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State of Washington

Improving Management of Dangerous Pharmaceutical Wastes in Washington

Challenges and Recommendations

Report to the Legislature as required by ESB 5577 (2015)

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Improving Management of Dangerous Pharmaceutical Wastes in Washington: Challenges and Recommendations

Report to the Legislature
Required by ESB 5577 (2015)

by
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Executive Summary

This Executive Summary gives a synopsis of the background, stakeholder process, stakeholder recommendations, and Ecology's next steps. More in-depth information follows in the full report.

The Washington State Department of Ecology (*Ecology*) was directed by the Legislature in ESB 5577 (2015) to convene a Stakeholder Work Group of parties with expertise related to managing pharmaceutical wastes in Washington State. This Work Group was directed to identify problems and recommend solutions to improve management of these wastes. This report addresses both those directives and provides the background information stakeholders relied on. In addition, this report presents Ecology's response to each problem and recommendation and discusses implementation considerations for each recommendation. The background information includes:

- The legislative requirement for this report and a brief description of the stakeholder process.
- A brief regulatory context for pharmaceutical waste, including applicable federal and state regulations as well as a summary of what actions are required of facilities that generate regulated pharmaceutical wastes and the various options available to those facilities for reducing or eliminating their regulatory obligations.
- A discussion about what causes a waste to be regulated and examples of regulated pharmaceutical wastes.

The report details six problem areas identified by the Stakeholder Work Group and gives Ecology's response to each of those problems. Ecology agrees with much of what the stakeholders presented, although there were some differing perspectives. Each Ecology response includes both Ecology's perspective on the problem statement as well as the steps Ecology is taking or will take to address each problem area.

In addition to problem statements, the stakeholders made seven recommendations. The report details each recommendation and gives Ecology's response to each. Again, Ecology agreed with much of what the stakeholders recommended and has developed a strategy to address each recommendation. Each Ecology response includes Ecology's perspective on the stakeholder recommendation, how Ecology plans to address or implement the recommendation, and the associated fiscal impacts.

Finally, we present a summary of Ecology's next steps and how we plan to continue our engagement with the healthcare industry.

The Stakeholder Work Group also submitted five additional comments and observations. These were included due to stakeholders' belief in the importance of each, even though they may address issues outside the Work Group's purview or repeat topics that have been addressed elsewhere in the report. Ecology presents and responds to each in a separate appendix.

Attached to this report, in its entirety, is the Stakeholder Work Group Final Report and its attachments.

Legislation and Stakeholder Process

In 2015, the Legislature passed ESB 5577, which directed:

> *…the department shall convene a work group to identify the problems of properly managing pharmaceutical wastes and recommend solutions to improve management of these wastes at the site of generation through treatment or disposal by commercial waste management facilities. The work group may develop recommendations including, but not limited to, new or revised policies to be issued by the department, recommendations for ensuring consistent interpretation and implementation of existing rules, recommendations for amendments to chapter 70.105 RCW or rules adopted pursuant to chapter 70.105 RCW, and recommendations on how the department will implement consistent regulatory oversight of pharmaceutical waste management facilities that receive waste from sources statewide…*

Pursuant to this legislative directive, Ecology recruited stakeholders involved in all aspects of pharmaceutical waste management, from the healthcare facilities that generate wastes to waste management companies that ultimately dispose of those wastes. Ecology was able to enlist a diverse group of stakeholders representing a variety of interests, including:

- Large Hospitals with 250 or more beds.
- Hospital/Clinic systems representing primary care clinics, specialty care clinics, surgical centers, hospice facilities, dialysis centers, and hospitals of all sizes.
- All pharmaceutical waste management companies currently known to be operating in Washington State.
- Retail and long-term care pharmacies.
- Pharmaceutical reverse distributors (special companies that arrange for return of pharmaceuticals to the manufacturer, sometimes for credit, or arrange for disposal).
- State agencies responsible for regulating one or more aspects that affect pharmaceutical waste management, including the Department of Ecology, the Department of Health, the Department of Labor and Industries, and the Utilities and Transportation Commission. The Department of Corrections, as a specialty healthcare provider, was also represented.
- Washington State industry associations representing hospitals, doctors, nurses, pharmacists, and hospice providers.
- Law enforcement representatives focused on pharmaceutical waste from both the local level and the federal Drug Enforcement Administration (*DEA*).
- Experts in wastewater treatment.
- Environmental advocates.

A complete list of Stakeholder Work Group participants and their affiliations is attached as Appendix D to this report. We believe this group of stakeholders represented the range of

perspectives on the relevant issues and had the necessary expertise to provide informed opinions. As directed by ESB 5577, Ecology hired an outside, independent consultant to serve as a facilitator for the Stakeholder Work Group process.

Participants in the Stakeholder Work Group had one-on-one interviews with the facilitator, met twice as a full group, and had additional one-on-one conversations with the facilitator as needed. Stakeholders had the opportunity to contribute to and review draft documents, voice their opinions in meetings or private conversations, and vote on Work Group proposals and documents. Each stakeholder interest that actively participated in the Work Group process affirmatively approved the Work Group's Final Report, including all identified problems and recommended solutions. The stakeholders who gave final approval to the report are noted by name on page 15 of the Work Group's Final Report, attached as Appendix E.

Regulatory environment

Ecology is the main environmental regulator in Washington State. For issues related to toxic and other hazardous wastes, Ecology's *Hazardous Waste and Toxics Reduction Program* (*HWTR*) is the main regulatory authority for both the federal hazardous waste laws as well as the state's dangerous waste laws. Unlike for some other environmental laws, Ecology is an *authorized program* for the federal hazardous wastes regulations. This means Ecology has assumed the authority of the federal *Environmental Protection Agency* (*EPA*) and is responsible for enforcing federal hazardous waste laws on EPA's behalf, subject to EPA's oversight. Ecology has adopted state regulations that mirror the equivalent federal regulations; state rules are at least as stringent as their federal counterparts and are sometimes more stringent. State rules can never be less stringent than the federal standards without jeopardizing the state's authorization.

This report discusses issues related to pharmaceutical waste. The term *pharmaceutical waste* refers to medications that have spoiled, are expired, or are no longer needed. This includes both prescription medicines as well as over-the-counter medicines. The term pharmaceutical waste may also include medication packaging, such as IV bags, syringes, and other containers that hold pharmaceutical products. Personal care products, like shampoos and creams, can also be pharmaceutical wastes when they are thrown away. Even though they may be beneficial products that help treat diseases, many of these products contain chemicals that can be harmful to human health and the environment. Because of this danger, many pharmaceuticals are subject to special regulations about how they are handled and disposed of.

Some pharmaceutical wastes are regulated under federal law, others are only regulated under state law (and some are not regulated at all). Since Washington State's regulations must be at least as stringent as the federal regulations, wastes that are regulated under federal law are also regulated under state law. Ecology does not have any discretion on how these federal wastes are regulated. In contrast, Ecology does have discretion when regulating wastes that are only subject to state law. These wastes are sometimes referred to as *Washington State-only wastes,* and include wastes such as solvents, antifreeze, and corrosive ash. To date, Ecology has used its discretion and provided a number of regulatory alternatives and easier disposal options for state-only wastes. These regulatory alternatives are not available for wastes regulated under the federal regulations. More details about these alternatives are provided later in this report.

EPA has recently proposed new federal regulations for management of hazardous pharmaceutical wastes. If adopted, these new regulations would simplify how healthcare facilities handle and dispose of pharmaceutical wastes. EPA is planning to adopt these rules in 2016. EPA has informed Ecology that most or all of the proposed rules will be mandatory for authorized programs to adopt. Many of the proposed federal regulations are similar to the regulatory alternatives Ecology has implemented for Washington State-only waste. As explained in more detail later in this document, Ecology plans to adopt the new federal regulations in Washington State as soon as possible after they are adopted by EPA.

Problems and recommendations

ESB 5577 directed the Stakeholder Work Group to identify problems associated with managing pharmaceutical wastes and to make recommendations to address those problems. In its final report, the Stakeholder Work Group identified six problem areas affecting the proper management of pharmaceutical wastes:

1. *Regulations capture too many pharmaceuticals.*

    - Many pharmaceuticals are being wasted and are unnecessarily ending up in the waste stream.

    Ecology agreed with the stakeholders on this point.

    - A few stakeholders also believed there are some wastes are unnecessarily regulated. These stakeholders instead would prefer that Ecology only regulate wastes that are captured under federal regulations.

    Ecology explained that Washington's regulations are intended to provide additional protection to the environment that federal regulations do not currently provide, especially for toxic pharmaceutical wastes.

2. *Requirements are too difficult to implement.* Competing interests involved in providing healthcare services make it difficult to manage wastes in compliance with applicable regulations. Worker safety and DEA drug disposal requirements were the primary competing concerns.

    Ecology explained how it has developed various regulatory options to assist healthcare facilities and make compliance easier, as well as how potential rule changes could resolve many of the stakeholders' concerns.

3. *Requirements and policies are confusing.* It is difficult for healthcare facilities to "see" themselves in the applicable waste regulations. They also have difficulty understanding the regulations when there are cross references. Training requirements were also a concern.

    Ecology acknowledged the complexity of the regulations and explained that the pending rule changes from EPA may help address this issue.

4. *Difficulties between generators and waste vendors.* Although stakeholders achieved consensus that there is a problem related to waste mismanagement, they differed on the exact nature of the problem. Most stakeholders felt their respective industries received

too much blame when wastes are mismanaged and that responsibility belonged elsewhere in the waste management chain.

Ecology acknowledged the difficulties involved with shared responsibility.

5. *Technical assistance inadequate and inspections inequitable.* Facilities receive disproportionate attention from Ecology and inspections are focused on paperwork rather than environmentally significant issues.

   Ecology recently changed its inspection practices to ensure consistency and equity across industries and across the state.

6. *Waste pharmaceuticals from households.* Stakeholders acknowledged this topic is outside the purview of the Work Group, but asked to have this problem included in their final report.

   Ecology acknowledges this problem and concurs that it is beyond the scope of the work group.

The Stakeholder Work Group made seven recommendations for changes that would address the six problems identified above. Ecology responded to each and provided comments regarding implementation and, where applicable, the fiscal impact of each recommendation:

1. *EPA pharmaceutical waste proposal.* Washington State regulations should track with new proposed federal regulations and that Ecology ensure our state rules are "consistent and complementary" with the federal regulations.

   Ecology agreed with this recommendation. We plan to implement this recommendation within existing resources to the extent possible. A rulemaking process is already planned, but adequate resources may not have been budgeted to accomplish this work given the short timeframe envisioned. This recommendation addresses problems #2 and #3.

2. *Dedicated section of the regulations for pharmaceuticals.* Ecology should create a new section of the regulations applicable to pharmaceutical waste and adopt the new section as soon as possible.

   Ecology agreed with this recommendation and anticipates it can be implemented without additional fiscal resources beyond what are needed for the rulemaking process. This recommendation addresses problems #2 and #3.

3. *Address "problem" waste streams.* Stakeholders mentioned four different wastes that may not need to be regulated as dangerous waste.

   Ecology agreed to look at these waste streams to determine whether a rule or policy change is in order for three of the wastes mentioned by stakeholders. The fourth waste mentioned is a federally-regulated waste, so Ecology does not have discretion to change how that waste is regulated. We anticipate a slight fiscal impact for implementation of this recommendation. This recommendation addresses problem #1.

4. *Compliance assistance.* Ecology should provide additional training and compliance assistance.

Ecology agreed that additional compliance assistance would be beneficial, but explained that the agency does not currently have resources to provide additional services beyond those currently offered. Instead, private sector consultants and organizations may be the best resource for compliance assistance at this time. This recommendation addresses problems #2, #3, and #5.

5. *Responsibilities when mistakes are made.* Additional clarification is needed on who is responsible when wastes are inadvertently mismanaged.

   Ecology agreed to provide additional guidance on this issue. Ecology also identified some potential regulatory changes that can reduce mismanagement of waste. There is a small fiscal impact for this recommendation. This recommendation addresses problem #4.

6. *Pharmaceutical waste characterization.* Stakeholders requested easy-to-use guidance to help them determine the proper method of management and disposal for each medication they handle.

   Ecology acknowledged the complexity of this issue and noted that new EPA pharmaceutical regulations would greatly simplify waste management. Ecology does not have the characterization information requested by stakeholders and would need to rely on other sources to obtain it, which would require additional resources. This recommendation addresses problems #1, #2, and #3.

7. *Wastewater treatment.* Ecology should provide clarification and assistance in determining what substances can be legally disposed of down the drain.

   Ecology explained that under EPA's new rules, no federally regulated pharmaceutical wastes may be sent down the drain. Implementing this recommendation could have a notable fiscal impact. This recommendation addresses problems #3 and #5.

Ecology's next steps

Ecology is already acting on some stakeholder recommendations, such as taking steps to ensure inspections are equitable across the state. Other steps will require additional resources. The next steps to further implement work group recommendations include:

- Revamp the existing "Interim Enforcement Policy" as a new pharmaceutical waste policy that implements as much of the new proposed federal regulations as possible. A draft is currently under internal review. This step addresses problems #2 and #3 and recommendations #1 and #2.
- Begin the planning process for proposing new rules for pharmaceutical waste management, in accordance with new EPA rules. Ecology is identifying the resources needed to accomplish the necessary rulemaking and anticipates a preliminary public outreach effort regarding proposed rules in the first part of 2016. This step addresses recommendations #1 and #2.
- Consult with interested stakeholders to consider issues related to epinephrine salts, saline solutions, and other wastes to determine an appropriate course of action for evaluating these waste streams. This step addresses recommendation #3.

- Better inform regulated facilities and the public about the agency's work. This step addresses problem #5.
- Work to provide waste generators with copies of inspection reports within 30 days and decrease follow-up times. This step addresses problem #5.
- Increase inspector training and mentoring. This step addresses problem #5.
- Reach out to key stakeholders, such as the Washington State Hospital Association, to determine how best to encourage continued dialogue between the industry and Ecology.

Background

To ensure readers of this report have the same information given to members of the Stakeholder Work Group, relevant background information is provided below. This information includes:

- A brief explanation of the applicable regulatory history.
- A description of the steps businesses must take to comply with the rules.
- A discussion of the various types of regulated wastes.
- An explanation of how pharmaceutical wastes are regulated in Washington State.

Brief regulatory history

Both Ecology and EPA have regulatory authority over certain types of wastes. This authority dates back approximately 40 years and applies to wastes produced by businesses, government agencies, and other entities. The discussion below does not apply to substances that are products, even though a "waste" and a "product" can be chemically identical. The discussion below only applies to businesses and other entities. A resident (commonly referred to as a *household* by Ecology) and a business could generate identical wastes, but only the waste from the business is regulated under the state's Dangerous Waste Regulations. *Household Hazardous Waste* is a separate class of waste and is not discussed in detail below.[1]

Chapter 70.105 Revised Code of Washington (1976)

The statutory authority for Ecology's Dangerous Waste Regulations comes from Chapter 70.105 RCW.

Federal Resource Conservation and Recovery Act (1976)

In October 1976, the U.S. Congress passed the *Resource Conservation and Recovery Act* (*RCRA*). For purposes of this report and topic, the relevant part of RCRA is Subtitle C, the Hazardous Waste Management Program which:

- Set national standards for how hazardous waste must be managed and disposed of.
- Gave EPA authority to enforce the regulations.
- Allowed states to assume EPA's authority, subject to EPA's oversight and approval.
- Required remediation and cleanup of spills and other releases of hazardous wastes to the environment.

[1] The Stakeholder Work Group commented about pharmaceutical take-back programs. The wastes generated by these programs are typically covered by the Household Hazardous Waste regulations and not by the Dangerous Waste Regulations. This is because the wastes originate from households, not businesses. Take-back programs that accept waste from businesses could become subject to the Dangerous Waste Regulations.

RCRA's administrative rules establish EPA's *cradle-to-grave* approach for regulating hazardous wastes and cover everything from creation to reuse or final disposal of these wastes. RCRA was amended several times since adoption including the federal Hazardous and Solid Waste Amendments in 1984. Most of those amendments have been incorporated into Washington's regulations, but some optional ones have not.

Pharmaceutical wastes are regulated under RCRA just as any other business waste. Business that generate or handle regulated pharmaceutical wastes, including hospitals and disposal companies, are regulated the same as any other business in Washington State that generates or disposes of hazardous waste.

Chapter 173-303 WAC (1982)

Subsequent to the adoption of the federal RCRA regulations, Washington State adopted Chapter 173-303 WAC, otherwise known as the *Dangerous Waste Regulations*. These regulations implement both Chapter 70.105 RCW and RCRA in Washington State. As with RCRA, pharmaceutical wastes are regulated under Chapter 173-303 WAC just as any other business waste.

Authorized Program

Although it is a federal law, RCRA is intended to be administered by the states with oversight from EPA. The authority to administer RCRA by a state agency is not automatic. States that want to administer RCRA in their jurisdiction must apply for *authorization* from EPA. EPA reviews the application and the state's laws related to hazardous waste to determine whether they meet the requirements. If so, the state agency is designated as an *authorized program*—that is, the state agency assumes EPA's authority to enforce the hazardous waste regulations. EPA retains jurisdiction over limited areas (including areas designated as "Indian Country" under federal law). EPA can also reassert jurisdiction anywhere in an authorized state if the authorized program does not perform enforcement and compliance activities to EPA's satisfaction.

The regulations for Washington's authorized program closely mirror the federal regulations, but there are some notable differences. The most significant differences between the federal regulations and Washington's authorized program is that Washington is more stringent in some respects, such as how Washington regulates wastes that are toxic to fish when EPA does not specifically consider this factor. Washington has also chosen to *not* adopt some federal regulations that EPA deemed optional.[2] EPA oversees Ecology's regulations and can withhold its authorization if it determines that Ecology's state regulations are less stringent than the federal regulations.

Regulated businesses

WAC 173-303-020 establishes that all businesses in Washington State are subject to the Dangerous Waste Regulations:

[2] Such as Washington State continuing to regulate dangerous wastes generated by mining and mineral processing. EPA excludes these wastes from regulation, which is commonly called the *Bevill Exclusion*.

Applicability.
Except as expressly provided elsewhere herein, this chapter 173-303 WAC applies to all persons who handle dangerous wastes and solid wastes that may designate as dangerous wastes including, but not limited to:
(1) Generators;
(2) Transporters;
(3) Owners and operators of dangerous waste recycling, transfer, storage, treatment, and disposal facilities; and
(4) The operator of the state's extremely hazardous waste management facility.

The following is a brief explanation of the various legal obligations of regulated businesses that generate or handle pharmaceutical wastes and some of the options these businesses have to minimize those obligations.

Generator responsibilities

All generators (companies that create a regulated waste) are subject to the same set of regulations. Businesses that generate large amounts of waste are assumed to have a higher risk to the environment and are subject to more requirements, but all generators must do the following to comply with RCRA, Chapter 70.105 RCW, and Chapter 173-303 WAC:

- *Designate*: all generators must evaluate the waste they create and determine whether it is a dangerous waste.
- *Count*: all generators must keep track of how much dangerous waste they create every month. These amounts determine whether the company is subject to stricter regulations.
- *Manage and accumulate*: all generators must follow the regulations about how they handle, store, and accumulate regulated waste. Wastes must be stored safely to prevent spills and environmental exposure. Wastes must also be properly labeled to help ensure worker and first responder safety. There are limits on the maximum time regulated waste may be kept on-site and the maximum amount allowed to be present at any time; generators who create smaller amounts of waste are generally allowed to keep waste on-site longer.
- *Keep good records*: all generators must keep track of all required paperwork. Recordkeeping requirements may include getting a RCRA site identification number, documenting employee safety training, and documenting where waste is sent. Generators who create smaller amounts of waste are assumed to pose less of a risk and are generally allowed more flexibility on some documentation requirements (*e.g.*, being allowed to use a bill of lading to ship waste for disposal instead of being required to use a federal *Uniform Hazardous Waste Manifest* form).
- *Dispose*: all generators must ensure the waste they create is disposed of properly. Generators who create smaller amounts of waste are generally allowed more flexibility on some disposal requirements, such as being allowed to send regulated wastes to a Moderate Risk Waste facility or a permitted Solid Waste facility instead of a TSD facility.
- *Report*: all generators that have a RCRA site identification number are required to file a Dangerous Waste Annual Report with Ecology detailing the types of wastes they generated in the previous year and where those wastes went for disposal or recycling.

Each of these obligations fulfills specific regulatory requirements. For example, tasks like recordkeeping and reporting are how Ecology holds generators accountable for the wastes they create. Manifests tell a receiving company what type of waste they are accepting so they know how to handle it safely. Manifests also aid first responders in case of an accident during transport. Manifests and bills of lading create a chain of custody document that can be used as evidence to prosecute illegal disposal. Annual reports ensure that dangerous waste is going where it is supposed to go and that it is handled safely while en route. These documents help guarantee wastes are actually managed cradle-to-grave as required by the original legislation adopted by Congress and the Washington State Legislature.

Current waste management options for generators in Washington

Generators that want to reduce the number of regulations they are subject to have a number of options. These off-ramps provide alternatives for businesses to minimize the time they spend focusing on regulatory compliance but still ensure that businesses manage their regulated wastes safely. Not all companies will qualify to use all these options, but many Washington businesses regularly use one or more of these options.

Options for Conditionally Exempt Small Quantity Generators

For businesses that produce small quantities of waste, one option may be to qualify as a *Conditionally Exempt Small Quantity Generator* or in common Washington State vernacular, an *SQG*.[3] Generally, businesses that generate less than 220 pounds of regulated waste every month qualify as SQGs (although that amount is just 2.2 pounds per month for a few substances called *acutely hazardous wastes* or *extremely hazardous wastes*). Businesses that qualify for SQG status must still designate their waste, manage and store it safely, and count all the waste they generate. They must also ensure their waste is sent for proper disposal, but have more options for choosing a disposal facility.[4] SQGs have reduced recordkeeping and reporting requirements and are allowed to store waste on-site with no time limit as long as they don't exceed 2,200 pounds on-site at any one time (or 2.2 pounds of acutely or extremely hazardous wastes).[5]

Options for Special Waste

Special waste is a category of waste that has specific characteristics: it is a solid (liquids and gases cannot be special waste) and it is a Washington State-only waste that is either corrosive, has a very low toxicity, is a polychlorinated biphenyl (PCB) that isn't regulated by EPA, or is persistent. Wastes that are *extremely hazardous wastes* can't be a special waste. Examples of pharmaceutical waste that might be eligible to be treated as special waste include three of the most common over-the-counter medications currently on the market: acetaminophen (aka

[3] There is a difference in the nomenclature between EPA and Ecology. The federal regulations and EPA refer to the generators as either *Conditionally Exempt Small Quantity Generator* (*CESQG*), a *Small Quantity Generator* (*SQG*), or *Large Quantity Generator* (*LQG*). In contrast, Ecology calls the same three levels *Small Quantity Generator*, *Medium Quantity Generator* (*MQG*), or *Large Quantity Generator.* We adopt Washington State's naming strategy and abbreviations in this report unless otherwise noted.

[4] Please note this is one of the issues the Stakeholder Work Group mentions in their report: that disposal options allowed by Ecology's regulations are, for all intents and purposes, frequently unavailable in the real world.

[5] Larger generators must ensure that their wastes are sent for disposal within either 90 days for LQGs or 180 days for MQGs. MQGs may accumulate up to 2,200 pounds of waste on-site per month; there is no volume limit for how much waste an LQG may accumulate on-site.

Tylenol), ibuprofen (aka Advil), and cetirizine (aka Zyrtec)[6]. Special wastes may be sent to a solid waste landfill that will accept them instead of a permitted TSD facility.

Options for Treatment by Generator
Generators are allowed to treat some regulated wastes so they don't have to be sent to a permitted TSD facility. Treatment is done to make waste less dangerous or make it safer and easier to transport. Some examples of allowable treatment might be:

- Treating the waste so that is no longer dangerous, such as neutralizing an acidic waste by bringing the pH level up to a non-regulated level.
- Converting a regulated waste to make it a special waste, such as solidifying a liquid toxic waste.
- Treating the waste so as to be in compliance with DEA regulations, such as solidifying a DEA liquid waste or using chemical digestion of a DEA solid waste, such as a tablet or capsule.

Incineration and other forms of burning are *never* allowed as forms of treatment by generator. Wastes that are to be incinerated must be sent to a proper incinerator; on-site burners and furnaces do not meet this requirement. Other generator rules still apply, but some are relaxed.

Using the conditional exclusion per WAC 173-303-071(3)(nn)
As explained more thoroughly under the heading *Washington State's regulation of pharmaceutical wastes* below, this option was originally developed as a regulatory benefit for law enforcement agencies. The existing conditional exclusion is now an option for all pharmaceutical wastes that are "…possessed by any licensee…" under state law. The exclusion allows licensee generators to send qualifying wastes for incineration at certain locations. It is important to note that this option is based on the type of waste, not the regulatory status of the generator. Any generator is allowed to use this option as long as they meet all of the applicable requirements. These requirements include:

- The generator must be a qualified "licensee" under Chapter 69.50 RCW (the Uniform Controlled Substances Act) or an applicable chapter of Title 18 RCW. If the generator is not a licensee, they are not eligible to use the conditional exclusion.
- The generator must ensure the wastes are not regulated under RCRA. Pharmaceutical wastes that are only regulated under Washington State law can be managed under the conditional exclusion. RCRA wastes are not eligible.
- The generator must ensure the wastes qualify for the exclusion. Only some Washington State-only pharmaceutical wastes are eligible under the exclusion: DEA controlled substances regulated under chapter 69.50 RCW, "legend" drugs regulated under chapter 69.41 RCW, and over-the-counter drugs regulated under chapter 69.60 RCW are eligible. Other pharmaceutical wastes are not.

[6] To qualify as a "special waste," state-only toxic wastes must be in toxicity category D (LD_{50} oral rat of 500-5000 mg/kg). The LD_{50} oral rat for acetaminophen is 1944 mg/kg, for ibuprofen is 636 mg/kg, and for cetirizine is 703 mg/kg.

- The generator must ensure the wastes are incinerated in a combustion unit that meets the requirements of the conditional exclusion. There are very strict temperature requirements for qualifying incinerators. Municipal solid waste incinerators (like those in Spokane, Washington and Brooks, Oregon) meet this requirement, as do some medical waste incinerators.

Following the Interim Enforcement Policy

The *Interim Enforcement Policy*—commonly referred to as the *IEP*—was developed in early 2008 with industry representatives to help healthcare facilities and pharmacies handle their pharmaceutical wastes more quickly and easily. It is not a regulation and it is not mandatory. Facilities may choose to use this option or may elect other management options. The IEP was intended to be a stopgap measure that would only be in place for a short time until EPA adopted a new pharmaceutical rule, which was anticipated in late 2008. It was referred to as the *Interim Enforcement Policy* because Ecology agreed to use its enforcement discretion and would "refrain from enforcing portions of the Dangerous Waste Regulations at facilities meeting the conditions of this policy."

The IEP simplified the requirements for generators, giving them a new option for managing their regulated pharmaceutical wastes. It also provided a simplified option for paperwork requirements when sending pharmaceutical wastes for disposal.[7] In exchange for these simplified options, facilities choosing to use the IEP can mix all of their regulated pharmaceutical wastes in a single waste stream and send it all to a permitted RCRA incinerator.

When EPA elected to withdraw its 2008 rule proposal, they could have forced Ecology to withdraw or revise the IEP to make it compliant with federal regulations. To date, that has not happened and Ecology has continued to offer the IEP as a choice to generators of pharmaceutical waste. The IEP is not an option for other waste streams.

