, pertinent, and applies to all settings. At a minimum, it should describe the basics of the regulation, the hazards associated with handling the waste, and how to handle unexpected exposure.

4) **Container management.** For security and safety reasons, the containers should be kept closed. Keeping the containers closed will also prevent these containers from being used as a regular trash can. Current containers available in the marketplace with a step device for opening have proved to be successful at eliminating improper disposal and inadvertent contamination.
5) **Tracking.** Use of the current non-hazardous waste manifest (NHWM) system should be sufficient. Additional tracking or identification of waste (eg, a log of all waste) being disposed would unduly burden hospital and retail pharmacies and likely be difficult to maintain. More important is the proper disposal of and subsequent handling of the containers for final incineration.
6) **Other key issues.**
    a. Professional samples – should be included in pharmaceutical universal waste
    b. Investigational pharmaceuticals – should be included in pharmaceutical universal waste
    c. Large volumes for institutions that do research – need to consider who is responsible for the disposal
    d. Pharmaceuticals in the community – proper disposal of pharmaceuticals that are in the community (ie, in a patient home) need to be addressed
    e. Ability of institution to accept pharmaceuticals for disposal from patients or other outside sources – needs to be addressed

Please let me know if you need clarification on any of these items. I look forward to continued participation in this Stakeholders group.

Kindly,



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