As discussed in more detail later in this document, EPA has revised and reissued proposed new rules for pharmaceutical waste management. Washington's IEP was one of the models for much of EPA's new proposed rules and the proposal mirrors the IEP in many ways. Also, as explained in more detail below, Ecology is creating an updated policy to replace the IEP in light of EPA's proposal and input from the Stakeholder Work Group.

Full regulation as a Washington State Dangerous Waste

If none of the options above are appropriate or available to a generator, then they must handle their waste as fully-regulated dangerous waste. This option means the business must follow all of the rules applicable to their generator status (MQG or LQG), just like any other business generating dangerous waste. All regulated wastes need to be properly managed; sent to a permitted TSD facility with proper documentation; and properly reported to Ecology in an annual report. There are no exceptions built into the rules specifically for healthcare facilities or other businesses handling pharmaceutical wastes, except the conditional exclusion and IEP options mentioned above.

[7] These changes were not strictly in compliance with federal regulations, but EPA did not push the issue as the new federal rule was imminent and Ecology's use of enforcement discretion was only applicable during the "interim."

Regulatory environment

To comply with the Dangerous Waste Regulations, waste generators and disposal companies must be familiar with the types of wastes they generate and handle. Federal and state regulations categorize these wastes slightly differently. All wastes must be handled, stored, transported, and disposed of according to the regulations that apply to that waste. The following describes various categories that wastes may fall into.

Categories of regulated wastes

The federal RCRA regulations divide wastes into two categories: *listed* wastes and *characteristic* wastes. This distinction is very important in some aspects of waste management and disposal. *Listed* wastes are those wastes that are specifically called out on one of four lists in the federal regulations.[8]

1. F-listed wastes, which are defined as "hazardous wastes from non-specific sources." The relevant list is found in 40 CFR 261.31(a).
2. K-listed wastes, which are defined as "hazardous wastes from specific sources." The relevant list is found in 40 CFR 261.32(a).
3. P-listed wastes, which are defined as "discarded commercial chemical products, off-specification species, container residues, and spill residues thereof" which are "acute hazardous wastes." These wastes are highly toxic. The relevant list is found in 40 CFR 261.33(e).
4. U-listed wastes, which are defined as "discarded commercial chemical products, off-specification species, container residues, and spill residues thereof" which are "toxic." The relevant list is found in 40 CFR 261.33(f).

The easiest way to think about the lists is that F-listed and K-listed wastes are usually leftovers from manufacturing processes, while P-listed and U-listed wastes are unused products and leftovers from products. A number of pharmaceutical wastes are P-listed or U-listed waste. Inclusion on any of these lists means wastes must be handled as directed in the federal regulations, which may include special disposal requirements (such as triple-rinsing empty containers that once held P-listed wastes).

Characteristic wastes do not appear by name on a list in the federal regulations, but are still regulated as hazardous waste. A waste is a characteristic waste if it meets at least one of the following four criteria, as determined by personal knowledge, laboratory testing, or other documentation:

- Ignitable wastes (sometimes called flammable wastes) are those that catch on fire very easily and which have a flash point below 60° C (140° F).

[8] There are parallel lists in the state's Dangerous Waste Regulations as well.

- Corrosive wastes are those that have a very low or very high pH level, either below 2.0 or greater than 12.5.[9]
- Reactive wastes generally are those that are explosive when mixed with water or placed under pressure.
- Toxic wastes are those that are poisonous in very small amounts. A list of 40 specific toxic chemicals is provided in the regulations. In order to exhibit the characteristic of toxicity under the federal regulations, a waste must contain an ingredient or component that is one of those 40 listed chemicals in an amount that exceeds the limit set in the rule (*See also* Appendix C.)

EPA's intent was to periodically update these lists to add new chemicals (including pharmaceuticals), but this has not happened.

Federal RCRA wastes versus Washington State wastes

As noted above, Ecology is an authorized program for EPA. This means Ecology administers RCRA in Washington State on behalf of and with the authority of EPA with certain jurisdictional limits and subject to EPA's oversight. Ecology's regulations must be at least as stringent as RCRA, but can be more stringent. The types of wastes regulated by Ecology are a good example of how this works.

RCRA regulations define what constitutes hazardous waste and how it must be handled. As explained above, hazardous waste may be a listed waste or it may meet one or more of the criteria for characteristic waste as provided in the regulations. Washington State's regulations likewise define what constitutes dangerous waste and how it must be handled. Dangerous waste includes everything that is a federal hazardous waste plus some additional wastes that are specific to Washington State's regulations. Federal waste lists are incorporated into state regulations at WAC 173-303-9903 and WAC 173-303-9904. Washington's criteria for characteristic waste include everything in the RCRA criteria plus the following:

- Wastes that persist in the environment. (Federal regulations do not examine whether a substance fails to break down over time.)
- Wastes that are toxic to fish.
- Wastes that are corrosive solids. (Federal regulations only regulate corrosive liquids.[10])
- Some other wastes that are inapplicable to healthcare facilities and pharmaceutical wastes (*e.g.*, PCBs and antifreeze).

The biggest difference between the federal and state regulations is how each set of regulations identify toxic wastes. The federal toxicity characteristic standard is entirely related to the various

[9] There is currently a petition pending before EPA requesting the top of the range be lowered to a pH level of 11.5. This would increase the number of wastes regulated under RCRA. EPA expects a decision on that petition by early 2016.

[10] The petition currently before EPA related to changing to the standards for corrosive wastes requests that the federal rule be amended to cover solid corrosives as well as liquids, which would match Washington State's rule.

lists contained in RCRA regulations. Some federal toxic wastes are listed wastes; if a substance is a listed waste, it is regulated accordingly.

If a substance is not a listed waste, it could still be a toxic waste under RCRA. The next step would be to determine if it fails the test known as *TCLP*, short for *Toxicity Characteristic Leaching Procedure*. In order to determine whether the waste passes or fails this test, the test results are compared against the table found at 40 CFR 261.30(b).[11] (*See also* Appendix C.) If the waste contains one of the listed substances in an amount more than what is allowed by the table, the waste fails the test and is regulated as a toxic waste. If the waste does not contain one of the listed substances in an amount exceeding what is allowed, it passes the test and is not a RCRA toxic waste.

Washington State takes a different approach to determining toxicity. Instead of maintaining lists, Washington instead looks at the actual toxicity of the waste. Actual toxicity is determined by the amount necessary to be a lethal dose.[12] Although there have been a number of amendments to the Dangerous Waste Regulations since they were first adopted, the levels for determining toxicity have remained fairly standard over the years. There was one major adjustment to fish toxicity standards occurring in 1995. Table 1 provides a comparison of how toxicity standards have changed since adoption.

Table 1: Comparison of Regulatory Levels, Fish Toxicity, LC_{50}

Toxicity Level[13]	WAC 173-302 (1977-1982)	WAC 173-303 (1982-1995)	WAC 173-303 (1995-Present)
X	N/A	<0.1 mg/L	<0.01 mg/L
A	<1.0 mg/L	0.1-1.0 mg/L	0.01-<0.1 mg/L
B	1.0-10 mg/L	1.0-10 mg/L	0.1-<1.0 mg/L
C	10-100 mg/L	10-100 mg/L	1.0-<10 mg/L
D	100-1000 mg/L	100-1000 mg/L	10-100 mg/L

Prior to the 1995 rule change, more wastes were regulated because they exhibited the toxicity characteristic, at least for fish. As part of the 1995 rule change package, Ecology recommended changing this standard to make it correspond more closely with the same level of real-world toxicity as the equivalent level based on oral toxicity in mammals. The rulemaking proposal in 1995 stated:

> *Recent scientific literature and Ecology staff analysis shows that the existing regulatory level for the fish bioassay of 1000 mg/L does not correlate well with*

[11] Washington State has a parallel list, found in WAC 173-303-090(8)(c).

[12] Regulatory levels for water and air exposure are reported in mg/L, or milligrams of chemical per liter of the air or water it is disbursed in. Exposure levels for ingestion are reported in mg/kg, or milligrams of chemical per kilogram of body weight. Both measurements are equivalent to parts per million (ppm).

[13] *Toxicity Level* is important when handling wastes that contain more than one substance. These levels are the basis for determining an "equivalent concentration" for the mixture, which determines whether the mixture is regulated as a dangerous waste and, if so, whether the waste is regulated as an extremely hazardous waste. Toxicity levels X, A, and B are extremely hazardous waste; toxicity levels C and D are not.

the waste concentration level for the rat bioassay of 5000 mg/kg. Adjusting the waste concentration for the fish bioassay to 100 mg/L offers the closest approximate equivalent to the rat bioassay.

Table 2: Comparison of Regulatory Levels, Oral Rat Toxicity, LD_{50}

Toxicity Level	WAC 173-302 (1977-1982)	WAC 173-303 (1982-1995)	WAC 173-303 (1995-Present)
X	N/A	<0.5 mg/kg	<0.5 mg/kg
A	<5.0 mg/kg	0.5-<5.0 mg/kg	0.5-<5.0 mg/kg
B	5.0-<50 mg/kg	5.0-<50 mg/kg	5.0-<50 mg/kg
C	50-<500 mg/kg	50-<500 mg/kg	50-<500 mg/kg
D	500-5000 mg/kg	500-5000 mg/kg	500-5000 mg/kg

Ecology's proposal to lessen the regulatory standard for fish toxicity was adopted into rule as part of the 1995 rule amendments and has remained unchanged since that time. The regulatory levels for mammals has remained unchanged since the Dangerous Waste Regulations were adopted.

In other words, the federal regulations only regulate wastes as toxic if they contain a substance on the lists found in the regulations *regardless of how poisonous the wastes actually are*. Some of the most deadly poisons in the world such as botulinum toxin (the active ingredient in Botox), ricin (related to production of castor oil), and tetrodotoxin (the poison from Fugu, a Japanese delicacy made from Pufferfish) could be in wastes produced by businesses. In sufficient amounts, each of these wastes would be regulated as Washington State-only wastes because each has an LD_{50} exceeding the regulatory threshold. However, these wastes would never be regulated under the federal toxicity regulations regardless of amount because they are neither a listed waste nor do they contain any of the substances on the TCLP table.

Determining hazardous waste or dangerous waste

All hazardous waste is dangerous waste, but not all dangerous waste is hazardous waste. As a general rule, Ecology uses the term *hazardous waste* to mean RCRA-regulated wastes, the term *state-only waste* to mean wastes regulated under state rules but *not* under RCRA; and the term *dangerous waste* to mean all wastes regulated under both RCRA and Washington State-only regulations. Washington has some flexibility when considering how to regulate Washington State-only dangerous waste, but not for wastes regulated under RCRA.[14]

Regulated pharmaceutical wastes

The term *pharmaceutical waste* refers to medications that have spoiled, are expired, or are no longer needed. This includes both prescription medicines as well as over-the-counter medicines. The term pharmaceutical waste sometimes also includes medication packaging, such as IV bags, syringes, and other containers that hold pharmaceutical products. Personal care products, like shampoos and creams, can also be pharmaceutical wastes when they are thrown away.

[14] Despite their different meanings, it is common for many people to use the terms *hazardous waste* and *dangerous waste* interchangeably.

Pharmaceutical wastes are regulated the same as any other type of waste generated by a business. If a pharmaceutical waste meets the definitions as laid out in the rules, that waste must be handled and disposed of according to the regulations. As the regulations are currently written, waste medications are no different from other types of business waste if they contain toxic, corrosive, or other dangerous components. There is no provision in either state or federal regulations for exempting a regulated waste merely because it is a medication that the federal Food and Drug Administration has approved for human consumption.

This can be confusing to many people since we commonly think of medicines as safe and helpful products. Even though a substance might be safe for human consumption in very small amounts under specific circumstances, it may not be safe in another situation. There is a very good reason medications come with child safety lids: the drugs inside can be toxic. Many familiar drugs can be very dangerous. The National Capital Poison Center Poison Control Hotline website[15] reports that five of the ten most common substances causing poisoning in adults are medications, noted in *italics*:

- *pain medicines*
- *sedatives, hypnotics, and antipsychotics*
- *antidepressants*
- *cardiovascular drugs*
- cleaning substances (household)
- alcohols
- pesticides
- bites and envenomations (ticks, spiders, bees, snakes)
- *anticonvulsants*
- cosmetics and personal care products

And five of the ten most common poisoning substances for children are also pharmaceuticals:

- cosmetics and personal care products
- cleaning substances and laundry products
- *pain medicine*
- foreign bodies such as toys, coins, thermometers
- *topical preparations (aka medicated creams, lotions, and sprays)*
- *vitamins*
- *antihistamines*
- pesticides
- plants
- *antimicrobials*

[15] As published October 19, 2015 at http://www.poison.org/common-and-dangerous-poisons.

In addition to posing risks to human health, pharmaceuticals in the environment can pose significant problems. Medications that are safe for humans are not necessarily safe for other species, including wildlife that may come into contact with improperly discarded medications or fish exposed to pharmaceuticals from sewer discharge. Even common medications such as ibuprofen and acetaminophen can be fatal if ingested by many small mammals (including dogs, cats, ferrets, and hamsters).[16]

Examples of regulated pharmaceutical wastes

There are many medications that are either listed or characteristic wastes under federal and state regulations. Some common examples of pharmaceuticals that are regulated as dangerous waste include:

RCRA listed wastes:

- Coumadin (aka Warfarin)[17] – blood thinner
- EpiPen (aka Epinephrine) – treats anaphylaxis and heart attacks
- Nicorette (aka Nicotine) – smoking cessation aide
- Selsun Blue Shampoo (aka Selenium sulfide) – dandruff treatment
- Lindane Lotion (aka Lindane) – anti-parasite (lice, scabies) drug

RCRA characteristic wastes:

- Erthromycin gel (ignitable) – antibiotic
- Taxol injection (ignitable) – cancer drug
- Bleomycin (corrosive) – cancer drug
- Barium sulfate (toxic) – X-ray contrast agent (aka "barium milkshake")
- Silvadene (toxic) – antibiotic

Washington State wastes:

- Atropine (State-only toxic) – treats Parkinson's Disease and heart conditions
- Vancomycin (State-only persistent) – antibiotic
- Clindamycin (State-only persistent) – antibiotic
- Ciprofloxacin (State-only toxic and persistent) – antibiotic
- Ibuprofen (State-only toxic) – anti-inflammatory/analgesic
- Aspirin (State-only toxic) – anti-inflammatory/analgesic
- Atenolol (State-only toxic) – treats angina and hypertension

[16] As published October 22, 2015 at http://www.petpoisonhelpline.com/pet-owners/basics/top-10-human-medications-poisonous-to-pets/.

[17] Manufacturers are phasing out their use of the chemical as a pesticide. The manufacturer of D-Con products, the leading brand, withdrew its pesticide registration for many (if not all) warfarin-containing products as of 2015. No such changes are anticipated for warfarin's use as a medication and regulation of the substance as a pesticide (or disallowance thereof) has no effect on regulation of the substance under RCRA. Warfarin will remain a listed hazardous waste until EPA determines otherwise.

Washington State's regulation of pharmaceutical wastes

Although pharmaceutical wastes are not treated differently than any other type of regulated waste, these wastes were not a regulatory focus until 2001 when Ecology received a citizen inquiry. As a result of further investigation, Ecology determined that many expired and otherwise unusable pharmaceuticals actually designated as dangerous waste.

In January 2002, Ecology adopted an emergency rule that provided law enforcement agencies an exemption from the Dangerous Waste Regulations for certain drug wastes if those wastes were incinerated at a proper incineration site (which included the Spokane incinerator). In response to an industry request, the next year Ecology expanded the conditional exemption to all pharmaceutical waste generators that are "licensees" under other state laws. The specific qualifications for being allowed to use the conditional exemption are explained more thoroughly in the section *Using the conditional exclusion per WAC 173-303-071(3)(nn),* above.

Stakeholder Work Group Process

The Stakeholder Work Group was convened as a result of legislation in the 2015 Session. Ecology began working on the stakeholder process as soon as an agreement had been reached.

Work Group Development

Legislative directive to Ecology

The Stakeholder Work Group process was mandated by ESB 5577 (2015). The bill was signed into law on April 25, 2015. The bill directed Ecology to "convene a work group to identify the problems of properly managing pharmaceutical wastes and recommend solutions to improve management of these wastes" no later than September 1, 2015. Ecology did not believe this was enough time to both conduct a thoughtful stakeholder process and complete that process in time to deliver this report to the Legislature by the end of 2015 as required. As such, we began developing the stakeholder process in spring 2015, even before the legislation was signed into law.

The bill provided guidance on the subjects that could be addressed by the stakeholders and required the group to "provide recommendations to the appropriate fiscal and policy committees of the Legislature by December 31, 2015." The bill required that the stakeholder group include representatives from Ecology, the Department of Health, the Department of Labor and Industries, waste handling facilities, statewide associations representing medical providers and hospitals, and "other parties with expertise in the field of pharmaceutical waste management." Finally, the bill required Ecology to hire an outside consultant as a facilitator.

Proponent/Ecology collaboration

The main proponents of ESB 5577, Stericycle, Inc. and the Washington State Hospital Association, consulted and collaborated with Ecology staff at the beginning of the stakeholder process. In addition to helping Ecology identify potential key stakeholders, the proponents were instrumental in clarifying expectations for the Work Group process.

Ecology and the proponents met twice early in the development process. At the first meeting, Ecology outlined their expectations for the process and received input and suggestions from the proponents about both the process and possible stakeholder representatives. Ecology also provided a draft technical assistance letter and a draft survey for healthcare facilities regarding issues related to waste management and disposal. The proponents assisted Ecology with revising the letter and survey questions as well as adding new survey questions. The proponents also assisted Ecology by reviewing and revising a draft solicitation for the Work Group facilitator. At the second meeting, these issues were all finalized and Ecology proceeded as agreed with the proponents.

Work Group implementation

Stakeholder identification and invitation

One of Ecology's primary concerns in developing the stakeholder group was ensuring that all affected stakeholders were represented by at least one member of the Work Group. We identified the following as interests that needed to be represented:

- Large hospitals (250 licensed beds or more)
- Medium hospitals (100-249 licensed beds)
- Small hospitals (fewer than 100 licensed beds)
- Specialty hospitals
- Urban hospitals
- Suburban hospitals
- Rural hospitals
- Western Washington facilities/organizations
- Eastern Washington facilities/organizations
- Medical clinics and doctors' offices
- Dental offices
- Long-term care facilities
- Hospice and home healthcare organizations
- Retail pharmacies
- Pharmaceutical Reverse Distributors
- Federal agencies
- State agencies
- Local government agencies
- Law enforcement
- Waste handling and disposal companies
- Wastewater treatment entities
- Relevant industry and environmental interest groups

One additional group that Ecology felt needed to be represented was veterinary offices. However, Ecology was concerned that increasing the Work Group size could make it unwieldy and unmanageable. As such, we looked for opportunities to consolidate stakeholder representation. Ecology decided that since the issues faced by veterinarians are very similar to those represented by doctors' offices (same types of medications, similar types of disposal issues) that it wasn't crucial to include veterinarians on the Work Group.

We also consolidated representation of long-term care pharmacies with other long-term care and hospice/home healthcare stakeholders, as they face many of the same issues concerning end-of-life pharmaceutical needs.

Finally, we did not specifically reach out to non-pharmacy retail establishments that might sell pharmaceuticals, such as supplement/nutrition stores and grocery or general purpose merchandise stores that do not have pharmacies. We felt the retail pharmacy representation on the Work Group was sufficient to represent these potential stakeholders as well.

Because we had difficulty recruiting representatives from small and medium-sized hospitals, we relied on a number of stakeholders from larger healthcare clinic systems to represent this perspective. We felt comfortable doing so because they have a variety of facilities in their systems, from small doctors' offices to smaller hospitals to large hospitals. We believe these stakeholders were able to voice concerns on behalf of their smaller facilities. We also relied on these stakeholders to represent interests from eastern and rural Washington, as we had difficulty getting in-person participation from these facilities, presumably due to the distances involved. Although we did offer the opportunity to participate in the Work Group meetings by electronic means, no facility accepted that offer.

When identifying potential Stakeholder Work Group members, Ecology started with facilities and representatives that have been active in dealing with pharmaceutical waste issues. We wanted to ensure that the voices at the table were the actual "boots-on-the-ground" staff members who could provide their real world experience. We reached out both to facilities that had a good compliance record as well as to those who have had compliance problems in the past. Based on information obtained from waste disposal company records, Ecology was able to identify the facilities that were responsible for the overwhelming majority of improperly handled pharmaceutical wastes—every one of these facilities was either invited to participate or their parent organization was invited to participate in the Stakeholder Work Group. Only one of these entities declined the opportunity.

Ecology personally reached out by telephone to potential stakeholders to explain the purpose of the Stakeholder Work Group and that we were looking for interested participants. When appropriate, we asked for suggestions of other potential stakeholders. We followed up each phone call with a more detailed email. Ecology then passed the list of Work Group participants to the facilitator.

Telephone pre-meeting interviews

Before the first stakeholder meeting, the facilitator contacted each stakeholder to conduct a pre-meeting interview. The purpose of these interviews was to narrow the possible topics and identify any common themes from multiple stakeholders. The questions for the interview were:

1. What is your role in pharmaceutical waste management?
2. What are your/your organization's main goals for management of the pharmaceutical waste you are responsible for?
3. What do you see as the main problems or challenges with the current pharmaceutical waste system?
4. Do you see Ecology's policies or interpretation of existing rules as a problem? Why or why not? If so, what is the main problem or challenge?
5. Do you think Ecology's regulatory oversight of pharmaceutical waste is consistent? Why or why not? What sort of problems or challenges do you see in this area?
6. How would you address these problems and challenges? What potential solutions would you propose?
7. Who would have to be involved, and who would have to take action, for potential solutions to be realized?
8. What else should we discuss so I can plan and facilitate the workgroup process effectively?

Each of the interviews lasted between 30-60 minutes and allowed the stakeholder the opportunity to bring up whatever issues he or she felt were relevant to the topic. The facilitator reported good feedback from stakeholders about the one-on-one interviews.

Pre-meeting interview synthesis document

The facilitator used the input she received from stakeholders during the one-on-one pre-interviews to develop a "Synthesis of Pre-Meeting Interviews" document, a copy of which is an attachment to Appendix E (the Work Group's Final Report). The synthesis document confirmed many of Ecology's previous assumptions about where regulated facilities were encountering problems complying with the regulations. It also confirmed there was inconsistency in perspectives of stakeholders in different industries.

Initial stakeholder meeting

The initial stakeholder meeting was held August 6, 2015 in Lacey, Washington. A combined 44 stakeholders, Ecology staff, and facilitation staff participated in the meeting (in addition to legislative staff observers). Attendees represented hospitals, health maintenance organizations, pharmacies, industry associations, federal agencies, state agencies, and local governments among others.

At the first meeting, the stakeholders agreed to a Work Group Charter, a copy of which is an attachment to Appendix E. They then received a background briefing on the task set before them by the Legislature, the current regulatory environment and options, and a draft proposal for new federal regulations from EPA. The Work Group then spent the remainder of the meeting

discussing their perception of the problems with the current system and potential solutions for those problems.

One notable takeaway from the first meeting for Ecology was more clarity on stakeholder problems with the current regulatory scheme. This was the first time Ecology and stakeholders both realized that previous attempts by Ecology to provide regulatory assistance were actually sometimes counterproductive. Stakeholders found the regulations difficult to comply with, so Ecology developed guidance to help. Stakeholders didn't understand the guidance, so Ecology developed the pharmaceutical conditional exclusion and made it applicable to healthcare facilities. The conditional exclusion didn't go far enough to solve some facilities' problems, so Ecology developed the IEP. Now, healthcare facilities have so many options to deal with their pharmaceutical waste, they find the options confusing and don't know what to do. Multiple stakeholders expressed the opinion that much of the problem isn't with the IEP or the other solutions developed by Ecology, but rather how available solutions are communicated.

Contrary to Ecology's expectations, some stakeholders expressed an interest in having *less* regulatory flexibility than is currently provided by Ecology. Instead, multiple stakeholders expressed the desire for a simplified, prescriptive program they could implement to guarantee compliance. The idea of a "model" program that could be implemented by any facility anywhere in the state held a great deal of appeal for some stakeholders.

Another discussion point that Ecology had not expected was stakeholders' interest in small changes or "tweaks" to the current state-only dangerous waste criteria on a case-by-case basis. While two stakeholders mentioned the possibility of eliminating or revamping the state-only waste criteria, most stakeholders instead were interested in minor revisions related to specific waste streams, such as saline solutions.

Finally, Ecology also gained significant insight from stakeholders about the problems of managing DEA controlled substances. Although Ecology was previously aware management of these wastes was a significant problem for regulated facilities, Ecology was not sufficiently aware of just how big a problem this issue was for healthcare providers.

Draft "Problem Statement and Potential Solutions"

As a result of the discussions at the first stakeholder meeting, the facilitator developed a draft Problem Statement. The draft was revised with input from stakeholders and was finalized prior to the second stakeholder meeting. The final version of the Problem Statement was incorporated into the final Stakeholder Report and is discussed in more detail below.

The facilitator also used stakeholder suggestions to develop a draft list of potential solutions. All suggestions that were offered by the stakeholders were included in this document, even if they were outside the scope of the Work Group's charter. The list originally encompassed 32 separate possible solutions, with two more suggested by a stakeholder during the document review process. Ecology reviewed each of these solutions and provided an "initial reaction" to each—a brief response to the idea, including whether it was legally possible, what steps might have to be taken to implement the solution, and some preliminary thoughts on what resources would be

required to implement the solution. The final version of this document, including additional proposed solutions and all of Ecology's initial responses, is attached to Appendix E.

Stakeholder "Potential Solutions" survey

After the draft Potential Solutions/Ecology Reaction document was circulated to stakeholders, the facilitator sent all stakeholders a link to an online survey about the document. The survey asked stakeholders to:

- Rate each of the potential solutions according to how much they supported the option, from "Strongly Support" to "Cannot Live With."
- Rate each of the potential solutions according to how responsive it was to the legislative charge to the Work Group, from "Very Responsive" to "Not Responsive."
- Rate each of the potential solutions according to its ability to make a difference to pharmaceutical waste management in the field, from "Significant Improvement" to "Negative Effect."
- Rate each of the potential solutions according to its likelihood of success, from "Very Likely" to "Not Likely."
- Identify the stakeholder's top potential solutions, in order of importance, both overall and broken down by category of solution.

Based on the results of this survey, the facilitator identified the potential solutions that were "Highly Supported," those that had a moderate level of support, and those that did not receive enough support to warrant continued discussion. The survey results were summarized in the Survey Results and Discussion document, a copy of which is an attachment to the Stakeholder Work Group Final Report.

Final stakeholder face-to-face meeting

The second and final stakeholder meeting was held October 6, 2015 in Lacey, Washington. A combined 38 stakeholders, Ecology staff, EPA staff, and facilitation staff participated in the meeting (in addition to legislative staff observers). As during the first stakeholder meeting, participants represented hospitals, health maintenance organizations, pharmacies, waste companies, industry associations, federal agencies, state agencies, and local governments among others.

Based on the results from the survey, the facilitator led the follow-up discussion. In addition to discussing which recommendations had sufficient support to be included in the Work Group's report, the stakeholders also received a detailed briefing from EPA staff on the newly-introduced proposed pharmaceutical waste rules. A copy of EPA's presentation is attached as Appendix G and was also emailed to all of the Work Group members.

New EPA pharmaceutical waste proposed rule

On September 25, 2015, EPA published its new proposed rules governing pharmaceutical wastes. A copy of the proposed rule was emailed to all of the Work Group members.

The proposed rule is similar to Ecology's IEP, so many of the concepts were familiar to many of the stakeholders. As noted in both the official rulemaking notice and in EPA's presentation to the Work Group, the new rules would allow healthcare facilities to use a simplified approach to managing pharmaceutical wastes. It would allow generators to exclude pharmaceutical wastes when determining their generator status. Both of these factors are important to healthcare providers: they result in simplified paperwork, simplified day-to-day operations, and may even reduce the amount of regulations with which they must comply.

Final stakeholder report

Based on the stakeholder discussions at the final face-to-face meeting, the facilitator prepared a "Pharmaceutical Waste Work Group Final Report" dated November 2015. A complete copy of the final report is attached as Appendix E. The report identifies six problems that need to be addressed and makes seven recommendations for changes to be made. Ecology has responded to each of these items below.

Stakeholder Problems Identified

The Stakeholder Work Group considered and discussed many issues as part of their work. One major part of their work was to identify the main problems related to pharmaceutical waste management. Below are summaries of the problems identified by the Stakeholder Work Group and Ecology's response to each. For the full text and context of each problem identified, please refer to the full text of the problem statement, which is part of the Work Group's Final Report.

Problem #1: Regulations capture too many pharmaceuticals

The stakeholders identified two different problems related to the regulatory status of pharmaceutical waste. The first problem identified was that, "too many pharmaceuticals that otherwise could go for beneficial reuse are moved into the waste stream." The reverse distribution system and other opportunities for reuse of unused, unexpired medications are underutilized.

The second problem identified by some members of the Work Group (but not a consensus) was that, "Ecology had not provided adequate information to justify regulation of waste pharmaceuticals beyond those already regulated by US EPA" and that this additional regulation caused disproportionate costs and burden on healthcare providers versus the level of environmental threat from these chemicals. However, other members of the Work Group, "expressed the concern that the Dangerous Waste Regulations might not capture enough waste pharmaceuticals, given that new drugs are reaching the market all the time, and that waste pharmaceuticals should be assumed hazardous unless proven otherwise."

Ecology response

Ecology agrees that too many pharmaceuticals are being wasted, but does not have the authority or ability to change this problem directly. The easiest way to reduce wastes (and the associated regulatory obligations) is to not create waste in the first place. Systems that redirect usable pharmaceuticals to those in need can prevent the creation of waste and reduce future use of resources while simultaneously providing a benefit to society. Redirecting usable pharmaceuticals also helps achieve the top two priorities for the management of dangerous waste, as dictated in statute[18]: waste reduction and waste recycling.

Requirements from other regulatory agencies, such as the DEA and Department of Health, are far more likely to affect the behavior of healthcare providers than Ecology's suggestions and guidance about waste pharmaceuticals. Ecology would support healthcare industry efforts to address this problem, but we believe it is beyond the scope of our authorizing statutes to take any direct regulatory action on this issue.

Regarding the problem of inadequate justification for inclusion of pharmaceuticals as regulated wastes, Ecology learned during the Stakeholder Work Group process that some stakeholders did not understand the regulatory structure. Ecology staff members were surprised to learn that some stakeholders did not know that the dangerous waste rules apply to all businesses equally, not just healthcare businesses.

The dangerous waste criteria (whether for toxicity, persistence, or any other characteristic) apply equally to all waste chemicals regardless of the industry that produces them. Ecology spent many months seeking and obtaining input from the public when establishing the regulatory criteria for dangerous wastes. Ecology does not believe it would be feasible or fair to develop separate criteria for different industries.

In identifying this problem, stakeholders also noted that there is a "relatively small potential environmental impact [from] these wastes." Ecology disagrees and believes that these wastes pose a threat to the environment. In support of the 2002 rulemaking process that adopted the conditional exclusion for pharmaceutical wastes, a survey was conducted by the *Interagency Regulatory Analysis Committee*.[19] The survey sampled a variety of pharmaceutical waste generators, including some members of the Stakeholder Work Group. The purpose of the survey was to "clarify the nature of potentially hazardous drug wastes generated in King County." Based on the results of this survey, the group estimated that state-only dangerous pharmaceutical wastes generated in Washington State included:

- Approximately 25,000 pounds of chemotherapy waste and 125,000 pounds of state-only dangerous waste annually.
- Approximately 20,000 pounds of state-only pharmaceutical wastes generated by medical clinics and doctors' offices annually.

[18] RCW 70.105.150(1)(a) and (1)(b).

[19] IRAC was a coalition of interested stakeholders, primarily local government waste agencies, and was the main proponent behind expanding the conditional exclusion industry-wide.

- Based on the amount of waste handled by one reverse distributor, an estimate for all state-only dangerous waste could be as high as 300,000 pounds annually in Washington State.

All of these amounts are for waste medications only and do not include packaging, which can sometimes be regulated waste as well. While these estimates are somewhat dated, total sales of pharmaceuticals have increased since the time of the original survey. IMS Health[20] reports that the total number of prescriptions written in the United States increased from 3.7 billion in 2006 to 4.2 billion in 2013. It is not unreasonable to assume that the amount of wastes generated from pharmaceuticals have increased proportionately to their use.

With regard to Washington's regulation of state-only waste, Ecology does not believe that the dangerous waste rules capture large quantities of wastes unnecessarily. In 2012, the EPA Office of Inspector General issued a report titled *EPA Inaction in Identifying Hazardous Waste Pharmaceuticals May Result in Unsafe Disposal*.[21] The report faulted EPA for not adding new pharmaceuticals to the lists of regulated wastes and found:

> *We identified eight chemicals found in pharmaceuticals that meet EPA's criteria for regulation as acute hazardous waste, but wastes containing these chemicals are not regulated as such. There are over 100 drugs that federal occupational safety organizations have identified as hazardous but may not have been reviewed by EPA to determine whether they may qualify as hazardous waste.*

Acute hazardous waste is the most dangerous level of toxic waste under RCRA, yet none of the pharmaceuticals that contain the eight identified wastes are regulated by EPA (to say nothing of the other hazardous drugs identified). This illustrates why Ecology believes the state's methodology for determining toxicity is beneficial to Washington's residents and our environment. The state's regulations act as a backstop for dangerous chemicals that the federal system misses, as evidenced by the fact that all eight of the wastes identified in the Inspector General's Report are regulated as Washington State-only wastes.

In 2015, the Inspector General's Office issued a follow-up report.[22] In that report, the Inspector General noted that EPA's new proposed rulemaking addressed the concerns from the original 2012 report. The proposed rulemaking specifically requests "stakeholders' input on the best course of action concerning regulation of additional pharmaceuticals as hazardous wastes."[23] EPA plans to conduct a separate rulemaking to adopt new regulations related to adding additional pharmaceutical wastes to the regulated universe.

Ecology believes the Washington State-only waste designations provide necessary environmental protections and help ensure wastes are disposed of safely.

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[20] Per http://www.imshealth.com/imshealth/Global/Content/Corporate/IMS%20Health%20Institute/Reports/Use_of_Meds_in_the_U.S._Review_of_2010.pdf and http://www.imshealth.com/cds/imshealth/Global/Content/Corporate/IMS%20Health%20Institute/Reports/Secure/IIHI_US_Use_of_Meds_for_2013.pdf.

[21] This report is located at http://www2.epa.gov/sites/production/files/2015-09/documents/20120525-12-p-0508.pdf.

[22] This report is located at http://www2.epa.gov/sites/production/files/2015-09/documents/20150819-15-p-0260.pdf.

[23] See Section VII.

Ecology action

Although Ecology believes the dangerous waste criteria help protect human health and the environment, we do agree that some pharmaceutical waste streams may not pose a significant environmental threat even though they designate as dangerous waste. Special wastes are a good example of wastes that may not need to be handled as carefully as other dangerous wastes even though they exhibit many of the same characteristics. During the Stakeholder Work Group process, Ecology committed to working with interested stakeholders to address concerns about some specific waste streams including Epinephrine salts (referred to in the Stakeholders' Final Report as "Epi salts"), a disinfectant known as *OPA* (short for *ortho-Phthalaldehyde*), and waste saline products. We believe this addresses the stakeholders' concerns on this issue, and we left the door open to future discussions with stakeholders as needed.

As noted in the Stakeholders' Final Report, specific attention was also given to waste nicotine products such as expired patches or gum. Nicotine is a RCRA listed waste, so Ecology does not have any discretion on how these wastes are regulated. EPA's proposed rulemaking has requested public comment on alternative regulation of nicotine-containing wastes, including whether some should be exempt from regulation. Although this is outside Ecology's regulatory authority, it appears that the concerns expressed by some stakeholders may be addressed at the federal level.

Problem #2: Requirements are too difficult to implement

Although many Washington businesses are subject to the Dangerous Waste Regulations, some facilities have more difficulty with the regulations than others. Stakeholders participating in the Work Group process expressed this sentiment, explaining that it was especially difficult for them to comply with the Dangerous Waste Regulations as written due to the unique requirements of their industry, the number of waste streams, and a multitude of overlapping regulatory requirements:

> *Work Group members emphasized that health care providers need to be focused on patient care and, therefore, any waste management expectations need to be simple to execute in that setting. Even Work Group members who feel that they have effective, compliant pharmaceutical waste management programs described the significant complexity of the pharmaceutical waste management requirements, and associated difficult in executing these requirements consistently.*

Stakeholders also expressed a number of specific concerns, including worker safety and DEA requirements for handling specific medications.

Ecology response

Ecology understands the stakeholders' perspective on this issue and agrees that the rules can be very complex. As noted previously, the Dangerous Waste Regulations were written to cover all qualifying wastes and were not written to address specific waste streams or industries. The healthcare industry has expressed similar concerns to Ecology in the past. These concerns are

why Ecology has attempted to modify the regulations and work with the healthcare industry to develop workable solutions and to help healthcare facilities comply with the regulations. Our previous attempts to create healthcare-specific accommodations include:

- Developing healthcare-specific and pharmaceutical-specific guidance, including the *Guide for Dangerous Pharmaceutical Waste Generators*, a webinar on pharmaceutical waste management, various technical assistance documents, a Best Practices Manual for healthcare facilities, and various web pages devoted exclusively to healthcare-related issues.
- Amending the rules to develop the conditional exclusion in WAC 173-303-071(3)(nn), allowing for easier waste disposal and reduced waste management obligations for healthcare facilities.
- Developing the IEP, allowing for reduced paperwork, waste generation, and waste management obligations for healthcare facilities.

Ecology understands that the healthcare industry continues to have special concerns and external demands that make it different from manufacturers and other industrial facilities. EPA has identified these differences in its proposed rulemaking.

Ecology action

Ecology concurs with EPA's analysis in the proposed rulemaking and believes it justifies a revised regulatory approach for pharmaceutical wastes. Modification of the current regulatory approach would likely be more effective for healthcare facilities and might help prevent environmental contamination from pharmaceutical wastes. We believe that EPA's new proposed rules will address the stakeholders' concerns on this issue. Ecology is committed to working with stakeholders to make sure the new rules address the problem areas healthcare facilities are encountering.

Regarding the specific issues raised in the Final Report, Ecology notes that EPA's proposed rules address the issue of partially-filled sharps (although EPA is asking for additional public comment on that proposal). The proposed rules also resolve the issue of managing DEA wastes.

Problem #3: Requirements and policies are confusing

Related to Problem #2 above, the Work Group also noted problems around understanding the regulations. Specifically, stakeholders mentioned:

- *The dangerous waste regulations are written for industrial generators, not health care facilities. The technical language is not intuitive and difficult for health care facilities to "see" themselves in and follow. In addition, cross referencing and switching back and forth between sections of the regulations is difficult to follow and obscures requirements.*
- *All elements of training were of concern including: distilling complex requirements to a manageable set of protocols; anticipating waste*

pharmaceutical types and providing relevant profiles and training; keeping profiles and training up-to-date; generating staff (and management) interest and support for training; maintaining training/competency in the face of staff turnover; ensuring consistent adherence to what may be different protocols at different facilities when nurses and providers travel among facilities or rotate among programs/specialties; and training on labeling and manifesting requirements.

Ecology response

Problem #3 relates to training and comprehension. Ecology has made efforts to develop guidance and other assistance materials, and conducts on-site visits with healthcare facilities to help with compliance.

The regulations are inherently complex because the issues involved are intricate. The potential consequences to human health and the environment from mismanagement of dangerous wastes can be significant. The complexity of the regulations is directly proportionate to the risk associated with the wastes involved. We acknowledge that the regulations can be challenging for industries (like healthcare) with competing regulatory requirements, unusual waste management concerns, and a general lack of familiarity with the regulations and how they work in the real world.

The Dangerous Waste Regulations are generally modeled on the parallel federal regulations both in content and structure and contain similar cross references. Cross references serve an important function: they allow a statute or regulation to be shorter while simultaneously being very precise. Without cross references, statutes and regulations would either lack clarity or would need to completely repeat existing regulatory language, perhaps multiple times.

Training issues are also not unusual and apply to many industries, including healthcare facilities. All regulated facilities are required to train their employees on the safe and proper management of regulated wastes. While healthcare facilities have multiple other types of training that they must provide their employees, other industries face similar requirements. Private sector vendors and service providers can fill much of the need of healthcare facilities, just as they have done in other industries. There are multiple training companies, healthcare-specific waste management organizations, and waste vendors who can help provide training services.

Ecology action

Ecology anticipates adopting the new EPA regulations, which should address much of the stakeholders' concerns about complexity and cross references. The new EPA regulations are shorter, have fewer cross references, and are specific to the healthcare industry. The new regulations should help make training of staff easier, since waste management options will be simplified under the new rules. Ecology also anticipates adopting a revamped pharmaceutical waste policy to make it easier for facilities to comply during the rulemaking process. More information about the rule adoption process and new pharmaceutical waste policy is provided under the *Recommendations* section below.

Problem #4: Difficulties between generators and waste vendors

This is a good illustration of the variety of stakeholder perspectives on issues related to pharmaceutical waste management. On one hand:

> *Waste generators, particularly those without dedicated staff, cite the complexity of this step and the need for help from waste vendors. Generators want to be able to rely on vendors to ensure provided containers are properly labeled and manifests and other paperwork properly completed and filed. When this does not happen, generators are subject to enforcement for what they see as "vendor mistakes."*

And on the other hand:

> *Some waste management vendors point out that when mistakes are made by generators (e.g., waste ending up in the wrong container) the enforcement actions are too often directed at waste handlers, leaving generators with little incentive for compliance since they have little risk of enforcement action.*

While there was a variety of perspectives on this issue, ultimately a consensus of the stakeholders agreed there were problems that need addressing.

Ecology response

Sometimes regulated wastes are going to be mishandled. Sometimes the waste generator doesn't properly designate their waste. Sometimes the waste disposal company gives incorrect instructions. Sometimes people simply make a mistake.

Ecology is not in the business of penalizing businesses for an occasional mistake. We want to work with facilities to make sure systems are in place to help prevent mistakes and to rectify them when they do happen. Regulated businesses can take steps to minimize the chance of mistakes at both generation and ultimate disposal. Although not mandatory, taking the following steps can help reduce the chances of a mistake and increase the ability to catch and rectify mistakes before they become a violation:

- *Using clear or translucent bins for sharps and other medical wastes*. This would allow healthcare facility staff to immediately identify when waste streams have become comingled. It would also allow waste disposal companies to ensure they are not accepting waste they are not permitted to take and to ensure DEA-regulated drugs are properly disposed of.
- *Implementing labeling systems on-site*. Marking all vials of regulated pharmaceuticals with color-coded labels would allow medical staff to quickly identify where to dispose of wastes.
- *Conducting regular, ongoing training for medical staff*. This would help ensure medical staff know how to properly dispose of waste pharmaceuticals.

Ecology action

In addition to identifying steps that regulated businesses can implement independently, Ecology is committed to working with stakeholders to address this issue. We anticipate developing some additional guidance or revising existing guidance to provide further clarity to generators and disposal companies.

Problem #5: Technical assistance inadequate and inspections inequitable

A number of Work Group members expressed dissatisfaction with Ecology's inspection and enforcement activities. The key issues they pointed to included that:

- Other waste pharmaceutical generators such as dentists, veterinary clinics/facilities, and long-term and skilled nursing facilities were not receiving the same scrutiny as hospitals.
- Inspections can seem "nit-picky" and not focused on environmentally significant issues, for example, mostly focused on labeling or manifest-related "paperwork" violations.
- Inspection reports could sometimes be received many months after an inspection had taken place.
- The tone, and in some cases the content, of inspections can be different across inspectors or between regional offices.

Ecology response

Ecology understands the stakeholders' perspective and has tried to address each. For some, we have reevaluated our assumptions, for others we have implemented changes. On some issues, we believe the stakeholders' perceptions aren't accurate and have identified steps Ecology needs to take to correct misunderstandings.

Regarding some stakeholders' perception that their industry receives undue scrutiny while related industries do not, Ecology does not believe that our compliance activities disproportionately burden any single industry. The stakeholder discussions regarding this issue reinforced Ecology's perspective on the issue: hospitals expressed the belief that other generators and waste companies weren't getting enough attention, while waste companies thought they got too much attention and generators weren't getting enough of Ecology's attention.

Many of the industries called out in the report do, in fact, receive less regulatory scrutiny than the stakeholders do. However, that is not due to a lack of attention or desire on Ecology's part to ensure fairness. It is instead due to the fact that these businesses are almost always *Small Quantity Generators* and are exempt from many of the regulations that larger generators—like hospitals and waste companies—are required to follow.

Ecology consistently strives to ensure regulatory fairness. For the most part, our compliance work is focused on MQGs, LQGs, and disposal companies. SQGs can be the subject of our compliance efforts, but this is less common. Most work with SQGs is done through Ecology's Local Source Control Partnership, which contracts with local jurisdictions to perform multimedia

compliance checks and compliance assistance at SQGs. If Local Source Control staff find problems and can't get the facility to comply, they refer the business to Ecology or the appropriate agency who can address the violation, such as a local air authority.

The tables below illustrate the difference between the types of businesses that receive compliance-related visits from Local Source Control staff and those that receive compliance-related visits and evaluations from Ecology inspectors. During FY 2014,[24] Local Source Control staff members made 1,890 visits to businesses in Washington State, many of them in the industries that Stakeholder Work Group members perceived were not being subject to the same scrutiny.

Table 3: Compliance Site Visits made in FY 2014 by Local Source Control Staff

Industry	Visits
Veterinarians (NAICS 541940)	69
Medical Laboratories (NAICS 621511) and Research Laboratories (NAICS 541711)	3
Medical Waste Disposal Companies (562111)	0
Office of Physicians, Dentists, and other Health Practitioners (NAICS 621), HMOs (NAICS 621491), and Freestanding Medical Centers (NAICS 621493)	198
Hospitals (NAICS 622)	0
Nursing and Residential Care Facilities (NAICS 623)	8
All other industries and NAICS codes	1,890[25]

In contrast, Ecology performed 687 compliance evaluations[26] in the same time period:

[24] July 1, 2013 – June 30, 2014, the last year that data is readily available for.

[25] Some businesses received more than one visit, such as a follow-up to confirm corrective measures had been implemented. There were 1,649 unique businesses that received at least one visit during the year.

[26] Some evaluations, such as those evaluating compliance with financial assurance regulations, are not done on-site and are not called an "inspection," but they may still result in enforcement or mandatory corrective measures.

Table 4: Compliance Visits/Evaluations made in FY 2014 by Ecology Staff

Industry	Inspections/Evaluations
Veterinarians (NAICS 541940)	0
Medical Laboratories (NAICS 621511) and Research Laboratories (NAICS 541711)	7
Medical Waste Disposal Companies (562111)	0
Office of Physicians, Dentists, and other Health Practitioners (NAICS 621), HMOs (NAICS 621491), and Freestanding Medical Centers (NAICS 621493)	3
Hospitals (NAICS 622)	6
Nursing and Residential Care Facilities (NAICS 623)	0
All other industries and NAICS codes	671[27]

Our data shows that Ecology is not focusing on just one type of healthcare facility or portion of the industry. Ecology is currently examining how we can better inform regulated facilities and the general public about our work and what we do.

Next, stakeholders expressed the belief that inspections can seem "nit-picky" and are not focused on environmentally significant issues, for example, mostly focused on labeling or manifest-related "paperwork" violations. Just as accuracy is important in maintaining patient records, it is also important in maintaining waste records. Accurate records help facilities document their compliance, plan for future facility needs, and provide information to other companies (like waste handling vendors).

Lack of proper paperwork can have a very real effect on the environment. Problems on manifest-related paperwork can lead to wastes being inappropriately handled and disposed of, contaminating the environment and exposing employees to dangerous chemicals (such as mislabeled hazardous waste being sent to a landfill that is not allowed to receive it). Lack of warning labels on storage and disposal containers can lead to reactive chemicals being inadvertently stored near each other, risking a fire or explosion. Proper paperwork establishes chain of custody and other documentation that ultimately may be needed to pursue—or potentially defend against—an enforcement action.

Next, stakeholders reported not receiving inspection reports promptly, sometimes many months after an inspection had taken place. Ecology strives to send reports to facilities within 30 days and we are committed to streamlining follow-up after a healthcare inspection, which may include procedural changes, additional inspector training, and mentoring.

Ecology action

Stakeholders noted that inspections can differ between inspectors and between Ecology's regional offices. Ecology believes it is important to ensure consistency across industries and geographic locations as much as possible. We have already begun to address this issue by implementing a number of changes, including:

[27] Some of these facilities also received more than one visit or evaluation. There were 505 different facilities evaluated during the year.

- Most waste disposal companies (and all pharmaceutical and medical waste disposal companies) are located in western Washington, an area covered by Ecology's Northwest Regional Office and Southwest Regional Office. A new inspection protocol for waste disposal companies is now in place. Compliance inspections are now conducted in a team format. The lead inspector for the Northwest Region is the backup inspector on inspections in the Southwest Region; the lead inspector for the Southwest Region is the backup inspector for inspections in the Northwest Region. This team approach is intended to ensure equitable standards are being applied regardless of where a facility is located.
- Regarding pharmaceutical and medical waste issues specifically, Ecology has a statewide "Health Care Workgroup" comprised of both inspectors and technical assistance staff from all four Ecology regions as well as a management sponsor. This team meets quarterly to discuss issues, share information about potential problems, and act as a staff resource for healthcare industry issues. We believe this team can help ensure more consistency across the state on healthcare issues.
- Ecology Headquarters staff has expanded their support role to the regional offices to help ensure consistency statewide on pharmaceutical issues. Some of the areas where Headquarters has expanded their role include the program chemist providing oversight and review of all Quality Assurance/Quality Control Plans; assistance from the program chemist in reviewing, commenting on, and suggesting revisions to sampling and analysis plans; senior Headquarters staff providing statewide regulatory interpretations; and senior Headquarters staff helping to train new inspectors and acting as mentors in their areas of expertise.
- Finally, EPA periodically conducts a review of Ecology's authorized program (commonly referred to as the *State Framework Review*) to ensure that Ecology is administering the authorized program appropriately and consistently across the state. If EPA is not satisfied that Ecology is being consistent in its application of the authorized program, EPA can require that Ecology make additional changes in order to meet EPA's expectations. Given EPA's current focus on pharmaceutical wastes, we believe this will be a key point during our next EPA State Framework Review.

We believe these steps will help ensure that Ecology's compliance assurance efforts are administered fairly across the state. Providing additional information to the regulated community in a timely fashion will help improve the working relationship between Ecology and regulated facilities, which may ultimately help improve the environmental performance of those facilities.

Problem #6: Waste pharmaceuticals from households

Although waste pharmaceuticals from households were not the topic of these deliberations, Work Group members emphasized the significant challenge these materials pose. Work Group members felt strongly that the main risks associated with waste pharmaceuticals, and the majority of the volume, are associated with unused medications originating in households, and that this demanded urgent attention.

Ecology response

Ecology agrees with the stakeholders that this issue deserves attention. While we believe improving management of pharmaceutical wastes in healthcare facilities will result in a reduced environmental risk, pharmaceutical wastes in other settings are still a concern. Medicines legally thrown in the trash by a homeowner are no less dangerous than the same medicines illegally disposed of by a business. However, because these wastes are regulated under the *Household Hazardous Waste* regulations, it is local health jurisdictions who oversee management of this waste stream instead of Ecology.

Ecology action

As wastes from households are not covered by the Dangerous Waste Regulations, we do not see any immediate steps we can take to address this problem. However, if the Legislature considers taking action on this issue, we would be happy to participate or lend any expertise we may have, as appropriate.

Stakeholder Recommendations

The Stakeholder Work Group reached consensus on seven recommendations. Below is a summary of each recommendation and Ecology's response to that recommendation along with an estimated fiscal impact for implementing the recommendation. The unedited version of the Work Group's recommendations can be found in Appendix E.

Recommendation #1: EPA pharmaceutical waste proposal

Stakeholders recommended Ecology:

> *Track developments in the EPA pharmaceutical waste rulemaking process to ensure state efforts are consistent and complementary. As much as possible, implement ideas in the EPA pharmaceutical waste proposal in advance of completion of the federal rulemaking.*

This recommendation addresses problems #2 and #3.

Ecology response and action

Ecology agrees with the stakeholders. We are currently reviewing the draft rules in depth to determine which provisions will be mandatory and which will be optional.[28] Ecology's plan is to begin developing the text of new Washington State pharmaceutical waste rules and begin asking for public comment on the proposal in spring 2016. We anticipate beginning the rule drafting process for Washington State before EPA has finalized the new federal rule. We hope to get

[28] Washington will be required to adopt any of EPA's proposed rules that are more stringent than Washington's current rules; proposed rules that are less stringent will be optional.

public input that would allow us to refine the Washington State pharmaceutical waste rules while EPA's rulemaking process is still happening. Ideally, Ecology would be able to adopt final state rules very soon after EPA adopts the final federal rules. This would allow for the quickest implementation of new rules that will satisfy EPA, Ecology, and the regulated community.

Implementation considerations
In addition to the fiscal impacts of rulemaking, timing may be challenging. Ecology's goal is to enact the rules as soon as possible, but not before EPA finalizes the federal rules. Because it is possible that EPA could change one or more provisions of their proposal, adopting new state rules too soon would present some risk. The easiest way to mitigate this risk is simply to wait to finalize new state rules until after EPA's final rules are released. This will allow Ecology to ensure the new state rules are consistent. Waiting for final adoption of the federal rules will not prevent Ecology from starting the public outreach process much sooner.

Scheduling the required agency resources for rulemaking, such as time for preparation of the economic analysis and Small Business Impact Statement, may also be challenging. Ecology had not originally planned to do an expedited rulemaking during 2016. We had planned to start a routine rulemaking process in 2016, but that would likely not result in new rules taking effect until 2018. Ecology is currently working through these issues.

Fiscal impact of recommendation
The rulemaking needed to implement this recommendation will likely require the work of HWTR's rules coordinator full-time for at least one year to develop the rule language, conduct public outreach, conduct public meetings, and coordinate with EPA for their review and oversight of the authorized program. We might be able to combine this work with other rulemaking that Ecology is required to do by EPA, but it is not yet clear whether that will be possible or desirable. If we cannot combine this work with other rulemaking, we anticipate the need for additional resources to prepare the necessary Small Business Impact Statement and related economic analysis. Other Ecology technical experts would also be required to assist in rule development and to work with stakeholders to develop the final version of the new regulations.

Recommendation #2: Dedicated section of the regulations for pharmaceuticals

Stakeholders recommended that Ecology create a separate portion of the regulations that is focused exclusively on pharmaceutical wastes. Stakeholders also recommended expediting the rulemaking process. The Stakeholders' Final Report specifically mentions:

> *Create a separate portion of the dangerous waste regulations focused on pharmaceutical waste so all pharmaceutical management requirements are in one place. (Note, this also is an element of the EPA pharmaceutical waste proposal.) Expedite this rulemaking process. As part of this rulemaking:*
>
> - *Clarify pharmaceutical waste identification and management requirements so generators can easily see what is expected and*

application of requirements can be more easily understood in the health care context.

- *Clarify different requirements/options for state-only v. federally-regulated waste pharmaceuticals and explore providing additional disposal options for state-only pharmaceutical waste such as amending the existing conditional exclusion for pharmaceutical waste to allow state-only waste pharmaceuticals to be disposed of at RCRA landfills and non-RCRA facilities that can appropriately treat them.*
- *Clarify requirements for management of pharmaceutical waste that also is regulated by the Drug Enforcement Agency and consider an exclusion for pharmaceutical waste managed in accordance with DEA requirements.*
- *Use more intuitive, user-friendly language, oriented to a heath care setting.*
- *Address commonly confusing situations such as partial doses of pharmaceuticals in sharps and pharmaceutical waste in sharps containers, and generally clarify the issue of dual waste. (Dual waste is regulated pharmaceutical and medical waste combined, such as a sharp with a partial dose of pharmaceutical in it.)*

This recommendation addresses problems #2 and #3.

Ecology response and action

The Stakeholder Work Group made a number of suggestions under the same recommendation, and we respond to each in turn. Generally speaking, Ecology agrees with this stakeholder recommendation, although there are some specific implementation issues that we need to clarify during the public outreach part of the rulemaking process. The Stakeholder recommendation focuses on creating a single set of rules that apply to pharmaceutical wastes. Ecology understands and appreciates the stakeholders' logic behind this suggestion. Ecology is partially able to implement this suggestion and will do so to the extent possible. Where it is not possible to do so, Ecology will continue to provide guidance to regulated facilities.

EPA's proposed rules create a new section of the federal regulations that applies exclusively to pharmaceutical waste management. The standards and requirements for these wastes will all be contained in a single section of the rules, just as was recommended by the Work Group. Ecology presumes that adoption of a Washington State version of the new rules will likewise be contained within a single, discrete section of the regulations. If companies manage their pharmaceutical wastes under the regulations in the new section, that single section should contain all the relevant regulations. However, facilities will still need to manage non-pharmaceutical wastes pursuant to the rest of the Dangerous Waste Regulations.

We believe the EPA proposed rules address the stakeholders' suggestions about clarifying requirements so generators can more easily understand what is required of them. As Washington State's regulations will be based on the EPA proposal, we presume that the state's version will likewise address this stakeholder suggestion. If the forthcoming regulations do not adequately resolve the stakeholders' concerns on this issue, Ecology can make further clarifications through additional guidance.

With regard to the stakeholders' suggestions about clarification of options for Washington State-only wastes versus federal wastes, we anticipate this will no longer be a concern under the new pharmaceutical waste management rules. Ecology will likely make state-only pharmaceutical wastes subject to the new pharmaceutical regulations also, so there will be no distinction between the two sets of regulatory requirements. State-only pharmaceutical wastes and RCRA pharmaceutical wastes can be treated as a single waste stream and no additional clarification will be needed.

EPA has addressed a key problem stakeholders discussed during the Work Group meetings: management of regulated waste that is also regulated by DEA. Stakeholders requested additional clarification and suggested Ecology consider excluding DEA-regulated wastes from regulation under the Dangerous Waste Regulations. EPA has proposed this type of exclusion for all RCRA wastes that are also DEA-regulated wastes. Ecology anticipates adopting the same exclusion for Washington State-only wastes that are also DEA wastes.

Stakeholders suggested that Ecology use more intuitive, user-friendly language. Ecology has attempted to do this in a new "Pharmaceutical Waste Policy," which is intended to be a successor to the IEP. Like the IEP, the new policy provides an optional way for regulated facilities to comply with the law. It lays out a set of standards that facilities can follow as well as the benefits they can receive by electing to follow the policy. As before, the policy is optional and no facility is required to follow the steps in the policy. Ecology attempted to write this new policy in easy-to-understand, plain English specifically for healthcare facilities. The new policy has a different layout than the old IEP, which Ecology hopes will make it easier to read and understand. If stakeholder reaction to the new policy is positive, Ecology can use the same type of language setup to revise additional guidance documents in the future.

Finally, stakeholders suggested Ecology address some important and complicated issues, such as leftover partial doses of medications, pharmaceutical wastes in sharps containers, and dual waste. At this time, Ecology is going to defer to EPA on these issues. EPA has specifically requested public comment on these issues, as well as a few others where their previous stakeholder work had not achieved consensus (*e.g.*, nicotine products and methods for adding new pharmaceuticals to the list of regulated federal wastes). Once EPA makes a determination on these issues, Ecology can better evaluate how much discretion it has and what Washington's strategy should be to regulate these wastes.

Implementation considerations

Ecology cannot implement these suggestions without going through a complete rulemaking process. Given the possibility that EPA will amend their proposed rules (maybe slightly, maybe significantly), Ecology does not think it is prudent to adopt new state rules prior to the completion of the federal rulemaking process. This is likely many months away. However, as noted above, Ecology does intend to jumpstart the rulemaking process as soon as possible to minimize the time stakeholders are subject to the current rules. Ecology also plans to offer the new pharmaceutical policy, which may provide the assistance stakeholders are seeking during the rulemaking process.

Fiscal impact of recommendation
The fiscal impacts of implementing this recommendation are included in our response to Stakeholder Recommendation #1 above. We would not anticipate any additional fiscal impacts from adopting the new pharmaceutical waste regulations in a single section.

Recommendation #3: Address "problem" waste streams

Stakeholders recommend that Ecology review the available scientific information on the physical and chemical properties of epinephrine salts and consider whether current state regulation of these and other specific chemical wastes may be unneeded. The Final Report specifically requests Ecology to consider whether these wastes:

> *…must be regulated as state-only acutely hazardous waste or, alternatively, could be safely regulated as non-acute state-only dangerous waste. Provide a clear and transparent pathway for state-wide interpretation and policy setting for specific problem waste streams and forms as they arise.*

This recommendation addresses problem #1.

Ecology response and action

As noted above, Ecology was actively involved in discussing this issue with members of the Work Group. This recommendation is a good example of how even identical regulations can sometimes have different outcomes. During the stakeholder meeting, Ecology explained that there is a difference in the interpretation of the federal listing of epinephrine and whether or not epinephrine salts are a regulated waste. EPA and Ecology agree that epinephrine is a RCRA listed waste. However, a number of years ago, EPA revised its interpretation of this listing and decided that if the epinephrine is in a form that is based on a salt (*e.g.*, epinephrine hydrochloride), it is not regulated as a listed waste.[29] Ecology disagreed with this interpretation and declined to adopt this as a change to our state's regulations, in large part because epinephrine is very toxic.

Ecology is committed to work with interested stakeholders to determine the best option for addressing the stakeholders' concerns. As noted earlier, some stakeholders also raised issues about OPA disinfectant and certain saline IV mixtures. Ecology has agreed to examine these issues. This may include using a petition process in WAC 173-303-910 to ensure the public has an opportunity to provide comments and input in the decision-making process. We will reach out to interested stakeholders to assist in this review. This could also provide a clear and transparent path for obtaining input on complex regulatory issues.

[29] At the second stakeholder meeting, EPA explained this determination was made because of a technicality. The original intent was to regulate all forms of epinephrine, including salts; however, because of a typographical mistake, the words "and salts" were omitted from the listing in the regulation. EPA decided this only gave them authority over the non-salts version of epinephrine.

Implementation considerations
Changing the regulatory status of a waste is not a determination that should be made lightly or without proper public input. While the stakeholders may be correct that these substances do not pose any significant environmental threat, there may be other stakeholders (such as wastewater treatment entities, environmental advocates, or others) that disagree with that assessment. The petition process outlined in WAC 173-303-910 provides for an opportunity for contrary views to be heard and considered by Ecology.

Fiscal impact of recommendation
Ecology estimates that the preliminary discussions related to these issues will have only a slight fiscal impact. However, if the discussions result in a change to Ecology's determination, rulemaking will likely be needed. We could roll any rulemaking into our next scheduled rulemaking.

Recommendation #4: Compliance assistance

Stakeholders recommended that Ecology provide more training and compliance assistance for facilities managing pharmaceutical waste. They provided a number of detailed suggestions, including the types of resources they would like to have made available to them.

This recommendation addresses problems #2, #3, and #5.

Ecology response and action

Ecology agrees that compliance assistance would be helpful and would like to provide more of these services. The stakeholder's recommendation closely mirrors the Work Group discussions and one-on-one conversations between Ecology staff and regulated facilities. Compliance assistance—that is, helping businesses learn how to be in compliance without fear of enforcement—is very important.

Neither RCRA nor the Dangerous Waste Regulations ever contained a compliance assistance component. However, over the years, the agency has provided some technical assistance measures to help businesses such as guidance documents, workshops, toxics reduction assistance, and technical assistance visits. We have not had sufficient resources to fully develop a true compliance assistance program statewide for businesses, focused on helping them learn and understand the rules and how to comply.

Ecology agrees with the stakeholders that training, videos, and new guidance would all be helpful to the healthcare industry. If new resources were to be provided for compliance assistance purposes, Ecology would be very interested in developing a consultation program similar to that at the Department of Labor and Industries. Currently, we do not have the ability to provide these services within our existing budget. Instead, stakeholders can access private sector consultants and service providers to obtain these services.

Implementation considerations
A stronger compliance assistance program would require development of new compliance assistance materials and adding new compliance assistance staff members. In addition, Ecology

would need to develop appropriate policies and procedures to ensure information is not inadvertently shared between compliance assistance and enforcement staff members. Assistance from the Department of Labor and Industries would benefit efforts to develop a compliance assistance program.

Fiscal impact of recommendation
The fiscal impact of implementing this recommendation would be significant. We anticipate it would require multiple new FTEs as compliance assistance staff, plus additional staff time to work on development of new assistance materials. These resources are not currently part of the HWTR Program's budget and are not feasible without significant new funds.

Recommendation #5: Responsibilities when mistakes are made

This recommendation relates back to Problem #4 discussed above: generators and waste disposal companies disagree about who should be responsible when pharmaceutical wastes are not properly managed. The stakeholders recommend that Ecology make additional clarifications about which company bears responsibility when wastes are not appropriately handled, including:

> *Provide clear protocols on what to do and expectations of each party (generator, transporter, receiving facility) and expectations for compliance/enforcement, particularly implications for generators when nonconforming waste is received at a receiving facility. Ensure that inspection, enforcement, and other follow-up when waste is placed in the wrong containers are consistent. Waste management vendors and waste handling facilities should be held to the same standard regardless of the container management system being used to collect wastes.*

This recommendation addresses problem #4.

Ecology response and action

Ecology agrees with the stakeholders that mismanagement of wastes is an issue that is extremely important. As part of the Stakeholder Work Group process, Ecology agreed to provide guidance regarding this issue. Based on the current regulatory scheme, when mistakes happen, all parties are responsible:

- Generators are responsible for ensuring that regulated wastes (such as partially-filled vials of medicine) are not mixed into unregulated wastes (such as sharps containers).
- If waste streams are co-mingled, transporters are responsible for ensuring that they don't accept regulated wastes unless they have a permit to do so and take that waste to a proper TSD facility.
- If transporters improperly accept regulated waste or deliver it to an improper disposal site, the disposal company is responsible for refusing the waste.
- If the disposal company improperly accepts waste it isn't permitted to accept, it is responsible for shipping the waste to a proper TSD facility. Because they improperly

> accepted the waste, they are now considered a generator or co-generator of that waste stream.

Because the regulations do not currently distinguish between wastes based on industry, healthcare facilities and medical waste companies are treated exactly the same as any other industrial generator. The protocol outlined above is the same as it would be at any one of thousands of other generators of dangerous waste throughout Washington State. Ecology agrees that all waste management vendors and waste handling facilities should be held to the same standard regardless of the container management system being used to collect wastes. Ecology endeavors (through sampling, testing, and inspections) to ensure that occurs.

As part of the additional guidance on this issue, Ecology will also reach out to stakeholders about practical solutions that might help further reduce the likelihood of wastes being inappropriately co-mingled.

Implementation considerations
As mentioned above, there is currently no regulatory requirement for facilities to use techniques such as transparent waste bins or color-coded labeling systems. New pharmaceutical waste rules should require that all medical waste containers be sufficiently transparent to allow the container's contents to be verified without opening the container. This would make it easier for facilities to verify compliance, allow transporters to easily see which containers can be sent for solid waste disposal versus incineration, and would allow waste disposal companies to ensure they aren't accepting waste they are not permitted to take. This requirement would also help ensure a level playing field among all waste handling companies and would make it easier for Ecology to ensure that all waste disposal companies are held to the same standard.

Fiscal impact of recommendation
Ecology anticipates approximately 0.1 FTE will likely be necessary to develop the appropriate guidance and conduct the stakeholder outreach on this issue, plus an additional 0.1 FTE for communications and website staff to distribute and publicize the new guidance. If stakeholders support the idea of a regulatory change, we would incorporate that into the new rules, so no additional cost would be incurred.

Recommendation #6: Pharmaceutical waste characterization

The stakeholders recommended that Ecology provide easy-to-use guidance to assist healthcare facilities in designating their waste pharmaceuticals. They requested particular help related to differentiating between state-only and federally regulated waste pharmaceuticals and assistance distinguishing between waste codes. They also requested:

> *As much as possible, provide easily accessible, frequently updated lists of pharmaceuticals/formulations that commonly designate as Federal or state-only waste. This may take the form of aggregating or linking to already available lists of pharmaceuticals that commonly designate.*

This recommendation addresses problems #1, #2, and #3.

Ecology response and action

While we understand stakeholder concerns, Ecology typically does not have access to the information being requested.

EPA has developed a new *Hazardous Waste Pharmaceuticals Wiki* page that contains information about regulated pharmaceutical wastes. Users can register, contribute, and search for information about RCRA-regulated wastes. There is some limited state-specific information as well. We are unsure whether this state-specific information feature will be sufficient to address the stakeholders' concerns.

Also, EPA's new proposed rules require that RCRA pharmaceutical wastes be incinerated at a RCRA-permitted incinerator. The proposal goes on to recommend a *Best Management Practice* (a *BMP*) for wastes like those regulated as Washington State-only pharmaceuticals:

> *Recommended BMPs for healthcare facilities managing non-hazardous waste pharmaceuticals possessing hazardous waste-like qualities. Currently, most pharmaceuticals are not regulated as RCRA hazardous wastes when discarded by healthcare facilities. These "non-RCRA-hazardous" pharmaceuticals can be divided into two categories: those that possess hazardous waste-like qualities and those that do not. As outlined in the Blueprint, there are pharmaceuticals that possess hazardous waste-like qualities, but for various reasons, are not regulated by the RCRA Subtitle C hazardous waste regulations. The Agency supports the Blueprint's recommendation of hazardous waste incineration as the BMP for healthcare facilities and pharmaceutical reverse distributors discarding pharmaceuticals that may possess hazardous waste-like qualities, but are not regulated as RCRA hazardous waste. This recommendation would apply to pharmaceuticals with more than one active ingredient listed on the P- or U-lists, chemotherapeutic agents characterized as bulk wastes, pharmaceuticals which meet the NIOSH Hazardous Drug Criteria, pharmaceuticals listed in Appendix VI of the OSHA Technical Manual, pharmaceuticals with LD50s ≤50 mg/kg, pharmaceuticals that are carcinogenic or endocrine disrupting compounds, and vitamin/mineral preparations containing heavy metals.*

Based on this recommendation and the fact that Ecology plans to adopt the EPA proposal for Washington State-only wastes as well, distinguishing wastes between RCRA and state-only wastes does not seem necessary. We assume healthcare facilities will simply co-mingle all pharmaceutical wastes irrespective of whether they are RCRA, state-only, or DEA wastes and send them all for disposal at a RCRA incineration site, just as many facilities are currently doing under the terms of the IEP.

Implementation considerations

A designation resource for healthcare facilities would rely heavily on stakeholders to provide the necessary information. Some stakeholders may not be inclined to share this information as it might be proprietary. If we were to develop a resource as envisioned by this stakeholder

recommendation, we would likely develop something similar to Ecology's existing Fertilizer Database and use that as a template.

Fiscal impact of recommendation
To develop an online designation resource, we estimate it would require at least 0.25 FTE (possibly more) of an environmental specialist, chemist, or toxicologist to do the necessary designation, 0.25 FTE for Information Technology development and website deployment, and 0.25 administrative help for database population (all for one year). These numbers would rely on significant assistance from key stakeholders on the designation tasks; without that help, the Ecology staff time required would be significantly higher. None of these resources is currently available in Ecology's budget.

Recommendation #7: Wastewater treatment

Finally, the Stakeholder Work Group recommended that Ecology clarify under what circumstances, if any, pharmaceutical wastes can be disposed of via wastewater treatment—in other words, disposed to the drain or sewer. The key consideration for this recommendation is that different sewer and water districts can have different rules.

This recommendation addresses problems #3 and #5.

Ecology response and action

With EPA's new rules, pharmaceutical wastes will no longer be permitted to be flushed or sewered as a method of disposal. Ecology plans to adopt the same proposal for state-only waste as well, meaning pharmaceutical wastes may not be disposed of via wastewater treatment. This will be a change in procedure for many healthcare employees.

However, it is possible that some substances may still be permitted to be discharged down the drain. A substance is only a regulated pharmaceutical waste if it meets the criteria for regulation. As explained earlier, substances that can be successfully treated and rendered non-dangerous would not be regulated as pharmaceutical waste. This may mean that some can be discharged down the drain even after the new rules go into effect.

Implementation considerations
Ecology would need to consult with regional wastewater treatment facilities to determine what substances they can safely accept, keeping in mind regional wastewater treatment acceptance differs from facility to facility. Ecology would also need to consult with healthcare providers to determine what substances they think should continue to be legal to discharge to the sewer. This would also involve Ecology staff from the Water Quality Program in addition to HWTR staff. Ecology is unsure that our efforts on this recommendation would be successful.

Fiscal impact of recommendation
Ecology estimates it would take at least 0.25 FTE to collect the necessary information, analyze the information collected, and develop sufficient regional outreach materials to properly address this recommendation. This estimate assumes significant assistance from both wastewater treatment entities and stakeholders. Without this assistance, Ecology does not believe it will be

possible, with any degree of reliability, to provide the information that stakeholders are interested in receiving. Ecology is unsure it can accomplish this recommendation even if additional funds are provided.

Other Stakeholder Observations

In addition to the problem identification and stakeholder recommendations, the Work Group's final report also contained some additional comments. These comments either did not receive a consensus or were outside the scope of the Work Group's charter. Each of these issues has been previously addressed in this report. A more detailed description of each additional observation as well as Ecology's response to each is attached as Appendix F.

Next Steps

Ecology's first step in implementing the Work Group recommendations is to revise and replace the existing IEP with a revamped "Pharmaceutical Waste Policy." The new policy is undergoing internal review and will give healthcare facilities a method of managing their dangerous pharmaceutical waste that is easier to understand and implement. Ecology will publish the final policy in the State Register and begin notifying healthcare facilities.

Ecology has begun the planning process for a new pharmaceutical waste rule. The agency will conduct an informal public comment period prior to a rule proposal to identify issues of concern for healthcare facilities and waste management companies. We expect to propose rule language soon after EPA announces the final federal pharmaceutical waste rule.

In addition to policy and rule changes, Ecology plans to discuss, with interested members of the Stakeholder Work Group, issues related to epinephrine salts, saline solutions, and other problematic wastes. Ecology plans to contact interested stakeholders to determine an appropriate course of action for these waste streams. We anticipate this will occur early in 2016, depending on workload for Ecology staff and events during the 2016 Legislative Session.

As noted in our response to Problem #5 above, Ecology is currently examining how to better inform regulated facilities and the public about our activities and what steps we are taking to ensure equitable treatment of facilities across the state in multiple industries. This may include a summary of Ecology activities and website publications. Ecology's next steps on this issue are to determine what information needs to be reported, assign staff to collect the relevant information, and update the agency's website accordingly. Depending on available resources, we anticipate these early planning steps will likely occur starting in mid-2016. Steps beyond planning will likely be contingent on new fiscal resources.

In order to provide inspection reports in a more timely manner, Ecology has established a goal of 30 days. Ecology will look into ways to streamline follow-up after a healthcare inspection,

including procedural changes, additional inspector training, and mentoring. This work has already begun and we anticipate it will continue throughout early 2016.

Although it was neither proposed by stakeholders nor discussed at any of the Work Group meetings, Ecology plans to reach out to key stakeholders such as the Washington State Hospital Association to determine if an informal forum for facilities dealing with pharmaceutical wastes would be helpful.

Conclusion

Ecology believes the Stakeholder Work Group process has been a successful endeavor despite the challenge to complete this work in such a short time. The process was both transparent and productive. We believe the dialogue between the stakeholders and Ecology has been beneficial to both. Ecology now has a better understanding of industry needs and industry has a better understanding of Ecology's expectations and limitations.

In addition to an increased understanding between Ecology and the regulated community, the stakeholder involvement process described in this report has led to concrete follow-up steps. Ecology has also received clear and detailed input on how to accomplish some of those steps, such as adopting new pharmaceutical waste rules. We have also learned what steps not to take, as they would not be supported by the regulated community. Ecology plans to take additional steps in 2016 to help healthcare facilities and waste companies improve both their environmental performance and regulatory compliance.

Appendices

Appendix A. List of Acronyms

The following acronyms are used in this report:

Acronym	Meaning
AHW	Acutely Hazardous Waste
BMP	Best Management Practice
CESQG	Conditionally Exempt Small Quantity Generator
DEA	Drug Enforcement Agency
DW	Dangerous Waste
EHW	Extremely Hazardous Waste
EPA	US Environmental Protection Agency
FY	Fiscal Year
HHW	Household Hazardous Waste
HW	Hazardous Waste
HWTR	Hazardous Waste and Toxics Reduction Program
IEP	Interim Enforcement Policy
LQG	Large Quantity Generator
MQG	Medium Quantity Generator
MSDS	Material Safety Data Sheet
NIOSH	National Institute for Occupational Safety and Health
OSHA	Occupational Safety and Health Administration
RCRA	Resource Conservation and Recovery Act
SDS	Safety Data Sheet
SQG	Small Quantity Generator (same as CESQG)
TCLP	Toxicity Characteristic Leaching Procedure

Appendix B. Selected Definitions

The following glossary defines selected words and phrases used in this report. For the technical definitions of these words and phrases, please refer to the applicable regulations.

"Acute hazardous wastes" or *"acutely hazardous wastes"* are wastes that are very toxic. Some of these wastes are produced as part of the manufacturing process for certain pesticides, while others are wastes from the RCRA P-list, such as Warfarin and Nicotine.

"Best Management Practice" or *"BMP"* is a practice that is recommended but not required by law or regulation.

"Corrosive wastes" are wastes that have a very low or very high pH level, either below 2.0 (acidic) or greater than 12.5 (alkaline). Under RCRA, only liquids can be "corrosive wastes" but under Washington State regulations, "corrosive wastes" can be either liquids or solids. (For comparison, battery acid has a pH of approximately 1.0 and lye has a pH of approximately 13.0.)

"Dangerous wastes" are wastes regulated by the Department of Ecology that require special handling and disposal because they meet one or more of the following criteria:

- Are on one of the federal RCRA lists of hazardous wastes (F-list, K-list, P-list, or U-list).
- Contain a toxic ingredient on the federal RCRA TCLP list in an amount over the allowed limit.
- Are corrosive, ignitable, or reactive wastes according to federal RCRA criteria.
- Are solid corrosive wastes, are toxic to fish, are persistent in the environment, are a type of PCB waste that isn't regulated by EPA, or meet one of the other Washington State-only dangerous waste criteria.

The term "dangerous wastes" includes acute hazardous waste, extremely hazardous waste, RCRA hazardous waste, and mixed waste.

"Designation" is the process of determining whether a waste is regulated under the dangerous waste rules. Designation can be done based on a generator's knowledge about the waste, documentation about the waste, or by testing the waste.

"Extremely hazardous wastes" are dangerous wastes that are toxic at a level X, A, or B according to the LD_{50} or LC_{50} listed on the Toxic Category Table in WAC 173-303-100.

"Generator" is any business or other entity who produces a dangerous waste or whose act causes a dangerous waste to become subject to regulation. Homeowners and other residential households are not generators. When more than one business is designated as a generator of the same waste, the term *"co-generators"* is used.

"Hazardous wastes" are all wastes regulated under RCRA.

"Ignitable wastes" are also sometimes called *"flammable wastes"* and catch on fire very easily. Any waste which has a flash point (the temperature where enough vapors evaporate to catch on fire in the air) below 60° C (140° F) is ignitable. (For comparison, the flash point of gasoline is approximately -45° F and the flash point of turpentine is approximately 95° F.)

"LC_{50}" is also referred to as *"Lethal Concentration 50"* and means the concentration of a substance in air or water needed to kill 50 percent of the population exposed, usually expressed in milligrams of substance per liter of air or water.

"LD_{50}" is also referred to as *"Lethal Dose 50"* and means the amount of a substance needed to kill 50 percent of the population when ingested, usually expressed in milligrams of substance per kilogram of body weight.

"Mixed wastes" are wastes that contain both a dangerous waste and radioactive waste.

"Persistent wastes" are wastes that linger in the environment for a long time. If a waste retains more than half of its initial activity after one year, in the dark, at ambient conditions, it is a persistent waste. Two groups of persistent wastes are highlighted in the Dangerous Waste Regulations: Polycyclic Aromatic Hydrocarbons (abbreviated *"PAHs"*) and Halogenated Organic Compounds (abbreviated *"HOCs"*). Wastes with more than 1% PAHs are a dangerous waste.

"RCRA hazardous wastes" means all wastes that are regulated under both RCRA.

"Reactive wastes" are wastes that are explosive when mixed with water or placed under pressure. Aerosol cans, lithium, silver nitrate sticks, and benzoyl peroxide can all be reactive wastes in some circumstances.

"State-only dangerous wastes" means wastes that are regulated under Washington State regulations but not under RCRA.

"Toxicity Characteristic Leaching Procedure" or *"TCLP"* is a laboratory test that determines whether a waste contains one or more of 40 specified toxic substances listed in state and federal regulations.

"Toxic wastes" are wastes that are poisonous in very small amounts and can cause or significantly contribute to death, injury, or illness of humans or wildlife.

"TSD" or *"TSD Facility"* is a facility with a RCRA permit that allows it to treat, store, process, or dispose of regulated wastes.

Appendix C. RCRA TCLP Wastes and Thresholds

40 CFR 261.30(b), Table 1

Code	Name	Regulatory Level (ppm)
D004	Arsenic	5.0
D005	Barium	100.0
D018	Benzene	0.5
D006	Cadmium	1.0
D019	Carbon tetrachloride	0.5
D020	Chlordane	0.03
D021	Chlorobenzene	100.0
D022	Chloroform	6.0
D007	Chromium	5.0
D023	o-Cresol	200.0
D024	m-Cresol	200.0
D025	p-Cresol	200.0
D026	Cresol	200.0
D016	2,4-D	10.0
D027	1,4-Dichlorobenzene	7.5
D028	1,2-Dichloroethane	0.5
D029	1,1-Dichloroethylene	0.7
D030	2,4-Dinitrotoluene	0.13
D012	Endrin	0.02
D031	Heptachlor	0.008
D032	Hexachlorobenzene	0.13
D033	Hexachlorobutadiene	0.5
D034	Hexachloroethane	3.0
D008	Lead	5.0
D013	Lindane	0.4
D009	Mercury	0.2
D014	Methoxychlor	10.0
D035	Methyl ethyl ketone	200.0
D036	Nitrobenzene	2.0
D037	Pentachlorophenol	100.0
D038	Pyridine	5.0
D010	Selenium	1.0
D011	Silver	5.0
D039	Tetrachloroethylene	0.7
D015	Toxaphene	0.5
D040	Trichloroethylene	0.5
D041	2,4, 5-Trichlorophenol	400.0
D042	2,4,6-Trichlorophenol	2.0
D017	2,4,5-TP (Silvex)	1.0
D043	Vinyl Chloride	0.2

Appendix D. Stakeholder Work Group Participant List

These stakeholders participated in a pre-meeting telephone interview and/or at least one stakeholder meeting (multiple individuals from the same organization may have represented that organization at different steps in the work group process):

Stakeholder Work Group Participants

Participant Name	Representing	Stakeholder Category
Jenny Arnold	Washington State Pharmacy Association	Industry Association
Bonnie Blachly	Leading Age Washington	Long-term Care
Jean Borth	CHI Franciscan	Hospital/Clinic System
Karen Bowman	Washington State Nurses Association	Industry Association
Gail Bunker	Multicare Pharmacy Services	Hospital/Clinic System
Ken Butti	LOTT Clean Water Alliance	Wastewater Treatment
Pam Cant	Department of Labor & Industries	State Agency
Matt Clark	Clean Harbors Environmental	Waste Handling Company
Ian Corbridge	Washington State Hospital Association	Industry Association
Leslie Emerick	Washington Hospice and Palliative Care Organization	Industry Association
Eric Feist	Veolia Environmental	Waste Handling Company
Dr. Mark Flanery	Washington State Medical Association	Industry Association
Doug Gallucci	University of Washington Medical Center	Large Hospital
Shawn George	PeaceHealth St. John Medical Center	Large Hospital
Scott Hancock	Propac Pharmacy	Long-term Care Pharmacy
Michael Hansen	PeaceHealth Southwest Medical Center	Large Hospital
William Hayes	Department of Corrections	State Agency/Specialty Medical Provider
Selin Hoboy	Stericycle	Waste Handling Company
Penny Ingram	Utilities and Transportation Commission	State Agency
Joseph Jordan	Sharps Compliance, Inc.	Waste Handling Company
Kim Kaminski	Waste Management	Waste Handling Company

Participant Name	Representing	Stakeholder Category
John Kelsey	Clean Harbors	Waste Handling Company
Danny Kermode	Utilities and Transportation Commission	State Agency
Liz Kindred	Harborview Medical Center	Large Hospital
John Kolojaco	Virginia Mason	Hospital/Clinic System
Mike Laffery	PS Industries	Reverse Distributor
Joyce Lindell	Providence Health	Hospital/Clinic System
Dedi Little	Washington State Pharmacy Association	State Agency
Jon McArthur	Costco	Retail Pharmacy
Mark McReynolds	Emerald Environmental	Waste Handling Company
Chief Jeff Myers	City of Hoquiam Police Department	Law Enforcement
Michael Ness	Virginia Mason	Hospital/Clinic System
Clair Olivers	Washington Association of Sewer & Water Districts	Wastewater Treatment
Frank Papp	Seattle Children's Hospital	Large Hospital
Mike Philpott	Stericycle	Waste Handling Company
Tom Prevoznik	Drug Enforcement Administration, HQs	Law Enforcement
Rick Quinteras	Drug Enforcement Administration, Seattle Division	Law Enforcement
Darin Rice	Department of Ecology	State Agency
Jack Rodgers	Multicare Health Systems	Hospital/Clinic System
Mike Smith	Swedish Medical Center	Hospital/Clinic System
Joanne Snarski	Department of Health	State Agency
Russ Snyders	Washington State Healthcare Safety Council	Industry Association
Lisa Thatcher	Lobbyist	
Ron Tolleson	PeaceHealth Southwest Medical Center	Large Hospital
Julie Tomaro	Department of Health	State Agency
Heather Trim	Futurewise	Environmental Advocate
Alex Truchot	Group Health Cooperative	HMO/Clinic System
Michelle Underwood	Department of Ecology	State Agency

Participant Name	Representing	Stakeholder Category
Bryce Yadon	Futurewise	Environmental Advocate

The following observers attended at least one stakeholder meeting but did not actively participate in the discussions:

Stakeholder Work Group Observers

Participant Name	Representing
Denise Clifford	Department of Ecology
Dan Jones	Washington State House Appropriations Committee
Jacob Lipson	Washington State House Environment Committee
Jan Odano	Washington State Senate Energy, Environment, and Telecommunications Committee
Sgt. Mike Murphy	Contraband Disposal/Tukwila Police Department

The following staff members presented information, answered questions, and otherwise assisted stakeholder discussions but were not part of the decision-making process:

Work Group Support/Facilitation Staff

Participant Name	Representing
Jack Boller	Environmental Protection Agency
Tom Cusack	Department of Ecology
Kristin Fitzgerald	Environmental Protection Agency
Kimberly Goetz	Department of Ecology
Jimmy Mahady	Ross Strategic
Elizabeth McManus	Ross Strategic

Appendix E. Stakeholder Report

Department of Ecology

Pharmaceutical Waste Work Group

Final Consensus Report: November 2015

Prepared by the Work Group facilitator, Ross Strategic

Contents

Background & Context

During the 2015 legislative session, the Washington State Legislature passed ESB 5577, which intends that Ecology should reexamine how pharmaceutical wastes are regulated in Washington and get input from the regulated community to develop an approach "that most effectively helps health care establishments, and pharmaceutical and medical waste handling businesses implement and comply with the regulation of pharmaceutical wastes under chapter 70.105 RCW."

The bill directed that Ecology "shall convene a work group to identify the problems of properly managing pharmaceutical wastes and recommend solutions to improve management of these wastes at the site of generation through treatment or disposal by commercial waste management facilities." The bill goes on to say that "The work group may develop recommendations including, but not limited to, new or revised policies to be issued by the Department [of Ecology], recommendations for ensuring consistent interpretation and implementation of existing rules, recommendations for amendments to chapter 70.105 RCW or rules adopted pursuant to chapter 70.105 RCW, and recommendations on how the Department will implement consistent regulatory oversight of pharmaceutical waste management facilities that receive waste from sources statewide."

Workgroup Process

Ecology convened the Pharmaceutical Waste Work Group in July 2015 and tasked them with deliberations to make recommendations in response to the legislative request. Ecology identified potential participants in the Pharmaceutical Waste Work Group by reaching out to individuals in the pharmaceutical waste regulated community including health care providers and hospitals, pharmacy providers, law enforcement, pharmaceutical waste management companies, and other interested stakeholders. Potential participants were invited by the Department of Ecology based on discussions with individuals in the pharmaceutical waste regulated community.

Specifically, the Work Group was tasked with deliberation on the following topics:

- How pharmaceutical waste is currently handled/regulated in Washington
- Problems associated with pharmaceutical waste handing/regulation in Washington
- Recommendations to overcome/address pharmaceutical waste handing/regulation problems, including but not limited to new or revised policies to be issued by the Department of Ecology, recommendations for ensuring consistent interpretation and implementation of existing rules, recommendations for amendments to chapter 70.105 RCW or rules adopted pursuant to chapter 70.105 RCW, and recommendations on how the Department will implement consistent regulatory oversight of pharmaceutical waste management facilities that receive waste from sources statewide.

The Work Group agreed that only recommendations on which the Work Group reached consensus would be forwarded to the Legislature. Consensus was defined as a recommendation that all participants can "live with," even though it might not be the first—or even the preferred—choice of each. In the event consensus was not reached on key issues, the Work Group agreed that the range of perspectives expressed by Work Group participants would be described in the Work Group report.

The Work Group met two times, and before the first and second meetings an interview and/or survey processes was used to gather and gauge Work Group member perspectives. At the first meeting the Work Group identified problems and shortcomings with pharmaceutical waste management and potential solutions to these problems. Potential solutions were further described and considered between the first and second Work Group meetings. At the second Work Group meeting, members discussed potential solutions and identified consensus recommendations.

Problem Statement

Work Group participants identified five main types of concerns with the current pharmaceutical waste management system: (1) dangerous waste regulations capture too many pharmaceuticals; (2) requirements for waste pharmaceuticals that are regulated as dangerous waste are too strict and too difficult to implement in a patient care setting; (3) requirements and related policies and guidance are difficult to understand and confusing; (4) difficulties between waste generators and waste management vendors; and (5) technical assistance for generators is not adequate and inspections/enforcement are not equitably distributed. Each of these concerns is discussed further below.

Work Group members also expressed serious concern about pharmaceutical waste from households, which many Work Group members saw as a much bigger problem—with more far-reaching, potentially adverse impacts—than pharmaceutical wastes from hospitals, pharmacies, long-term care facilities, and other health-care-related generators. Pharmaceutical waste from households is exempt from the dangerous waste regulations and therefore outside the scope of the Work Group's charge; however it is mentioned here because of the issue's importance to many Work Group members.

Dangerous Waste Regulations Capture Too Many Pharmaceuticals

There were two concerns in this area. First, some Work Group members expressed concern that too many pharmaceuticals that otherwise could go for beneficial reuse are moved into the waste stream. This often was a concern from representatives of pharmacy and long-term care facility interests, who also emphasized the importance of not over-prescribing/overfilling prescriptions in the first place, effective use of the reverse distribution system, and additional opportunities to direct un-used, un-expired medications that are no longer needed by the patient to whom they were prescribed to beneficial use by other patients.

Second, some Work Group members expressed concern that, in general, Ecology had not provided adequate information to justify regulation of waste pharmaceuticals beyond those already regulated by

US EPA, or that some specific waste pharmaceuticals or other hospital products were mentioned (e.g., Epi-salts, OPA disinfectant, and nicotine). A number of Work Group members expressed the perspective that, across the board, the large cost and burden of managing relatively small amounts of pharmaceutical waste in a health-care setting are not warranted given the relatively small potential environmental impact of these wastes.

On the other hand, some Work Group members expressed the concern that the dangerous waste regulations might not capture enough waste pharmaceuticals, given that new drugs are reaching the market all the time, and that waste pharmaceuticals should be assumed hazardous unless proven otherwise.

Requirements for Waste Pharmaceuticals That Are Captured Are Too Strict and Too Difficult to Implement in a Patient-Care Setting

Work Group members emphasized that health care providers need to be focused on patient care, and therefore any waste management expectations need to be simple to execute in that setting. Even Work Group members who feel that they have effective, compliant pharmaceutical waste management programs described the significant complexity of the pharmaceutical waste management requirements and the associated difficulty in executing these requirements consistently. Depending on the material, pharmaceutical waste might fall into a number of categories: dangerous waste; dangerous waste/P-listed, which has implications for determining which containers are empty and for management of "empty" containers; state-only dangerous waste (of various categories); or dual waste, which is pharmaceutical waste that is cross-contaminated with biological waste. These waste categories are further complicated by the need to understand related rules for containers. For some types of dangerous pharmaceutical waste a container, such as a vial or a sharp, can be determined empty by visual inspection; that is, if it appears to be empty it can be considered empty for purposes of the dangerous waste regulations. However, for P-listed dangerous pharmaceutical waste, containers cannot be considered empty unless they are rinsed three times, and until empty, the entire container must be managed as dangerous waste.

Work Group members that generate pharmaceutical waste in a patient-care (i.e., non-pharmacy) setting seemed to use one of two waste management methods. Some Work Group members focus on characterizing waste pharmaceuticals at or near the patient bedside, using multiple bins either in patient rooms or at a near-by more central location. Other Work Group members collect waste pharmaceuticals in a single stream at the patient bedside and characterize them at a central location on site. In both cases generators report difficulties related to developing simple waste management protocols and systems, developing and providing training in these systems, and maintaining attention to the details of pharmaceutical waste management requirements. Work Group members with programs that focus on characterizing waste pharmaceuticals at or near the patient bedside further describe the difficulty of maintaining consistent attention to the need to sort waste pharmaceuticals into different bins depending on type, and even the difficulty in obtaining and finding the space for multiple bins. On the other hand, Work Group members with programs that focus on later sorting cite the expense of such programs.

Neither type of program provides an easy solution for sharps that might contain partial doses of pharmaceutical and/or sharps that contain P-listed pharmaceuticals (dual waste). These materials generally must be managed as hazardous waste, which means that any collection method must: (1) be safe for management of sharps; and (2) ensure proper management and treatment of the biologic medical waste, in addition to the waste pharmaceutical. Management of sharps presents particular concerns, and there are practical difficulties associated with safety. Because of concerns for worker health and safety, health care workers and providers have been trained to move used sharps as quickly as possible into the sharps container, and never to re-cap used sharps or put them in a pocket or move them a significant distance (e.g., down the hall) from patient rooms. If a sharp contains a partial dose of pharmaceutical, management options are limited and more complicated. Because of the emphasis in training on getting sharps into a sharps container, mistakes can happen in this area. Management of glass ampoules can present similar difficulties when they break and can become cross-contaminated with body fluids. If there is a concern/mistake, most institutions do not want people sorting through sharps containers looking for ampoules because of the very real risk of serious injury.

Further complicating the situation, pharmaceutical wastes often are subject to multiple layers of requirements, from the Drug Enforcement Agency (DEA), the Department of Labor and Industry, and the Board of Pharmacy. Sometimes these requirements seem at cross-purposes or even to be conflicting. DEA and dangerous waste regulations, in particular, were cited as difficult to harmonize. Some Work Group members expressed concerns about (1) health-care staff mistakenly disposing of controlled substances into the pharmaceutical waste bins, even with training to the contrary; and (2) the presence of the pharmaceutical waste bins in patient rooms—which is needed to facilitate compliance with the dangerous waste regulations—creating a potential for tampering with the bin in an effort to obtain controlled substances (even though the bins are labeled “No Controlled Substances”).

Finally, there are issues with disposal of waste pharmaceuticals to the sewer. It can be difficult to determine when this practice is allowed by the dangerous waste regulations and, even if allowed, difficult to obtain necessary permissions from sewer utility districts/treatment authorities. Moreover, different districts may have different policies about the acceptability of waste pharmaceuticals. Information on how well pharmaceuticals are treated by conventional, and even advanced, waste water treatment technologies is incomprehensive, causing some Work Group members to advocate for a total prohibition on disposal of waste pharmaceuticals to sewer. A number of Work Group members also noted that many pharmaceuticals that show up in waste water are naturally excreted in the feces and urine of patients, and are an unavoidable source of contamination to sewer and wastewater facilities, confounding the picture.

It is left to health care facilities to determine how best to design programs that comply with complex requirements. With multiple and sometimes seemingly conflicting options for “compliant” programs, this can be very difficult to sort through, especially at facilities that lack dedicated or experienced pharmaceutical waste management staff. A number of Work Group members noted that expecting

100% compliance with complex waste characterization and segregation requirements is not realistic in a health care setting, and not warranted given the small volumes of waste generated.

Requirements and Related Policies Are Difficult to Understand and Confusing

All Work Group members felt strongly that the requirements and policies for waste pharmaceuticals are too complicated and confusing. This situation causes difficulties in designing stable programs that can be practically implemented (especially in the patient care setting) and creates challenges for maintaining staff training and consistent compliance. Work Group members cited a number of specific concerns, including:

- The dangerous waste regulations are written for industrial generators, not health care facilities. The technical language is not intuitive and difficult for health care facilities to "see" themselves in and follow. In addition, cross referencing and switching back and forth between sections of the regulations is difficult to follow and obscures requirements.
- All elements of training, in particular, were of concern, including: distilling complex requirements to a manageable set of protocols; anticipating waste pharmaceutical types and providing relevant profiles and training; keeping profiles and training up-to-date; generating staff (and management) interest and support for training; maintaining training/competency in the face of staff turnover; ensuring consistent adherence to what may be different protocols at different facilities when nurses and providers travel among facilities or rotate among programs/specialties; and training on labeling and manifesting requirements.

Difficulties Between Waste Generators and Waste Management Vendors

Under the dangerous waste regulations, generators are required to characterize (also known as "designate") their waste to determine if it is considered dangerous and, if so, what type of dangerous waste it is. Waste generators, particularly those without dedicated staff, cite the complexity of this step and the need for help from waste vendors. Generators want to be able to rely on vendors to ensure provided containers are properly labeled and manifests and other paperwork properly completed and filed. When this does not happen, generators are subject to enforcement for what they see as "vendor mistakes." Transporters need to be able to rely on the characterization information provided by generators.

Some waste management vendors, on the other hand, expressed concern about generator errors. In some waste management service approaches, it is less (or not at all) feasible for waste handlers/transporters to independently verify generator assertions about waste types and characterization. This came up particularly in the context of sharps or other bio-hazard waste, where waste pharmaceuticals are not intended to be intermixed, and opening of containers could expose workers to health and safety risks. Some waste management vendors point out that when mistakes are made by generators (e.g., waste ending up in the wrong container) the enforcement actions are too often directed at waste handlers, leaving generators with little incentive for compliance since they have little risk of enforcement action. (Other waste management vendors had fewer concerns about

generator error or verification; the level of concern seems to be related to the amount of waste sorting responsibility placed on the generator as opposed to the waste management vendor.)

Technical Assistance for Generators Is Not Adequate and Inspections/Enforcement Are Not Equitably Distributed

A number of Work Group members felt that Ecology's inspection and enforcement activities were not evenly distributed, in particular, that other waste pharmaceutical generators such as dentists, veterinary clinics/facilities, and long-term and skilled nursing facilities were not receiving the same scrutiny as hospitals. Some Work Group members felt that inspections can seem "nit-picky" and not focused on environmentally-significant issues (e.g., mostly focused on labeling or manifest-related "paperwork" violations). Work Group members noted that often inspection reports were issued many months after an inspection had taken place, which creates challenges because the lag time associated with concerns noted in the report often makes it difficult to track the details or find the staff who may have been involved. Also, it can be hard for upper management to perceive concerns as important if there is significant time between the actual inspection and the concerns being brought to a facility's attention. Finally some Work Group members noted that the tone, and in some cases the content, of inspections can be different across inspectors or between regional offices.

Waste Pharmaceuticals from Households

Although waste pharmaceuticals from households were not the topic of these deliberations, Work Group members emphasized the significant challenge these materials pose. Although household hazardous wastes are exempt from the dangerous waste regulations, household pharmaceutical take-back programs are nonetheless stymied by the tangle of waste management requirements that may apply once the materials are collected and by a lack of capacity and interest on the part of waste management vendors and disposal providers. Work Group members felt strongly that the main risks associated with waste pharmaceuticals, as well as the majority of the volume, are associated with unused medications originating in households, and that this demanded urgent attention.

Recommendations

The Work Group makes seven consensus recommendations. As described earlier in this report, consensus is defined as a recommendation that all participants can "live with," even though it might not be the first—or even the preferred—choice of each. Other issues discussed by the Work Group are described in the next section.

The Work Group did not prioritize recommendations. The numbers here are simply the order in which recommendations were developed; they do not signify priority order.

1. **EPA pharmaceutical waste proposal**. Track developments in the EPA pharmaceutical waste rulemaking process to ensure state efforts are consistent and complementary. As much as possible, implement ideas in the EPA pharmaceutical waste proposal in advance of completion of the federal rulemaking.

2. **Dedicated section of dangerous waste regulations for pharmaceuticals**. Create a separate portion of the dangerous waste regulations focused on pharmaceutical waste so all pharmaceutical management requirements are in one place. (Note, this also is an element of the EPA pharmaceutical waste proposal.) Expedite this rulemaking process. As part of this rulemaking:

    - Clarify pharmaceutical waste identification and management requirements so generators can easily see what is expected and application of requirements can be more easily understood in the health care context.
    - Clarify different requirements/options for state-only v. federally-regulated waste pharmaceuticals and explore providing additional disposal options for state-only pharmaceutical waste such as amending the existing conditional exclusion for pharmaceutical waste to allow state-only waste pharmaceuticals to be disposed of at RCRA landfills and non-RCRA facilities that can appropriately treat them.
    - Clarify requirements for management of pharmaceutical waste that also is regulated by the Drug Enforcement Agency and consider an exclusion for pharmaceutical waste managed in accordance with DEA requirements.
    - Use more intuitive, user-friendly language, oriented to a heath care setting.
    - Address commonly confusing situations such as partial doses of pharmaceuticals in sharps and pharmaceutical waste in sharps containers, and generally clarify the issue of dual waste. (Dual waste is regulated pharmaceutical and medical waste combined, such as a sharp with a partial dose of pharmaceutical in it.)

3. **Epi salts and other problem waste streams/forms**. Review information on the physical and chemical properties of epi salts that was considered in development of the state epi salt policy interpretation against information considered in the federal epi salt interpretation and in light of data and information on epi salts from health care facilities. Consider whether epi salts must be regulated as state-only acutely hazardous waste or, alternatively, could be safely regulated as non-acute state-only dangerous waste. Provide a clear and transparent pathway for state-wide interpretation and policy setting for specific problem waste streams and forms as they arise.

4. **Compliance assistance**. Provide more training and compliance assistance for pharmaceutical waste generators, considering the Labor and Industries "consultation" and related programs as a model for compliance assistance. This should include guidance that more clearly describes potential programs/paths to compliance for pharmaceutical waste management, oriented to a health care setting, and workshops, training (in person and/or video) and other resources for the health care industry and workers. This could include opening Ecology inspector training to pharmaceutical waste generators or reinstituting Ecology's generator training and workshop programs. All materials should be in plain, user-friendly language oriented towards a health care setting. Guidance also should address and clarify realistic disposal options for state-only waste pharmaceuticals and small-quantity generator waste pharmaceuticals recognizing that some disposal pathways which might be allowed under the dangerous waste regulations are prohibited by other programs and/or by receiving facilities. Clarify the role of municipal solid waste landfills and medical waste treatment/disposal facilities in pharmaceutical waste management.

5. **Responsibilities when mistakes are made**. Clarify the respective responsibilities of waste management vendors, waste handling facilities, and waste generators in situations where it appears an error or mistake in waste management may have been made, such as nonconforming waste reporting (e.g., if waste pharmaceuticals are placed/found in a sharps container). Provide clear protocols on what to do and expectations of each party (generator, transporter, receiving facility) and expectations for compliance/enforcement, particularly implications for generators when nonconforming waste is received at a receiving facility. Ensure that inspection, enforcement, and other follow up when waste is placed in the wrong containers are consistent. Waste management vendors and waste handling facilities should be held to the same standard regardless of the container management system being used to collect wastes.
6. **Pharmaceutical waste characterization**. Provide easy-to-use guidance for characterization of waste pharmaceuticals, in particular, for distinguishing between state-only and federally regulated waste pharmaceuticals and, within state-only waste pharmaceuticals, for distinguishing between waste codes. As much as possible, provide easily accessible, frequently updated lists of pharmaceuticals/formulations that commonly designate as Federal or state-only waste. This may take the form of aggregating or linking to already available lists of pharmaceuticals that commonly designate.
7. **Wastewater treatment**. Clarify the circumstances, if any, under which state-only pharmaceutical wastes can be disposed of via wastewater treatment (i.e., disposed to the drain or sewer), recognizing that individual sewer districts may have different requirements and protocols for evaluation and disposal of waste pharmaceuticals and compiling these different sets of requirements as much as possible. This is particularly an issue for saline and lactated ringers. Over time, support development of a better understanding of which pharmaceutical wastes can be effectively treated by common wastewater treatment processes and consistency in wastewater treatment requirements for pharmaceutical waste processing facilities.

Additional Work Group Observations and Discussion

The majority of issues on which the Work Group deliberated and the majority of the problems identified by the Work Group in the problem statement are addressed by the consensus recommendations described above. At the same time, the Work Group observed and deliberated on a number of additional issues but either did not reach consensus or did not make recommendations because the issues were outside the scope of the Work Group charter.

Household pharmaceutical waste take-back programs. Pharmaceutical wastes from households are exempt from the dangerous waste regulations. However, a number of Work Group members, including those from law enforcement, report significant problems and barriers to these programs, in particular difficulty finding affordable disposal options for pharmaceutical wastes collected by take-back programs. The Work Group had a number of discussions about the urgent need to establish reliable, implementable solutions for pharmaceutical waste take-back programs and the importance of this issue to preventing release of pharmaceutical wastes to the environment and to preventing diversion (e.g.,

abuse) of waste pharmaceuticals. Police take-back programs are not really law enforcement functions, but local agencies have absorbed the activity and associated cost because "it is the right thing to do" in the face of no reasonable options for citizens to safely dispose of unwanted medications. They are not universal across the state and may be disproportionately located. While this issue was determined to be beyond the scope of the Work Group charter, all Work Group members were in agreement about its importance and urgency. Furthermore, to the extent that the dangerous waste regulations may be perceived as a barrier to reasonable disposal options for waste pharmaceuticals collected in take-back programs, the issue is addressed in recommendation two.

Pharmaceutical waste minimization. The Work Group discussed a number of ideas oriented towards reducing the amount of pharmaceutical waste generated. These included requiring pharmaceutical manufacturers, wholesalers, and/or distributors to take-back expired or almost expired samples; encouraging appropriate use of the reverse distribution system; partial filling of prescriptions where appropriate; re-use of un-opened, un-used, un-expired prescriptions that can no longer be used by the patient as provided for under State Law; and establishing an extended producer responsibility program for pharmaceuticals. While there was interest in these approaches and broad support for effective, appropriate approaches to minimizing pharmaceutical waste, in the end the Work Group felt these issues were beyond the scope of their charter.

Joint comments on the EPA pharmaceutical waste proposal. A number of Work Group members advocated for the Work Group to develop and submit joint comments on the EPA pharmaceutical waste proposal. While there was not time during this Work Group process to fully take up this idea, Ecology has offered to serve as a facilitator for any Work Group participants who might be interested in coordinating or submitting joint comments on the EPA proposal.

Equity between waste handlers. A Work Group participant expressed concern that all facilities which handle state-only pharmaceutical waste, or inadvertently receive it for processing, might not be treated consistently in the future. The participant pointed out that different medical waste and sharps handing approaches (e.g., sealed bags vs. containers intended to facilitate reuse/recycling) create different opportunities for oversight and inspection and expressed the concern that unless waste handling/processing facilities are held to the same standard, generators who are serviced by those facilities would not be doing the same things to ensure compliance. The Work Group discussed this concern at length and their consensus on the issue is described in recommendations two, four and five; however, a Work Group participant continued to feel the issue was not directly enough addressed.

Justification for regulating state-only pharmaceutical waste. Finally, there were some Work Group members who questioned the justification for regulating any pharmaceutical waste that is not already regulated by the federal government. They expressed concern that a material that in one moment was a medicine given to a patient to cure disease or relieve suffering could, in the next moment, be a dangerous waste requiring special management, and advocated that no waste pharmaceutical should be regulated unless it had been documented as present and having adverse impacts in the environment. Other Work Group members were less concerned about regulation of state-only pharmaceutical waste

in general, or had concerns only about specific state-only pharmaceutical wastes (e.g., see recommendation three), or were concerned that given the rate at which new pharmaceuticals and pharmaceutical formulations are created, too few waste pharmaceuticals are regulated.

Attachments

1. Work Group charter

2. Work Group participant list

3. Synthesis of Work Group interviews

4. Potential solutions considered by the Work Group, with Ecology's initial reactions

5. Synthesis of Work Group survey

Attachment 1: Work Group Charter

WASHINGTON DEPARTMENT OF ECOLOGY PHARMACEUTICAL WASTE WORK GROUP

REVISED DRAFT CHARTER

I. Background

During the 2015 legislative session, the Washington State Legislature passed ESB 5577, which intends that Ecology should reexamine how pharmaceutical wastes are regulated in Washington and get input from the regulated community to develop an approach "that most effectively helps health care establishments, and pharmaceutical and medical waste handling businesses implement and comply with the regulation of pharmaceutical wastes under chapter 70.105 RCW."

The bill specifically directs that Ecology "shall convene a work group to identify the problems of properly managing pharmaceutical wastes and recommend solutions to improve management of these wastes at the site of generation through treatment or disposal by commercial waste management facilities." The bill goes on to say that "The work group may develop recommendations including, but not limited to, new or revised policies to be issued by the Department [of Ecology], recommendations for ensuring consistent interpretation and implementation of existing rules, recommendations for amendments to chapter 70.105 RCW or rules adopted pursuant to chapter 70.105 RCW, and recommendations on how the Department will implement consistent regulatory oversight of pharmaceutical waste management facilities that receive waste from sources statewide." Recommendations to the appropriate fiscal and policy committees of the legislature are due by December 31, 2015.

II. Purpose and Anticipated Outcomes

The Washington Department of Ecology Pharmaceutical Wastes Work Group is established to fulfill the direction of the Legislature. It is expected that the Work Group will deliberate on the following topics.

- How pharmaceutical waste is currently handled / regulated in Washington
- Problems associated with pharmaceutical waste handing / regulation in Washington
- Recommendations to overcome / address pharmaceutical waste handing / regulation problems, including but not limited to, new or revised policies to be issued by the Department of Ecology, recommendations for ensuring consistent interpretation and implementation of existing rules, recommendations for amendments to chapter 70.105 RCW or rules adopted pursuant to chapter 70.105 RCW, and recommendations on how the Department will implement consistent regulatory

oversight of pharmaceutical waste management facilities that receive waste from sources statewide.

Note that some requirements for pharmaceutical waste management are established by the Federal government through the US Environmental Protection Agency under the Resource Conservation and Recovery Act. Washington State does not have the ability to waive or otherwise modify Federal requirements.

III. Membership and Participation

Ecology identified potential participants in the Pharmaceutical Wastes Work Group by reaching out to individuals in the pharmaceutical waste regulated community including health care providers and hospitals, pharmacy providers, law enforcement, pharmaceutical waste management companies, and other interested stakeholders. Potential participants were invited by the Department of Ecology based on discussions with individuals in the pharmaceutical waste regulated community.

Direct participation of all participants is essential to the success of the Work Group. For that reason, participants are asked to make every effort to attend in-person meetings and participate in conference calls. In the rare occasions that a participant cannot be present, an alternate may be sent to participate on his or her behalf. It is the responsibility of the participant to ensure that any alternate is fully briefed and prepared to participate in deliberations.

All participants are expected to participate throughout the duration of the process. Only participants who participate fully in the process will be included in the Work Group consensus.

Participants are requested to:

- Represent their community/sponsoring organization.
- Actively engage in discussion and bring constituent concerns to the table, as well as seek an increased understanding of other's views.
- Speak candidly and bring their ideas and expertise to the table to help inform Ecology's choices.
- Communicate back to their communities/sponsoring organizations.

IV. Decision Making and Consensus

Only recommendations on which the Work Group reaches consensus will be forwarded to the Legislature. Consensus is defined as a recommendation that all participants can "live with" even though it might not be the first, or even the preferred, choice of each. In the event consensus is not reached on key issues, the range of perspectives expressed by Work Group participants will be described in the Work Group report.

Consensus will be evaluated through a variety of techniques, including one-on-one conversations with Work Group participants, straw polling, and other methods. Throughout the process there will be documentation of Work Group discussions in meeting notes, the draft Work Group report, and other

documents (if needed); the primary purpose of these documents is to summarize Work Group deliberations and explore and describe emerging and final Work Group consensus.

IV. Tentative Work Flow, Meeting Topics, Schedule, and Duration

The Work Group will meet twice between July 1, 2015 and November 30, 2015, with the possibility of additional meetings if needed and if resources are available. Preliminary meeting topics are described below. In addition, Work Group members will be offered a one-on-one telephone interview with the Work Group facilitator before the first meeting. The purpose of the interview will be to gather information on each Work Group participant's individual perspectives to begin to understand potential areas of consensus and information needed to support Work Group deliberations.

Before first meeting:

- One-on-one telephone interviews with participants.

Late July or Early August 2015 – First Meeting

- Overview of current regulatory status of pharmaceutical waste in Washington State, distinguishing Federal and State-only requirements.
- Problems associated with pharmaceutical waste handing / regulation.
- Brainstorm initial perspectives on potential solutions, criteria or principals against which to evaluate potential solutions, and information needed to further describe / deliberate on potential solutions.

Between first and second meetings:

- Refine problem statement(s), and describe consensus (or range of perspectives) on problem statement(s).
- Refine list of potential solutions and criteria or principals against which to evaluate potential solutions. Describe consensus (or range of perspectives) on criteria.

Mid September – Second Meeting

- Review initial draft of Work Group report covering background, problem statement and solution criteria/principals.
- Deliberation on potential solutions.
- Describe consensus (or range of perspectives) on potential solutions.
- Identify remaining issues and next steps.

After second meeting

- Finalize Work Group report.

DEPARTMENT OF ECOLOGY PHARMACEUTICAL WASTE WORK GROUP GROUND RULES

1. All participants have equal opportunities to participate.

2. Discussions will stay within the objectives and scope of the Charter.

3. Participants will strive for honest and direct communication, allow open discussion and the right to disagree, and look for opportunities to find common interests, agreements, and solutions.

4. Participants will focus on clarifying their own views and interests; they will refrain from characterizing the views of other participants.

5. Participants and/or the facilitator may request a caucus break at any time during a meeting. In order to keep the flow of meetings on track, individual caucus breaks may not exceed 15 minutes

6. The facilitator is a neutral third party with no stake in the outcome of the project. Ross Strategic will structure meetings to support a respectful atmosphere and the development of trust among participants.

7. Meetings are expected to start and end on time.

Attachment 2: Work Group Participant List

DEPARTMENT OF ECOLOGY PHARMACEUTICAL WASTE WORK GROUP

Participant List

The following individuals participated in the Pharmaceutical Work Group process and are in agreement with the consensus recommendations presented in the report.

Jenny Arnold, Washington State Pharmacy Association

Jean Borth, CHI Franciscan Health

Ken Butti, LOTT Clean Water Alliance

Pam Cant, Department of Labor and Industries

Leslie Emerick, Washington Hospice Association

Eric Feist, Veolia Environmental

Mark Flanery, Washington State Medical Association

Doug Gallucci, UW Medical Center

Shawn George, PeaceHealth SW Medical Center

William Hayes, Department of Corrections

Penny Ingram, Utilities and Transportation Commission

Kim Kaminski, Waste Management

John Kelsey, Clean Harbors Environmental

Liz Kindred, Harborview

John Kolojaco, Virginia Mason

Joyce Lindell, Providence Health

Jon McArthur, Costco

Marc McReynolds, Emerald Services

Jeff Myers, City of Hoquiam Police

Clair Olivers, Washington Association of Sewer and Water Districts

Frank Papp, Seattle Children's Hospital

Mike Philpott, Stericycle

Jack Rogers, Good Samaritan Hospital/Multicare

Mike Smith, Swedish Health Services

Julie Tomaro, Washington Department of Health

Heather Trim, Futurewise

Alex Truchot, Group Health Cooperative

In addition, Karen Bowman from the Washington State Nurses Association participated in the Pharmaceutical Waste Work Group process, but did not take a position on the final report.

Attachment 3: Synthesis of Work Group Interviews

DEPARTMENT OF ECOLOGY PHARMACEUTICAL WASTE WORK GROUP

Synthesis of Pre-Meeting Interviews

BACKGROUND

The Department of Ecology Pharmaceutical Waste Work Group is charged with developing recommendations to the Washington State Legislature on management of pharmaceutical waste and is expected to deliberate on the following topics.

- How pharmaceutical waste is currently handled / regulated in Washington
- Problems associated with pharmaceutical waste handing / regulation in Washington
- Recommendations to overcome / address pharmaceutical waste handing / regulation problems, including but not limited to, new or revised policies to be issued by the Department of Ecology, recommendations for ensuring consistent interpretation and implementation of existing rules, recommendations for amendments to chapter 70.105 RCW or rules adopted pursuant to chapter 70.105 RCW, and recommendations on how the Department will implement consistent regulatory oversight of pharmaceutical waste management facilities that receive waste from sources statewide.

To prepare for the Work Group's first meeting, individual 30-60 minute telephone interviews were offered to participants and potential participants. Interviewees were asked about their role in pharmaceutical waste management, their goals for pharmaceutical waste management, their perspectives on how pharmaceutical waste management is currently working and any problems / challenges with the current system, and potential solutions. This document summarizes the results of the interviews. Please note the following.

- "Statements of fact" made by interviewees have been taken as given, but not verified.
- The summary seeks to strike a balance between respecting the richness and detail of the interviews/survey while providing a reasonably digestible and compact presentation.
- The material is drawn from individual contributions – any given statement should not be viewed as a consensus perspective, and, at times, statements reflective of different perspectives can contradict each other.
- Statements /points are numbered for ease of reference, and like ideas have been grouped, but statements are not presented in any priority order.

Goals for Pharmaceutical Waste Management

Interviewees expressed a variety of goals related to pharmaceutical waste management. Many interviewees' goals focused on ensuring compliance with applicable regulations. A number of interviews also expressed broader goals such as preventing pharmaceuticals from reaching the environment. Expressed goals included the following. The goals listed are not in priority order.

1. Reduce/ minimize the amount of pharmaceutical waste generated; maximize therapeutic use of medications and use of reverse distribution.
2. Maintain cost / business-competitiveness.
3. Ensure protection of staff / worker health and safety.
4. Prevent unwanted / waste pharmaceuticals from falling into the wrong hands.
5. Prevent unwanted / waste pharmaceuticals from entering the environment through landfills and/ or the wastewater treatment process.
6. Ensure compliance with environmental, worker-safety, board of pharmacy, DEA, and other applicable laws and regulations.
7. Streamline / simplify the process of pharmaceutical waste management. This was most often presented as a goal in the context of a discussion of compliance with environmental laws and regulations, and/or in the context of a discussion about efficiency and maintaining cost competitiveness.

Concerns With Current Pharmaceutical Waste Management

The most common concern expressed by interviewees is that pharmaceutical waste management requirements and policies are too complicated and/or the requirements too confusing, resulting in significant difficulties in designing programs and in training staff.

Concerns with the underlying rules and regulations

1. Some pharmaceuticals that are unused and unexpired end up in the waste stream unnecessarily, for example, partially used blister packs that are no longer needed by a patient.
2. The state-only waste system captures too many pharmaceuticals as dangerous waste.
    a. Epi-salts, OPA disinfectant, nicotine, Barium, and aerosol cans were identified as particular concerns.
    b. There does not seem to be scientific or environmental health data behind some of the pharmaceutical waste listings / designations.
    c. Materials that were administered to patients in the morning therapeutically, can become waste and require disposal at a hazardous waste facility in the afternoon.
    d. State-only waste requirements might be appropriate for large-volume industrial wastes but are not necessary for the smaller volumes generated by health care facilities.
3. The dangerous waste regulations are written for industrial generators and are very difficult to navigate / understand / apply in a health care setting.
    a. Technical language is not intuitive and difficult for health care facilities to "see" themselves in.

b. Cross referencing and switching back and forth between sections of the regulations is difficult to follow and obscures requirements.

4. On the one hand, segregation of waste pharmaceuticals into multiple categories is difficult in a health-care setting.
    a. Health care providers are not focused on disposal of waste beyond getting the sharps in the sharps container; pharmaceutical waste management is not a focus in nursing training; it is difficult to get patient-care staff focused on this issue.
    b. Even when there is interest, implementing multiple management regimes depending on the waste types (RCRA hazardous, state-only dangerous, duel, medical only, e.g.) is difficult and can be cumbersome to implement in the context of patient care.
    c. Despite training, mistakes happen.
    d. Access to multiple containers can present practical challenges - e.g. there may not be space in patient rooms for multiple containers.
    e. Segregation programs are time consuming and very expensive.
5. On the other hand, single stream programs over-capture / over manage waste pharmaceuticals and are a costly burden.
6. Management of sharps presents particular concerns; there are practical difficulties associated with safety.
    a. In some cases a sharp contains a partial dose of pharmaceutical; management options in this case are limited and partial doses may end up being sent to the wastewater treatment system.
    b. It is not considered viable to recap open sharps or to move them significant distance (e.g., down the hall) from patient rooms because of concerns for worker health and safety.
    c. Management of glass ampoules can present similar difficulties as management of sharps when they become broken and potentially cross-contaminated with body fluids. If ampoules are empty they can go into sharps container unless they are P-listed. If there is a concern / mistake, do not want people sorting through sharps containers looking for ampoules.
7. Protecting waste pharmaceuticals from falling into the wrong hands also is a concern.
8. All elements of training are a challenge.
    a. Distilling complex requirements to a manageable set of protocols.
    b. Anticipating waste pharmaceutical types and providing relevant profiles and training.
    c. Keeping profiles and training up-to-date.
    d. Generating staff (and management) interest and support for training. Encouraging attention to pharmaceutical waste management generally and training in particular.
    e. Maintaining training / competency in the face of staff turnover.
    f. Ensuring consistent adherence to what may be different protocols at different facilities when nurses and providers travel among facilities or rotate among programs/specialties.
    g. Training on labeling and manifesting requirements also mentioned as difficult.
9. Multiple sets of requirements apply to pharmaceuticals – DEA, Labor and Industry, Board of Pharmacy, and hazardous/dangerous waste. Sometimes these regulations seem at cross-purposes or even to be conflicting. DEA and hazardous waste regulations in particular were cited as difficult to harmonize.

10. It can be difficult for generators to determine which materials can be appropriately managed through disposal in the sink, and different sewer districts have different requirements. Wastewater treatment providers, in general, are very focused on keeping all waste pharmaceuticals out of the liquid waste stream.
    a. Information on how well pharmaceuticals are treated by conventional, and even advanced, waste water treatment technologies is incomplete.
11. It is not feasible for waste handlers / transporters to independently verify generator assertions about waste types and characterization in general and particularly in the context of sharps or other bio-hazard waste. When mistakes are made by generators (e.g., waste ending up in the wrong container) the enforcement actions are too often directed at waste handlers.
    a. Waste handlers felt like they bear too much of the "risk" of generator mistakes, leaving generators with little incentive for compliance since they have little risk of enforcement action.
    b. Generators felt like waste handlers should have more responsibility, particularly around proper labeling and manifesting.

Concerns with Implementation of the Regulations

1. It is left to health care facilities to determine how best to design programs that comply with complex requirements; with multiple and sometimes seemingly conflicting options for "compliant" programs, this can be very difficult to sort through especially at facilities which lack dedicated or experienced pharmaceutical waste management staff.
    a. Generators are placed in the position of relying on waste management service vendors for program design advice and training and sometimes receive conflicting advice.
    b. Generators expect to be able to rely on vendors to ensure that provided containers are properly labeled and manifests and other paperwork properly completed and filed; when this does not happen, generators are subject to enforcement for what they see as "vendor mistakes."
2. On the other hand, waste management service vendors are left to rely on generators to have proper waste profiles and training in place so wastes are identified accurately and placed in appropriate containers for proper handing. When this doesn't happen, vendors are subject to enforcement for what they see as "generator mistakes."
3. Other waste pharmaceutical generators are not receiving the same scrutiny as hospitals.
    a. Dentists, veterinary clinics/facilities, and long-term and skilled nursing facilities were mentioned.
4. Inspections can seem "nit-picky" and not focused on environmentally significant issues. For example, focused on labeling or manifest-related "paperwork" violations.
    a. Expecting 100% compliance with complex waste segregation requirements is not realistic in a health care setting and not warranted given the small volumes of waste generated.
5. Tone and, in some cases, content of inspections can be different across inspectors or between regional offices.
6. Delay in receiving repots after inspections; this is challenging because if concerns are noted in the report, they often are so far back in time it can be difficult to track the details or find the staff who

may have been involved. Also, it can be difficult for upper management to experience concerns as important if there is significant time between the actual inspection and the concerns being brought to a facility's attention.

Potential Solutions / Improvements to Pharmaceutical Waste Management

1. Reduce the amount of pharmaceutical waste that is captured by the state-only system.
2. Provide additional management / disposal options for state-only wastes
    a. Address appropriate do-disposal with biological waste
    b. Allow alternative disposal / treatment technologies, e.g., gasification, other?
    c. Allow small quantity generators to bring wastes to household HW events and household/ SQG collection at regular landfills.
3. Create more user friendly rules or guidance so generators can easily understand what is expected of them.
    a. A special section of the dangerous waste rules describing what is needed for pharmaceutical waste management
    b. Codify the interim enforcement policy and other important policies in plain language
    c. More intuitive, user friendly rules and guidance, oriented to a heath care setting
4. Create guidance that more clearly describes potential programs / paths to compliance, oriented to a health care setting, and in plain, user-friendly language, and provide workshops and training for health-care workers.
    a. Make clear the respective responsibilities of waste vendors and generators
    b. Compile and share information on best practices and examples of successful programs
    c. Provide model policies and materials, around program requirements, but also around effective staff outreach and training
    d. Create a dedicated, easy-to navigate, web portal for waste pharmaceutical information
5. Clarify appropriate management practices for partial / residual doses that remain in syringes. Options that prevent these materials from being disposed to sinks/drains are of particular interest.
6. Clarifying appropriate disposal practices for controlled substances that also designate as state-only dangerous waste.
    a. Partial / residual doses in syringes are particular changes.
    b. Clarifying options that keep these materials from being disposed to sinks/drains is of interest.
7. Provide easy-to-use guidance for characterization of waste pharmaceuticals, in particular, for distinguishing between Federally-hazardous and state-only DW, and between state-only toxicity and other state-only codes.
    a. Lists of pharmaceuticals / formulations that commonly designate as Federal or state-only waste would be very helpful.
8. Emphasize additional inspections, assistance, and, where needed, enforcement at waste generators to ensure better attention to requirements and compliance.
    a. Need attention by health care administers to ensure adequate funding / oversight of programs.

    b. Provide generators with inspection reports / follow up much more quickly after the inspection event.
    c. Ensure generators have a written record of technical assistance provided so they have something to refer back to.
9. Ensure / incentivize pharmacies to partial fill prescriptions to ensure that there is not too much medication out in the community potentially subject to wastage.
    a. Particularly for controlled substances.
10. Allow for un-used, un-expired prescriptions that can no longer be used by the patient to be returned to the pharmacy and re-prescribed / re-used.
    a. Particularly for medication that is issued in blister packs.
11. Ensure reliable, implementable solutions for waste pharmaceuticals from householders.
    a. Clarification of requirements applicable to pharmacy "take back" programs is needed and incentives for these programs.
    b. Provide incentives for take back programs, for example, allowances for less than 100% compliance for pharmaceutical wastes generated in clinics / health care portions of facility
12. Encourage more use of the reverse distribution system.
13. Establish / expand extended producer responsibility for pharmaceuticals, so manufacturers have more responsibility for management throughout the material's lifecycle.
14. Track developments in the EPA pharmaceutical waste rulemaking process to ensure state efforts are consistent / complementary.

Attachment 4: Potential Solutions Considered by the Work Group, with Ecology's Initial Reactions

DEPARTMENT OF ECOLOGY PHARMACEUTICAL WASTE WORK GROUP

Revised Draft Potential Solutions and Ecology Initial Reactions

Potential solutions are drawn from interviews and from the first Work Group meeting. This is a preliminary list, and additions and clarifications can be made based on Work Group input.

The column for "Needs RCW change" means new Legislation would be necessary to implement the change. The Legislature also, of course, has the discretion to direct things that can be implemented by regulation or policy. The column "Needs WAC change" reflects that some of the solutions suggested by Work Group members either would need a change to the Dangerous Waste regulations, or are already allowed under the current system, but perhaps are blocked by another agency or jurisdiction. Suggestions that demonstrate the current regulatory system or requirement is simply not well understood or broadly implemented are noted under the "Notes" column.

Overall Ecology comment:
Many of the solutions presented by the stakeholders have some overlap and almost all would require additional Ecology staff time to complete. Ecology will develop these costs further for the final report, but funding will undoubtedly be an issue that will need to be addressed by the Legislature. Most of the suggestions are also things that can't be done immediately, but will require time to consider, develop, and implement.

When taken as a whole, it seems that what stakeholders are really requesting is for Ecology to help them develop, implement, and maintain efficient waste management systems that are in compliance with the applicable regulations—something Ecology would call "compliance assistance." Ecology sees this as indicative of a larger problem that comes from how RCRA and the state's Dangerous Waste regulations were originally written almost 40 years ago: the regulations are "self-implementing" and never contained a compliance assistance component. Ecology's responsibility has been to verify that regulated businesses are complying with the law, not to teach or train them in the rules or how to be in compliance. Over the years, the agency has attempted to provide some stopgap technical assistance measures to help businesses (e.g., guidance documents, workshops, toxics reduction technical assistance visits, etc.), but has never had the resources to fully develop a compliance assistance program for businesses to help them learn and understand the rules and how to comply.

Ecology sees compliance assistance as the next logical step in helping generators understand how to be in compliance, which will help protect Washington's environment. Ecology agrees with stakeholders that compliance assistance to learn how to be in compliance without fear of enforcement is a key solution. If this is the solution that stakeholders want, Ecology would support efforts to make it a reality. We have noted below which of the suggestions we believe could be addressed through the development of a compliance assistance program. If a compliance assistance program were to have a pilot project phase, Ecology believes healthcare facilities and other businesses involved with pharmaceutical waste would be a good choice for the first sector.

Potential Solutions to Reduce Amount of Pharmaceutical Waste Regulated

	Work Group Solution	Who would implement	Needs RCW change	Needs WAC change	Needs Policy change	Notes
1	Using the existing petition process at 173-303-910(4), or another existing petition process under -910, to review state-only waste pharmaceuticals captured and determine if exemptions are warranted.	Regulated facilities initiate; Ecology reviews and approves		Yes, if petition successful		No statute change needed as the process already exists in the Dangerous Waste regulations.
	Ecology initial reaction: *This option already exists in state regulation; no legal change is necessary to create the petition process. The regulations require the regulated facility provide documentation as referenced in WAC 173-303-072(6). If the petition to exclude a waste is approved, Ecology would need to do rulemaking to adopt the new exclusion.* ***Workload/fiscal impact:*** *Each petition would be a moderate fiscal impact and increased workload to Ecology, but specific estimates have not been calculated. Rulemaking could probably be included with into other (already planned and budgeted) rulemaking activities.*					
2	Establish a new petition process for exclusion, or conditional exclusion, of state-only waste pharmaceuticals.[1]	Maybe Legislature; Ecology	Possible	Possible		Existing statutes might already address this suggestion.
	Ecology initial reaction: *The current petition process in WAC 173-303-910(4) likely addresses this solution. The current pharmaceutical exclusion in WAC 173-303-071(3)(nn) already excludes state-only controlled substances, legend drugs and over the counter drugs allowing them to be burned in a specific unit. This exclusion could be amended to allow other disposal options, but rulemaking would be needed. However, if there are situations that WAC 173-303-910 wouldn't address, then Ecology would need to rethink this option and a statute change might be needed.* ***Workload/fiscal impact:*** *Possible new Ecology workload for petition review. Rulemaking could probably be rolled into other (already planned and budgeted) rulemaking activities over the next two years or so, so might not be additional work for this rulemaking.*					

[1] If Federal wastes are to be excluded EPA must also be petitioned and must take independent action.

	Work Group Solution	Who would implement	Needs RCW change	Needs WAC change	Needs Policy change	Notes
3	Establish a new conditional exclusion for state-only waste pharmaceuticals that are managed in accordance with DEA requirements.	Ecology		Yes		EPA's new rule addresses this suggestion.
	Ecology initial reaction: *The current exclusion in WAC 173-303-071(3)(nn) would need to be amended if stakeholders wish to broaden the current wastes and/or disposal methods to mimic DEA. It appears the new EPA pharmaceutical rule provides a conditional exclusion for RCRA wastes; Ecology could adopt the same process for state-only pharmaceutical wastes as well.* ***Workload/fiscal impact:*** *Slight workload impact to develop new conditional exclusion. Rulemaking could probably be rolled into other (already planned and budgeted) rulemaking activities. As with other rulemaking, this would likely take about two years to accomplish.*					
4	Encourage or incentivize partial filling of prescriptions when there is a high risk that a patient might not use the full amount, to minimize the amount of pharmaceuticals circulating. This is particularly an issue for controlled substances.	Healthcare providers & regulators		Maybe, but not Ecology's regulations	Possible Ecology guidance revision	No barrier under existing Dangerous Waste regulations. This could be addressed as part of a compliance assistance program.
	Ecology initial reaction: *Ecology supports this solution and could help encourage by incorporating this suggestion into a compliance assistance program. Ecology could coordinate with the Department of Health and the Pharmacy Commission, who are probably better suited to handle this recommendation. "Incentivizing" activities may not be possible, as it potentially runs afoul of the Washington State Constitution. Subject could be included as part of a compliance assistance program.* ***Workload/fiscal impact:*** *Possible new Ecology workload for guidance revision. No Ecology rulemaking anticipated.*					

	Work Group Solution	Who would implement	Needs RCW change	Needs WAC change	Needs Policy change	Notes
5	Encourage or incentivize appropriate use of the reverse distribution system.	Healthcare providers & regulators; possibly Legislative action also	Maybe, but not Ecology's laws	Maybe, but not Ecology's regulations	Possible Ecology guidance revision	Private sector solutions may already exist. This could be addressed as part of a compliance assistance program.
	Ecology initial reaction: *Ecology supports this solution and could help encourage by incorporating this suggestion into a compliance assistance program. Ecology currently encourages reverse distributors to take back "viable" drugs for credit and eventual disposal as allowed in the Interim Enforcement Policy (IEP). Ecology could conduct dangerous waste inspections at reverse distributors in Washington State to ensure only "viable" drugs are taken back for reuse or disposal if no second-life of the drug is found. Ecology will be evaluating how EPA's new pharmaceutical rule manages the reverse distribution system. If stakeholders have additional suggestions about other methods to "encourage" use of reverse distributors, Ecology would be interested in learning what those are. "Incentivizing" may not be possible as it potentially runs afoul of the Washington State Constitution. Subject could be included as part of a compliance assistance program.* ***Workload/fiscal impact:*** *Possible new Ecology workload for guidance revision. Additional inspections at reverse distributors will also be new workload. No additional Ecology rulemaking anticipated (other than possible adoption of EPA's rule).*					
6	Encourage un-opened, un-used, un-expired prescriptions that can no longer be used by the patient to be returned to the pharmacy and re-prescribed / re-used. This is particularly appropriate for medications that are issued in blister packs. (SB 5148 2013-14 allows this.)	Healthcare providers / regulators; possibly Legislature	Maybe, but not Ecology's laws	Maybe, but not Ecology's regulations	Possible Ecology guidance revision	Per Pharmacy Commission: Allowed in certain long-term care settings, but not appropriate for general population. This could be addressed as part of a compliance assistance program.

	Work Group Solution	Who would implement	Needs RCW change	Needs WAC change	Needs Policy change	Notes
	Ecology initial reaction: *This was adopted into law in 2013 and is codified at RCW 69.70. Ecology could help encourage this activity by incorporating this suggestion into a compliance assistance program. Other solutions for encouraging re-use may exist in the private sector.* ***Workload/fiscal impact:*** *Changes to existing Ecology guidance documentation should incur a fairly small fiscal impact. No additional Ecology rulemaking anticipated (other than possible adoption of EPA's rule).*					
7	Require pharmaceutical manufacturers, wholesalers, and/or distributors to take-back expired or almost expired samples.	Legislature; could be implemented by individual healthcare providers	Yes, but probably not Ecology's laws	Maybe, but maybe not Ecology's regulations	Possible Ecology guidance revision	Private sector solutions may exist. This could be addressed as part of a compliance assistance program.
	Ecology initial reaction: *Ecology supports this solution and anticipates a statutory change by the Legislature would be needed. Ecology could help encourage by incorporating this suggestion into a compliance assistance program.* ***Workload/fiscal impact:*** *Possible new workload for guidance revisions. No additional Ecology rulemaking anticipated.*					
8	Establish extended producer responsibility for pharmaceuticals, so manufacturers have more responsibility for management of medications throughout the material's lifecycle.	Legislature; coordinate with the Governor's Office	Yes, but maybe not Ecology's laws	Yes, but maybe not Ecology's regulations	Possible Ecology guidance revision	Private sector solutions may exist.
	Ecology initial reaction: *Ecology supports this solution and anticipates a statutory change by the Legislature would be needed.* ***Workload/fiscal impact:*** *This suggestion would potentially have a high fiscal impact, depending on who has to do the work (private sector vs. state employees). At the very least, there would be a fiscal impact for the new workload to update existing Ecology guidance documents to account for changes. Ecology rulemaking might or might not be required.*					

	Work Group Solution	Who would implement	Needs RCW change	Needs WAC change	Needs Policy change	Notes
9	Entirely exempt / exclude pharmaceutical wastes generated in healthcare setting from the dangerous waste regulations and invest instead in treatment of wastewater / sewage, which is unavoidably contaminated with patient's excretion of metabolized and unchanged medications.	EPA; Legislature	Yes, for Washington State-only wastes only	Yes, for Washington State-only wastes only	Yes	Not allowed under RCRA regulations; moved to second list. Would result in reduced attention to healthcare industry.
	Ecology initial reaction: *Ecology would strongly support efforts to address pharmaceuticals in wastewater, but would not support a blanket exemption of pharmaceutical wastes from regulation. These chemicals pose a significant threat to our environment, regardless of whether they are coming from sewer effluent, leaking landfills, or improper disposal. Wastewater treatment facilities are simply not built to handle these chemicals and would need significant, costly upgrades. It is cheaper to prevent pollution than to clean it up after the fact. The state's fishing, shellfish, and agriculture industries could all be harmed by pharmaceutical contamination, which we believe would be the result if more pharmaceutical wastes were simply disposed of in the regular trash. Washington State does not have the authority to exempt pharmaceutical wastes from RCRA regulations even with Legislative action (EPA would simply enforce those regulations directly instead of Ecology being the responsible agency).* ***Workload/fiscal impact:*** *Ecology's workload would actually decrease, as EPA would need to take the lead for inspections and enforcement. However, there wouldn't be any notable fiscal gain, as existing resources would be reassigned to other priorities.*					
10	Track developments in the EPA pharmaceutical waste rulemaking process to ensure state efforts are consistent / complementary	Ecology; maybe Legislature	Possible	Probable	Probable	Ecology already starting to implement.
	Ecology's initial reaction: *Ecology supports this solution and is looking for input from stakeholders as to whether Ecology should adopt this new rule in total, including whether we should adopt it for state-only wastes.* ***Workload/fiscal impact:*** *As with all other federal rules the state adopts, this would be a normal rulemaking process and not a new, separate workload or fiscal impact.*					

	Work Group Solution	Who would implement	Needs RCW change	Needs WAC change	Needs Policy change	Notes
11	Ensure reliable, implementable solutions for waste pharmaceuticals from households. Clarify requirements applicable to pharmacy "take back" programs and provide incentives and funding for these programs.	Legislature; possibly local health departments and private sector	Yes, but maybe not Ecology laws	Yes, but maybe not Ecology's regulations	Probable	Private sector could do. Pharmaceuticals from households are exempt from the dangerous waste regulations and are not the subject of this work group. However, a number of work group members emphasized the importance of this point, so it is included for completeness.
	Ecology's initial reaction: *Ecology is not opposed to this solution and would likely be supportive of a statewide take-back program, but we don't have any authority to make that happen. A manufacturer-supported take-back program would be consistent with previous product stewardship efforts sponsored or supported by Ecology. A program of that type would have to be adopted by the Legislature.* ***Workload/fiscal impact:*** *The fiscal impact would depend on the specifics of the program, but could be fairly high (thought maybe not to Ecology).*					

Potential Solutions to Reduce the Stringency of Requirements for Regulated Pharmaceutical Waste

	Work Group Solution	Who would implement	Needs RCW change	Needs WAC change	Needs Policy change	Notes
12	Provide additional disposal options for waste pharmaceuticals by modifying the existing conditional exclusion at WAC 173-303-071(3)(nn) to allow state-only waste pharmaceuticals to go to RCRA landfills or to non-RCRA facilities that can safely treat the waste so it no longer designates (e.g., saline disposed of to a POTW, alcohol based drugs flammability removed).	Ecology	Probably not	Yes		EPA's new rule may address at least part of this suggestion.
	Ecology initial reaction: *Ecology supports this solution and rulemaking would be needed. Typical rulemaking process would take approximately two years.* ***Workload/fiscal impact:*** *Slight workload impact to modify conditional exclusion. Rulemaking could probably be rolled into other (already planned and budgeted) rulemaking activities. As with other rulemaking, this would likely take about two years to accomplish.*					
13	Update the Interim Enforcement policy to allow all pharmaceutical wastes managed under the IEP to go to any approved hazardous waste facility that will accept them (e.g., including RCRA landfills), not just a RCRA incinerator. Other suggestions?	Ecology			Yes and would require publication in the State Register	This could be addressed as part of a compliance assistance program.
	Ecology initial reaction: *Ecology supports this solution and the IEP would need to be updated and republished in the State Register. Ecology is not sure there are many additional facilities that will accept these waste streams other than incinerators; capacity would need to be researched. If stakeholders have additional specific suggestions, Ecology would need to ensure that any alternative disposal method is still protective of the environment.* ***Workload/fiscal impact:*** *Slight workload impact to update the IEP and meet necessary administrative responsibilities.*					

	Work Group Solution	Who would implement	Needs RCW change	Needs WAC change	Needs Policy change	Notes
14	Provide other additional disposal and/or treatment options for waste pharmaceuticals. Suggestions?	Ecology and others?	Depends on proposal	Depends on proposal	Depends on proposal	This could be addressed as part of a compliance assistance program.
	Ecology initial reaction: *Ecology is open to considering all other disposal and/or treatment options for waste pharmaceuticals, however actions cannot jeopardize Ecology's authorization by EPA or violate state law without appropriate Legislative changes. This topic could be included as part of a compliance assistance program.* ***Workload/fiscal impact:*** *Would depend on the exact nature of the proposal.*					
15	Work with local health departments to remove barriers to disposal of small quantity generator (SQG) waste at household HW events and municipal landfills.	Ecology and counties and local health departments	Maybe	Yes	Maybe	Unsure whether there is a path forward on this proposal.
	Ecology initial reaction: *Not all counties have an MRW facility and due to costs and liability concerns, only one county is taking waste pharmaceuticals from households that we are aware of. A Legislative change would be needed to implement this solution.* ***Workload/fiscal impact:*** *Probably very small.*					

Potential Solutions to Provide Additional Support to Generators

	Work Group Solution	Who would implement	Needs RCW change	Needs WAC change	Needs Policy change	Notes
16	Create a separate / special portion of the DW regulations focused on pharmaceutical waste, so all the requirements are in one place and generators can easily see what is expected. Use more intuitive, user friendly language, oriented to a heath care setting.	Ecology	Maybe	Yes	Yes	EPA's new rules would accomplish this if adopted for all Washington wastes.
	Ecology initial reaction: *Ecology is not opposed to this solution, but implementation would be expensive. Due to extensive rulemaking being needed, this would not be a quick fix. However, Ecology expects the new EPA proposal is basically a scaled-back variation of this suggestion, with a new "pharma only" section of rules.* ***Workload/fiscal impact:*** *Significant new workload to develop new rules.*					
17	Codify the interim enforcement policy, and other important guidance such as the treatment by generator guidance, in clear, plain regulatory language.	Ecology		Not possible as written; could only apply to state-only wastes.	Yes	Not allowed under RCRA regulations; moved to second list. This could be addressed as part of a compliance assistance program.

	Work Group Solution	Who would implement	Needs RCW change	Needs WAC change	Needs Policy change	Notes
	Ecology initial reaction: *Interim Enforcement Policies (IEPs) have traditionally been used as a regulatory pathway to allow generators to manage waste with less administrative burden as long as the treatment, storage, or disposal options are environmentally protective. Ecology developed the current IEP because EPA was several years out from finalizing new pharmaceutical rules. It does not make fiscal sense at this time for Ecology to codify the current IEP since EPA is now finished developing the pharmaceutical waste rules. Ecology will be evaluating the new EPA rules and making a recommendation on whether to adopt all or parts of the new rule. Once this adoption process is done, the IEP will likely be rescinded. Moreover, given that some stakeholders have expressed confusion with the IEP, codification may not be the best way to address this issue even if Ecology decides to not adopt the new EPA rules to apply to state-only wastes. Ecology thinks this could be included in a compliance assistance program.* ***Workload/fiscal impact:*** *Rulemaking would be included with into other (already planned and budgeted) rulemaking activities.*					
18	Create guidance that more clearly describes potential programs / paths to compliance, oriented to a health care setting, and in plain, user-friendly language, and provide workshops and training for health-care workers.	Ecology			Ecology guidance revision	Private sector solutions exist, including Practice Greenhealth. This could be addressed as part of a compliance assistance program.
	Ecology's initial reaction: *Ecology is not opposed to this solution. However, implementation would be expensive and Ecology would need additional funding and resources to create effective guidance, programs, videos for training, and resources to hold training workshops on a regular basis to train new health care workers that move in and out of the sector. Ecology's responsibility to date has been to verify that regulated businesses are complying with the law, not to teach or train them in the rules or how to be in compliance. This would be precedent-setting for Ecology to spend a disproportional amount of funds on just one sector creating new training and guidance. This could better be addressed as part of a compliance assistance program.* ***Workload/fiscal impact:*** *Significant new workload to revise existing guidance and create new guidance as needed.*					

	Work Group Solution	Who would implement	Needs RCW change	Needs WAC change	Needs Policy change	Notes
19	Clarify the respective responsibilities of waste management vendors and waste generators to address issues such as waste handling, nonconforming waste management and reporting, and wastewater management at processing facilities.	Ecology		Possible	Ecology guidance revision	This could be addressed as part of a compliance assistance program.
	Ecology's initial reaction: *This seems to be a component of a compliance assistance program.* ***Workload/fiscal impact:*** *Revising all Ecology guidance for pharmaceutical wastes and healthcare facilities would be a significant new workload that is currently not in Ecology's budget.*					
20	Compile and share information on best practices and examples of successful pharmaceutical waste management programs. Provide model programs and materials for program elements and effective staff outreach and training.	Ecology could coordinate, but not able to lead			New Ecology guidance	Private sector solutions may exist; would need to rely on EPA for info portal. New EPA rule addresses this suggestion. This could be addressed as part of a compliance assistance program.

	Work Group Solution	Who would implement	Needs RCW change	Needs WAC change	Needs Policy change	Notes
	Ecology's initial reaction: *Ecology is not opposed to this solution. However, implementation would be expensive and Ecology would need additional funding and resources to create effective guidance, programs, videos for training, and resources to hold training workshops on a regular basis to train new health care workers that move in and out of the sector. Ecology's responsibility to date has been to verify that regulated businesses are complying with the law, not to teach or train them in the rules or how to be in compliance. This would be precedent-setting for Ecology to spend a disproportional amount of funds on just one sector creating new training and guidance. Additionally, some of this solution may already be built in EPA's new pharmaceutical Wiki website, which means Ecology would not need to find funding to implement this part of the solution. Practice Greenhealth has a significant number of resource materials, including a model program that could be used as the basis for an industry-created statewide model program. Ecology believes it might be more successful to address these suggestions through a larger compliance assistance program.* ***Workload/fiscal impact:*** *This would be a significant workload for Ecology to adopt unilaterally. We would likely be unable to do so. Instead, we would rely on EPA's new web portal to provide the information at little to no cost to the state. Developing new guidance, updating and revising guidance, and working with the private sector to assist them in developing a model program would all be an additional workload to Ecology better addressed through a compliance assistance program. We would anticipate a moderate fiscal impact for this portion of the workload.*					
21	Create a dedicated, easy-to navigate, web portal for waste pharmaceutical information.	Ecology could coordinate, but EPA lead			Not possible – would rely on EPA instead.	New EPA rule addresses this suggestion.
	Ecology's initial reaction: *Ecology is not opposed to this solution however implementation would be expensive and Ecology would need additional funding and resources to create a new web portal. Some of this solution may already be built in EPA's new pharmaceutical Wiki website; modification to or supplementation of EPA's Wiki would be a more cost effective solution. It is probably not feasible for Ecology to develop its own web portal.* ***Workload/fiscal impact:*** *If Ecology relies on EPA's web portal, small workload and fiscal impact to update guidance accordingly.*					

	Work Group Solution	Who would implement	Needs RCW change	Needs WAC change	Needs Policy change	Notes
22	Provide easy-to-use guidance for characterization of waste pharmaceuticals, in particular, for distinguishing between Federally-hazardous and state-only DW, and between state-only toxicity and other state-only codes.	Ecology could coordinate, but EPA lead			Ecology guidance revision	New EPA rule addresses this suggestion. This could be addressed as part of a compliance assistance program.
	Ecology's initial reaction: *Ecology is not opposed to this solution, but we are not sure we could characterize all pharmaceuticals. Ecology could not legally possess the necessary prescription drugs or wastes for testing, but we could "book designate" many drugs based on information readily available to patients and healthcare providers. Ecology would need additional funding and resources to implement this solution. Support from the healthcare industry and waste management companies is vital on this issue as they are the stakeholders with the necessary information. This solution would probably be more effective as part of a larger compliance assistance program.* ***Workload/fiscal impact:*** *If Ecology relies on EPA's web portal, small workload and fiscal impact to update guidance accordingly.*					
23	Provide easily accessible, frequently updated lists of pharmaceuticals / formulations that commonly designate as Federal or state-only waste.	Ecology could coordinate, but EPA lead			Ecology guidance revision	New EPA rule addresses this suggestion. This could be addressed as part of a compliance assistance program.

	Work Group Solution	Who would implement	Needs RCW change	Needs WAC change	Needs Policy change	Notes
	Ecology's initial reaction: *Ecology is not opposed to this solution, but we are not sure we could characterize all pharmaceuticals. Ecology could not legally possess the necessary prescription drugs or wastes for testing, but we could "book designate" many drugs based on information readily available to patients and healthcare providers. Ecology would need additional funding and resources to implement this solution. Support from the healthcare industry is vital on this issue. As mentioned above, Ecology thinks it may be more effective and financially feasible to instead rely on EPA's new pharmaceutical Wiki website instead of developing a new system. This solution would probably be more effective as part of a larger compliance assistance program.* ***Workload/fiscal impact:*** *If Ecology relies on EPA's web portal, small workload and fiscal impact to update guidance accordingly.*					
24	Provide an easy-to use directory of what types of waste pharmaceuticals can be disposed to the sewer in each sewer district.	Ecology or sewer districts			New Ecology guidance	New EPA rule addresses this suggestion. This could be addressed as part of a compliance assistance program.
	Ecology's initial reaction: *EPA's new pharmaceutical rule prohibits disposal of all regulated wastes to sewers, so no RCRA wastes may be disposed of in this manner. The preamble to the new EPA rule also says that EPA is now recommending that no pharmaceuticals of any kind be disposed of to the sewer at all, even if it is legal to do so. If Ecology decides to adopt EPA's new rule for state-only wastes, then state-only wastes would also be prohibited from being disposed of to the sewer. Ecology would need to work with local jurisdictions and sewer districts to develop a list like this if it were needed. Ecology believes that issues and questions such as this one would be best handled as part of a larger overall compliance assistance program.* ***Workload/fiscal impact:*** *Small new Ecology workload and fiscal impact to assemble and maintain information and update guidance.*					

	Work Group Solution	Who would implement	Needs RCW change	Needs WAC change	Needs Policy change	Notes
25	Provide waste designation / management information on the pharmacy label for pharmaceuticals used in hospitals and clinics, e.g., through color coding or other means.	Private sector			Ecology guidance revision, if statewide program adopted	No barrier under the dangerous waste regulations, but not likely an Ecology action. Falls to healthcare facilities and regulators. This could be addressed as part of a compliance assistance program.
	Ecology's initial reaction: *There isn't much Ecology can do as far as day-to-day operations go under Ecology's current structure. We view this as something healthcare facilities would need to implement on their own. This suggestion is a good example of something that a larger compliance assistance program could incorporate into guidance materials.* ***Workload/fiscal impact:*** *None if private sector handles on their own. Moderate workload and fiscal impact to assist in development of model program and guidance revision if Ecology participates in the process. Workload could be absorbed into larger compliance assistance program.*					
26	**ECOLOGY PROPOSAL:** Create a true "Compliance Assistance" program, using L&I's DOSH Safety and Health Consultation Program and Ecology's Local Source Control Program as models.	Ecology			Yes	As explained in more detail on page 1 of this document.

	Work Group Solution	Who would implement	Needs RCW change	Needs WAC change	Needs Policy change	Notes
	Ecology's reasons for proposing this solution: *When taken as a whole, the stakeholders' comments and proposed solutions seem to indicate there is a need for compliance assistance that Ecology simply is unable to provide with existing resources and the way RCRA and the Dangerous Waste programs were developed. This sort of assistance program would be welcomed by Ecology and we think the agency could handle this program given sufficient resources. This sort of program could prepare up-to-date guidance documents, consult one-on-one with healthcare facilities, and provide direct compliance assistance to regulated facilities without risk of an enforcement action.* ***Workload/fiscal impact:*** *The new workload and fiscal impact would both be significant. To create a pilot Compliance Assistance Program focused on the healthcare industry (perhaps including all businesses that have some role in handling pharmaceutical wastes), would likely require 3 FTEs and cost approximately $500,000 per year. Although this approach could be implemented much more quickly than rulemaking could occur, there is no funding in Ecology's existing budget to implement this solution. Ecology would either need to wait for the next budget cycle and request funding from the Legislature or would need to secure outside funding such as grants to fund the program. Even if Ecology requests new funding for a program like this, there is no guarantee that the Legislature would support or fund our request.*					

Potential Solutions to Improve Program Implementation

	Work Group Solution	Who would implement	Needs RCW change	Needs WAC change	Needs Policy change	Notes
27	Emphasize additional inspections, assistance, and, where needed, enforcement at waste generators to ensure better attention to requirements and compliance. Support attention by health care administers to ensure adequate funding / oversight of programs.	Ecology for inspections; Legislature for funding			Possible revision of inspection scheduling criteria; development of new sector focus	Other than additional inspections, this could be addressed as part of a compliance assistance program.

	Work Group Solution	Who would implement	Needs RCW change	Needs WAC change	Needs Policy change	Notes
	Ecology's initial reaction: *Ecology supports this solution, but additional funding and resources would be needed. Additionally, representatives from each part of the industry have expressed the belief that their portion of the industry receives more than their fair share of inspections and attention from Ecology. Inspections are determined by a number of factors, including complaints, the last time a site was inspected, the number if OFM required inspections, the number of EPA required inspections, the number of staff available to do inspections, any enforcement-related actions, and any required sector focus based outreach or sweeps. Ecology has already increased inspections at a variety of healthcare facilities due to the existing sector focus. This suggested solution is a good example of what a compliance assistance program could address.* ***Workload/fiscal impact:*** *Depending on the scope, the fiscal impact of this suggestion could be significant.*					
28	Provide generators with inspection reports / follow up much more quickly after the inspection event.	Ecology			Yes	Ecology already considering steps to implement.
	Ecology's initial reaction: *Ecology supports this solution and agrees this is very important. Ecology strives to provide each generator a copy of the inspection report in a timely manner, preferably within 30 days. Ecology will look into ways to decrease the time after a healthcare inspection for follow up, including procedural changes and additional inspector training and mentoring.* ***Workload/fiscal impact:*** *The fiscal impact of this suggestion could be fairly small to moderate.*					
29	Ensure generators have a written record when technical assistance is provided during site visits / meetings so they have something to refer to.	Ecology			Yes, and possible development of new forms	This could be addressed as part of a compliance assistance program.

	Work Group Solution	Who would implement	Needs RCW change	Needs WAC change	Needs Policy change	Notes
	Ecology's initial reaction: *Ecology agrees this is very important and always provides follow-up written information after a technical assistance visit. Often inspectors and technical assistance officers need to conduct research on regulatory interpretations and not all violations or possible problems could be noted at the end of a site visit. This type of information and assistance is exactly what a compliance assistance program could address.* ***Workload/fiscal impact:*** *Depending on what facilities are looking for, the workload and fiscal impact of this suggestion could be fairly small to moderate to change procedures, or could be large to develop additional materials for a compliance assistance program.*					
30	Provide allowances for less than 100% compliance for pharmaceutical wastes generated in clinics / health care portions of facility; for example, if a facility also has a pharmaceutical waste "take back" program allow for less than 100% compliance for pharmaceutical waste generated in the patient care setting.	Ecology		Not possible as written		Not allowed under RCRA regulations; moved to second list.
	Ecology's initial reaction: *Depending on what is really meant by this suggestion, Ecology doesn't think this is a viable suggestion we could implement. We interpret this suggestion to mean that if a facility has a take-back program that they could essentially earn a free pass despite not being in compliance. Ecology is sure that EPA would never approve that sort of arrangement as it applies to RCRA wastes, and we don't think that would be a very fair approach to facilities that don't or can't sponsor a take-back program. Ecology typically doesn't penalize facilities for first-time violations; agency policy is to work with generators through informal means to gain compliance before resorting to formal enforcement and penalties.* ***Workload/fiscal impact:*** *As we do not believe we could implement this change without jeopardizing our federal authorization, we don't anticipate a fiscal or workload impact.*					
31	Open Ecology's inspector training to pharmaceutical waste managers.	Ecology			Development of new / expanded training	This could be addressed as part of a compliance assistance program.

	Work Group Solution	Who would implement	Needs RCW change	Needs WAC change	Needs Policy change	Notes
	Ecology's initial reaction: *Ecology supports the concept behind this solution, however additional funding and resources would be needed to implement. New inspectors are trained and mentored in each region by senior staff. Ecology provides specific training on various topics on an "as-needed-basis" and the training is not specific to pharmaceutical wastes or the healthcare sector. There would a fiscal impact for training materials and extra staff time to coordinate offering a version of inspector training to healthcare facilities. Ecology would need adequate resources to make it happen (which do not exist in our current budget, and are unlikely to be added in the future without Legislative action). This is a subject that could be included in a larger overall compliance assistance program.* ***Workload/fiscal impact:*** *There would be a significant fiscal and workload impact from this suggestion, although much of that impact would be temporary. Costs and workload associated with on-going activities (such as regular training) would also be ongoing.*					
32	Consider options to increase Washington State-based incineration capacity for waste pharmaceuticals.	Ecology				New Ecology work load
	Ecology's initial reaction: *Ecology doesn't have the ability to unilaterally increase incineration capacity – we can't open our own incinerator or force out-of-state incinerators to process more waste. However, Ecology could investigate whether siting or locating a RCRA incinerator somewhere in the state would be possible.* ***Workload/fiscal impact:*** *The fiscal impact of this investigation could be moderate, depending on how much investigation is required.*					

Attachment 5: Synthesis of Work Group Survey

DEPARTMENT OF ECOLOGY PHARMACEUTICAL WASTE WORK GROUP

Survey Results and Discussion

Highly Supported Potential Solutions

These are solutions that are highly supported and do not have any "can't live with" comments. The assumption is that the Work Group will craft recommendations around each of these solutions. Numbers refer to the numbering on the revised potential solution set / survey.

8. Track developments in the EPA pharmaceutical waste rulemaking process to ensure state efforts are consistent / complementary. (10)
9. Align interpretation of waste codes to match federal (epi salts are excluded in RCRA but not in WA). (B)
10. Create a separate / special portion of the DW regulations focused on pharmaceutical waste, so all the requirements are in one place and generators can easily see what is expected. Use more intuitive, user friendly language, oriented to a heath care setting. (16)
11. Create guidance that more clearly describes potential programs / paths to compliance, oriented to a health care setting, and in plain, user-friendly language, and provide workshops and training for health-care workers. (18)
12. Clarify the respective responsibilities of waste management vendors and waste generators to address issues such as waste handling, nonconforming waste management and reporting, and wastewater management at processing facilities. (19)
13. Provide easy-to-use guidance for characterization of waste pharmaceuticals, in particular, for distinguishing between Federally-hazardous and state-only DW, and between state-only toxicity and other state-only codes. (22)
14. Provide easily accessible, frequently updated lists of pharmaceuticals / formulations that commonly designate as Federal or state-only waste. (23)
15. Open Ecology's inspector training to pharmaceutical waste managers. (31)

Other Potential Recommendations to Explore

These solution categories / themes had some strong support but also some concerns and "can't live with" comments. The Work Group might explore these potential solutions to see if they wish to craft a recommendation. If consensus is not reached around a recommendation, the range of workgroup perspectives will be presented in the Work Group report. Numbers refer to the numbering on the revised potential solution set / survey.

- Something around providing additional disposal options for hazardous waste pharmaceuticals for example through:
    - Allowing them to go to RCRA landfills or non-RCRA facilities that can safely treat then (12)
    - Working with local health departments to remove barriers to disposal of CESQG and SQG waste pharmaceuticals at household HW events and municipal landfills (15)
    - *Updating the interim enforcement policy to allow for disposal at any approved HW facility (including RCRA landfills) (13)
    - Providing additional disposal and/or treatment options for waste pharmaceuticals (14)
    - Consider options to increase Washington State-based incineration capacity for waste pharmaceuticals. (32)

  However some concerns around disposal in landfills (even RCRA landfills?). Interest in using existing (or new?) waste-to-energy capacity. Some interest in exploring creation of additional incineration capacity in Washington; also some "can't live withs" with respect to additional incineration capacity.

- Something around reducing the number of waste pharmaceuticals that are captured as state-only waste through, for example:
    - Establishing a new conditional exclusion for state-only waste pharmaceuticals that are managed in accordance with DEA requirements. (3)
    - Establish a new petition process for exclusion, or conditional exclusion, of state-only waste pharmaceuticals. (2)
    - Use the existing petition process at 173-303-910(4), or another existing petition process under -910, to review state-only waste pharmaceuticals captured and determine if exemptions are warranted. (1)

  However, also concerns that the petition process would be too cumbersome and that rulemaking would take too long.

- Something around pharmaceutical waste minimization for example through:
    - Require pharmaceutical manufacturers, wholesalers, and/or distributors to take-back expired or almost expired samples. (7)
    - Establish extended producer responsibility for pharmaceuticals, so manufacturers have more responsibility for management of medications throughout the material's lifecycle. (8)
    - Encourage or provide incentives for appropriate use of the reverse distribution system. (5)
    - Encourage or provide incentives for partial filling of prescriptions when there is a high risk that a patient might not use the full amount, to minimize the amount of pharmaceuticals circulating. This is particularly an issue for controlled substances. (4)
    - Encourage un-opened, un-used, un-expired prescriptions that can no longer be used by the patient to be returned to the pharmacy and re-prescribed / re-used. This is particularly appropriate for medications that are issued in blister packs. (6)

  But also some concerns with these approaches, particularly reverse distribution, partial filling of prescriptions, and reuse of blister packs. And comments that DEA and PQAC rule changes would

be required around partial filling of, at least, controlled substances; and concern with conformance with DEA requirements for these ideas in general.

- Something around additional guidance or a compliance assistance program, for example:
    - Compile and share information on best practices and examples of successful pharmaceutical waste management programs. Provide model programs and materials for program elements and effective staff outreach and training. (20)
    - Create a dedicated, easy-to navigate, web portal for waste pharmaceutical information. (21)
    - Provide waste designation / management information *(including donation/reuse if appropriate)* on the pharmacy label for pharmaceuticals used in hospitals and clinics, e.g., through color coding or other means. (25)
    - Provide an easy-to use directory of what types of waste pharmaceuticals can be disposed to the sewer in each sewer district. (24)
    - Create a true "Compliance Assistance" program, using L&I's DOSH Safety and Health Consultation Program and Ecology's Local Source Control Program as models. (26)

  While there was support for many of the individual ideas listed, there was no clear convergence around what additional guidance / tools are needed, and at least one "can't live with" survey result for each of these ideas.

- Something around improving the way Ecology follows up on inspections and/or increasing the number of inspections/ enforcement, for example through:
    - Ensure generators have a written record when technical assistance is provided during site visits / meetings so they have something to refer to. (29)
    - Provide generators with inspection reports / follow up much more quickly after the inspection event. (28)
    - *Emphasize additional inspections, assistance, and, where needed, enforcement at waste generators to ensure better attention to requirements and compliance. Supports attention by health care administers to ensure adequate funding / oversight of programs. (27)

  However, also comments that there should be additional guidance and compliance assistance for generators before any additional emphasis on enforcement.

Potential Solutions that Drop Off

These solutions are outside or inconsistent with the Work Group charter and therefore drop out of discussions. Numbers refer to the numbering on the revised potential solution set / survey.

- Entirely exempt / exclude pharmaceutical wastes generated in healthcare settings from the dangerous waste regulations and invest instead in treatment of wastewater/sewage, which is unavoidably contaminated with patient's excretion of metabolized and unchanged medications. (9)

- Establish reliable, implementable solutions for waste pharmaceuticals from households. Clarify requirements applicable to pharmacy "take back" programs and provide incentives and funding for these programs. (11)
- Codify the interim enforcement policy, and other important guidance such as the treatment by generator guidance, in clear, plain regulatory language. (17)
- Provide allowances for less than 100% compliance for pharmaceutical wastes generated in clinics / health care portions of facility; for example, if a facility also has a pharmaceutical waste "take back" program allow for less than 100% compliance for pharmaceutical waste generated in the patient care setting. (30)
- Eliminate the state only wastes that are treated in a facility from being part of their generation status determination (onsite treatment of OPA and Formaldehyde). This is not a pharmaceutical waste issue directly but, since they affect generator status, they also affect disposal options for pharmaceutical waste. (A)

Appendix F. Other Stakeholder Comments

Comment #1: Household pharmaceutical take-back programs

Pharmaceutical waste take-back programs were an important topic of conversation, especially at the first Stakeholder Work Group meeting. The stakeholders' final report states:

> *Pharmaceutical wastes from households are exempt from the dangerous waste regulations. However, a number of Work Group members, including those from law enforcement, report significant problems and barriers to these programs, in particular difficulty finding affordable disposal options for pharmaceutical wastes collected by take-back programs. The Work Group had a number of discussions about the urgent need to establish reliable, implementable solutions for pharmaceutical waste take-back programs and the importance of this issue to preventing release of pharmaceutical wastes to the environment and to preventing diversion (e.g., abuse) of waste pharmaceuticals. Police take-back programs are not really law enforcement functions, but local agencies have absorbed the activity and associated cost because "it is the right thing to do" in the face of no reasonable options for citizens to safely dispose of unwanted medications. They are not universal across the state and may be disproportionately located. While this issue was determined to be beyond the scope of the Work Group charter, all Work Group members were in agreement about its importance and urgency. Furthermore, to the extent that the dangerous waste regulations may be perceived as a barrier to reasonable disposal options for waste pharmaceuticals collected in take-back programs, the issue is addressed in recommendation two.*

Ecology response

Ecology agrees that take-back programs can be an important component in reducing the amount of pharmaceutical waste that ends up in our landfills, where they can potentially contaminate the water and expose wildlife to dangerous chemicals. However, this topic was outside the purview of the current stakeholder process. Creating more take-back opportunities for households is important, but a complicated issue that deserves separate attention. Participation by law enforcement, local health departments, and all aspects of the pharmaceutical industry would be needed for program development.

Comment #2: Pharmaceutical waste minimization

The need to reduce the amount of pharmaceutical products becoming waste was a concern for the Stakeholder Work Group:

The Work Group discussed a number of ideas oriented towards reducing the amount of pharmaceutical waste generated. These included requiring pharmaceutical manufacturers, wholesalers, and/or distributors to take-back expired or almost expired samples; encouraging appropriate use of the reverse distribution system; partial filling of prescriptions where appropriate; re-use of un-opened, un-used, un-expired prescriptions that can no longer be used by the patient as provided for under State Law; and establishing an extended producer responsibility program for pharmaceuticals. While there was interest in these approaches and broad support for effective, appropriate approaches to minimizing pharmaceutical waste, in the end the Work Group felt these issues were beyond the scope of their charter.

Ecology response

Ecology agreed this is a significant concern, but believes this Stakeholder Work Group was not the appropriate venue to address these problems. Issues related to stewardship and take-back programs are complicated and need their own forum. Ecology would be happy to participate in future discussions, especially as they relate to stewardship programs, but defers to healthcare facilities, medical personnel, and the agencies that regulate those facilities when it comes to issues related to reducing the generation of pharmaceutical wastes.

Comment #3: Joint comments to the EPA pharmaceutical waste proposal

A number of Work Group members advocated for the Work Group to develop and submit joint comments on the EPA pharmaceutical waste proposal. There was not time during this Work Group process to fully take up this idea, and not all stakeholders were interested in making a joint comment.

Ecology response

Ecology offered to serve as a facilitator for any Work Group participants who were interested in coordinating or submitting joint comments on the EPA rulemaking proposal. Two stakeholders expressed interest in preparing a joint comment letter. Because there was not broad support for a joint letter, Ecology (with stakeholders' consent) took the comments and suggestions submitted and instead drafted a form letter stakeholders could use to comment to EPA. The form letter was sent to all stakeholders as an editable Word document. Stakeholders who wanted to comment could use this form letter as is, or could customize it to meet their own needs. Ecology made its own, separate comments to EPA.

Comment #4: Equity between waste handlers

In addition to the recommendations in #2, #4, and #5 above, the Stakeholders' Final Report notes:

A Work Group participant expressed concern that all facilities which handle state-only pharmaceutical waste, or inadvertently receive it for processing, might not be treated consistently in the future. The participant pointed out that different medical waste and sharps handing approaches (e.g., sealed bags vs. containers intended to facilitate reuse/recycling) create different opportunities for oversight and inspection and expressed the concern that unless waste handling/processing facilities are held to the same standard, generators who are serviced by those facilities would not be doing the same things to ensure compliance. The Work Group discussed this concern at length and their consensus on the issue is described in recommendations two, four and five; however, a Work Group participant continued to feel the issue was not directly enough addressed.

Ecology response

While Ecology understands this stakeholder's concerns, we agree with the rest of the Work Group that the issue is addressed through other recommendations. We believe that this issue can be addressed through adopting new rules, developing a new pharmaceutical waste policy, and providing additional and revised guidance on waste management responsibilities. As mentioned earlier, Ecology plans to propose standards for transparent waste bins, which would help address this stakeholder's concerns.

Comment #5: Justification for regulating state-only pharmaceutical waste

In addition to the discussions above, the final Stakeholder Report noted the following:

Finally, there were some Work Group members who questioned the justification for regulating any pharmaceutical waste that is not already regulated by the federal government. They expressed concern that a material that in one moment was a medicine given to a patient to cure disease or relieve suffering could, in the next moment, be a dangerous waste requiring special management, and advocated that no waste pharmaceutical should be regulated unless it had been documented as present and having adverse impacts in the environment. Other Work Group members were less concerned about regulation of state-only pharmaceutical waste in general, or had concerns only about specific state-only pharmaceutical wastes (e.g., see recommendation three), or were concerned that given the rate at which new pharmaceuticals and pharmaceutical formulations are created, too few waste pharmaceuticals are regulated.

Ecology response

As previously noted, Ecology believes the long-standing regulations governing toxic and persistent wastes help protect the health of Washington's environment and its residents. We believe that the best cure is prevention. By the time a chemical is causing adverse environmental impacts, the time for regulation has long since passed. Prevention is not only more effective, it is far less expensive than cleanup.

The Dangerous Waste Regulations were subjected to both public and legislative scrutiny and review before they were adopted. These regulations have been in place, substantially in the same form, for almost 40 years, and the Washington State-only criteria are virtually unchanged since they were last amended in 1995. When evidence justified relaxing the regulations, Ecology did so. Although some specific state regulations may be more stringent than their federal counterparts, we believe they provide good environmental protection while not being unduly burdensome on businesses that generate and dispose of these toxic and persistent wastes.

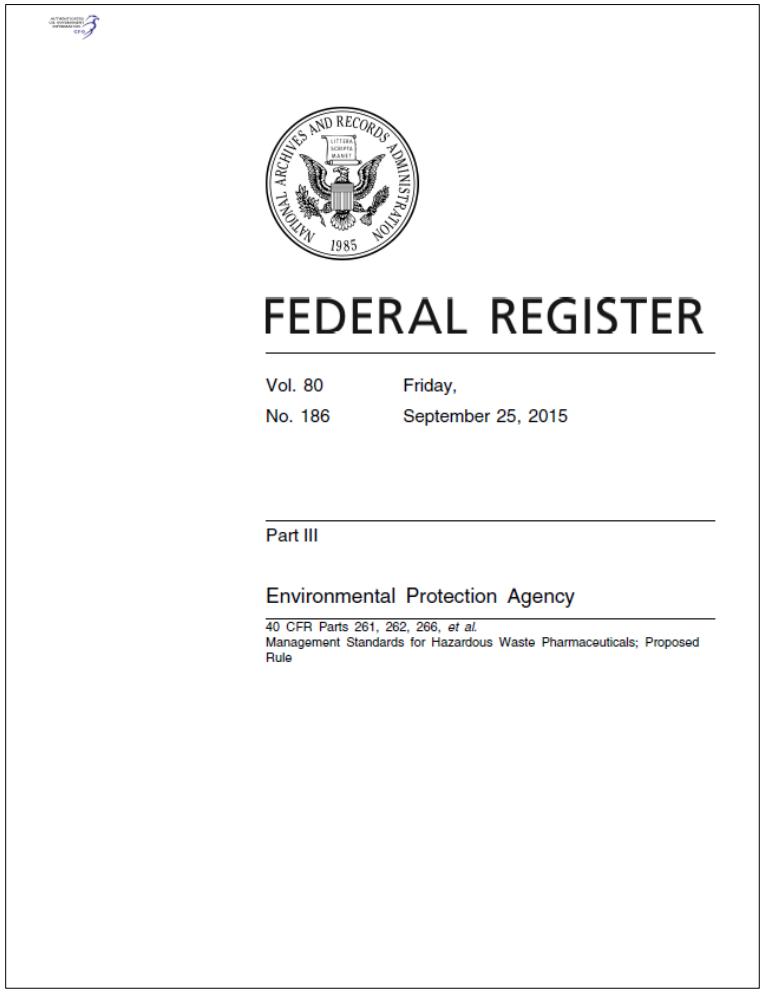
Appendix G. EPA Presentation on proposed rule

Hazardous Waste Pharmaceuticals Proposed Rule

Washington Ecology Pharmaceutical Waste Workgroup
Tuesday, October 6, 2015

Outline of Today's Briefing

- Part I: Background
  - Flow of Pharmaceuticals & Problem Areas
- Part II: Overview of Major Provisions of Proposal
  - Defining Some Key Terms
  - Standards for Healthcare Facilities
  - Standards for Reverse Distributors
- Part III: What's Ahead?



FEDERAL REGISTER

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Part III

Environmental Protection Agency

40 CFR Parts 261, 262, 266, *et al.*
Management Standards for Hazardous Waste Pharmaceuticals; Proposed Rule

Part I: Flow of HW Pharmaceuticals

Potentially Creditable Pharmacy Drugs

Healthcare Facility/ Pharmacy

1st Reverse Distributor

2nd Reverse Distributor

HW TSDF

Flow of HW Pharmaceuticals

Potentially Creditable Pharmacy Drugs

Non-creditable Floor Waste & Pharmacy Drugs

1st Reverse Distributor

Healthcare Facility/ Pharmacy

2nd Reverse Distributor

HW TSDF

Flow of HW Pharmaceuticals

Potentially Creditable Pharmacy Drugs

Non-creditable Floor Waste & Pharmacy Drugs

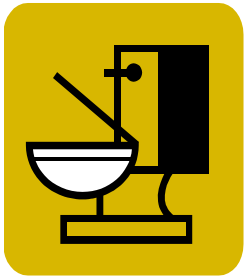
1st Reverse Distributor

Healthcare Facility/ Pharmacy

2nd Reverse Distributor

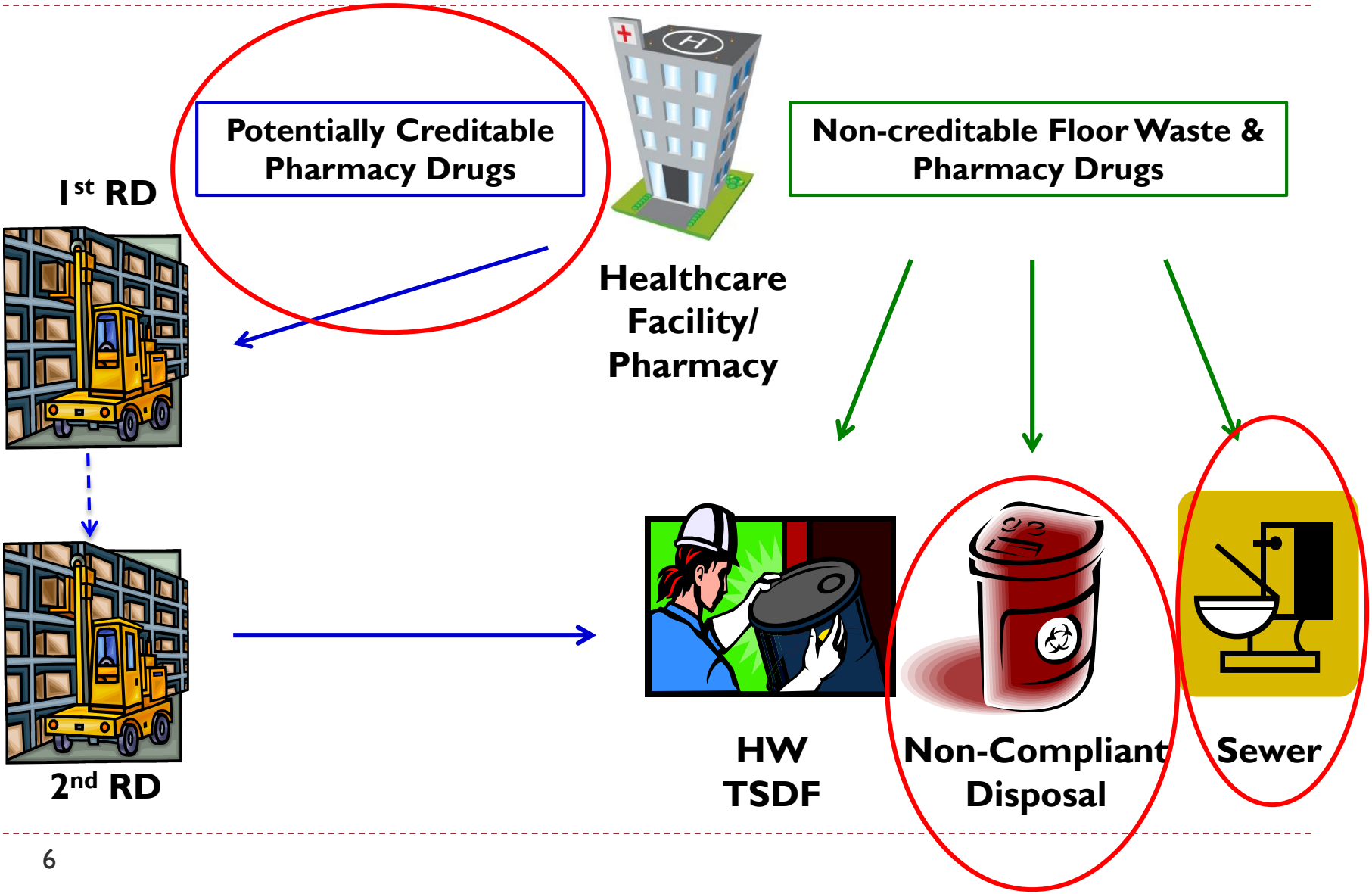
HW TSDF

Non-Compliant Disposal



Sewer

3 Problem Areas to Address in Rule



How RCRA Applies to Healthcare Facilities

- Healthcare facilities that generate hazardous waste are regulated the same as any industrial facility that generates hazardous waste
  - The level of regulation increases with the amount of hazardous waste that is generated (CESQG < SQG < LQG)
  - If a facility generates >1 kg acute HW/month $\Longrightarrow$ LQG
    - Many healthcare facilities/pharmacies are LQGs due to discarded nicotine or warfarin

Why a Pharmaceuticals Rulemaking?

- We have issued clarifying guidance where possible and within the confines of the current regulations

- Remaining issues require regulatory fixes via rulemaking

6 Main Remaining Issues for Rulemaking

1. Regulatory status of creditable pharmaceuticals
2. LQG status due to P-listed hazardous waste
   - Warfarin & nicotine
3. Manufacturing-oriented framework of the generator regulations
4. Intersection of EPA & DEA regulations
5. Containers with P-listed pharmaceutical residues
6. Pharmaceuticals being flushed/sewered

Part II: Overview of Proposed Rule

- Proposed to add hazardous waste pharmaceuticals to the Universal Waste program (2008)
  - Commenters felt UW was inadequate for pharmaceuticals
  - Could not address negative comments on proposal without re-proposing

- New approach has been to build on the 2008 Universal Waste (UW) proposal by:
  - Keeping the aspects of the UW proposal that commenters liked
  - Addressing commenters' concerns about the UW proposal
  - Addressing new areas that the UW proposal did not
  - Coordinating with other federal agencies (e.g., DEA)
  - Promoting national consistency

Overview of Proposed Rule

- We are proposing sector-specific standards for the management of hazardous waste pharmaceuticals for:
  - Healthcare facilities/pharmacies, and
  - Reverse distributors

- The two flows of hazardous waste pharmaceuticals are addressed differently by the rule:
  1. Creditable hazardous waste pharmaceuticals that go through reverse distribution to obtain manufacturer's credit
  2. Non-creditable hazardous waste pharmaceuticals that do not and should not go through reverse distribution

Pop Quiz


TRUE or FALSE?
The proposed rule will establish an extended producer responsibility (EPR) program

What is a Pharmaceutical?

- The proposed definition of "Pharmaceutical"
  - Includes prescriptions, over-the-counters and dietary supplements
  - Includes all dose forms including tablets, capsules, gums, lozenges, liquids, ointments, lotions, IVs, antiseptics, patches, etc.
  - At commenters' request, it is broader than it was in the Universal Waste proposal
  - Borrows heavily from the FDA's definition of "drug"
  - A rule of thumb for OTCs: If FDA requires a "Drug Facts" label, it would be considered a pharmaceutical under this proposed rule
  - Does not include sharps (e.g., needles)

Which Pharmaceuticals Will be Covered?

- Only those pharmaceuticals that are already considered hazardous waste will be covered by the new rule

- This rule does NOT propose to expand the number of pharmaceuticals that are considered hazardous waste

- **We encourage healthcare facilities to manage <u>all</u> waste pharmaceuticals under the new rule**

Examples of HW Pharmaceuticals

- Listed hazardous wastes
  - P-listed (acute HW): Warfarin, Nicotine, etc.
  - U-listed: Mitomycin C, Chloral hydrate, Lindane, Selenium sulfide, Cyclophosphamide, etc.
- Characteristic hazardous wastes
  - Ignitable (D001): Preparations with >24% alcohol
  - Toxicity (D004-D043): if present above certain concentrations in the leachate during TCLP test
    - m-Cresol (preservative in insulin)
    - Mercury (preservative thimerosal)
    - Selenium (multi-vitamins)
    - Chromium (multi-vitamins)
    - Silver (burn creams)

Examples of HW Pharmaceuticals

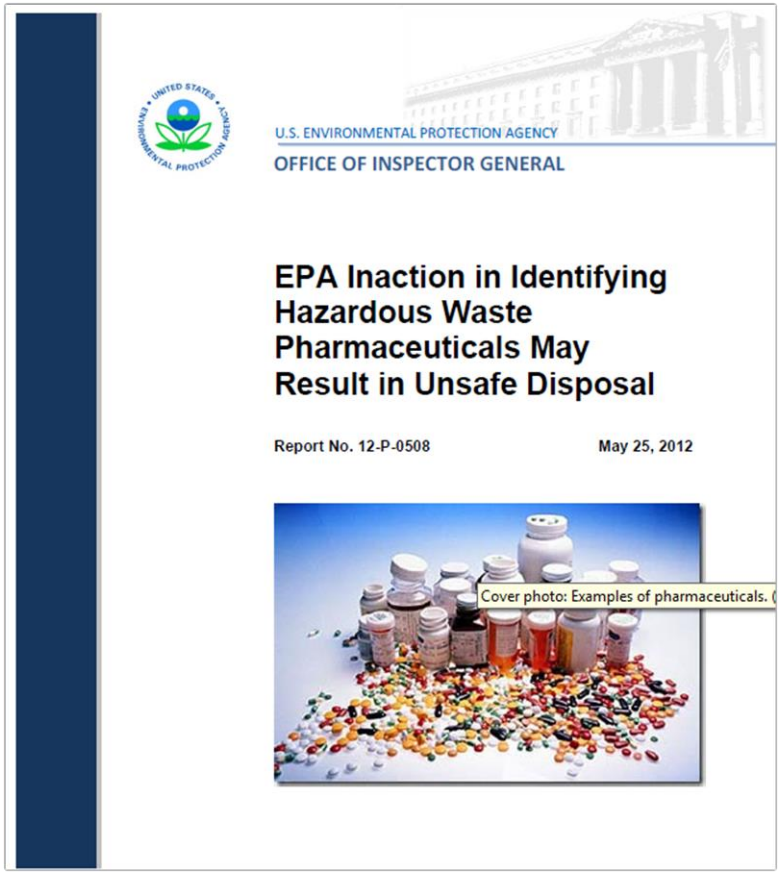
- The chemical names on the P- and U-list are different than the drugs' brand names and generic names, for example -
  - If you are a pharmacist: Brand name Trisenox
  - If you speak RCRA: Arsenic trioxide = P012
- The characteristic hazardous wastes (D001-D043) are descriptive:
  - Do not give any indication which specific drugs might exhibit a characteristic and
  - Can vary for different forms of the same drug, for example -
    - Fentanyl sublingual spray is dissolved in alcohol – D001 (ignitable)
    - Other forms of fentanyl are not hazardous waste

Which Pharmaceuticals Will be Covered?

EPA Inspector General Report:

(May 2012)

EPA Inaction in Identifying Hazardous Waste Pharmaceuticals May Result in Unsafe Disposal



Seek Comment for Possible Future Rules

In response to the 2012 IG Report:

- Seek comment on expanding what pharmaceuticals are hazardous waste
  - What's the best way to incorporate new drugs into RCRA?
  - Are there alternative methods other than the current listings and characteristic approaches?

Seek Comment for Possible Future Rules

In response to the 2014 Retail Notice of Data Availability (NODA):

- Seek comment on 2 Options for addressing low-concentration nicotine smoking cessation products
  1. Exemption from P075 Listing for FDA-Approved Over-the-Counter Nicotine-Containing Smoking Cessation Products
  2. Concentration-Based Exemption from P075 Listing for Low-Concentration Nicotine-Containing Products
  - Both of these options require data on nicotine toxicity to evaluate against the acute listing criteria

There's nothing wrong with my eye.
It's a nicotine patch – I'm trying to quit smoking

Who Will be Covered by the Rule?

- Healthcare facilities that generate hazardous waste pharmaceuticals
  - Does not include healthcare facilities that are CESQGs

- The proposed definition of *Healthcare facility* is: any person that

  (1) provides preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or

  (2) sells or dispenses over-the-counter or prescription pharmaceuticals.

Who Will be Covered by the Rule?

- Healthcare facilities – include (but are not limited to):
  - Hospitals, including psychiatric hospitals
  - Pharmacies, including
    - Long-term care pharmacies
    - Mail-order pharmacies
    - Retail stores with pharmacies
  - Health clinics
  - Surgical centers
  - Long-term care facilities
  - Physicians offices, including dental, optical, & chiropractors
  - Veterinary clinics and hospitals
  - Drug compounding facilities
  - Coroners & medical examiners

- Drug manufacturers are not considered healthcare facilities

Who Will be Covered by the Rule?

- All pharmaceutical reverse distributors - regardless of current generator category

- The proposed definition of *Pharmaceutical Reverse Distributor* is
  - Any person that receives and accumulates potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer's credit
  - Any person, including forward distributors and pharmaceutical manufacturers, that processes pharmaceuticals for the facilitation or verification of manufacturer's credit is considered a pharmaceutical reverse distributor

- Some drug manufacturers may operate as pharmaceutical reverse distributors

Problem Area #1

HCF

Potentially Creditable Pharmacy Drugs (20%)

Non-creditable Floor Waste & Pharmacy Drugs (80%)

1st RD

2nd RD

HW TSDF

Non-Compliant Disposal

Sewer ≈20%

6 Main Remaining Issues for Rulemaking

1. Regulatory status of creditable pharmaceuticals
2. LQG status due to P-listed hazardous waste
   - Warfarin & nicotine
3. Manufacturing-oriented framework of the generator regulations
4. Intersection of EPA & DEA regulations
5. Containers with P-listed pharmaceutical residues
6. Pharmaceuticals being flushed/sewered

#6: Sewering Pharmaceuticals

Problem

- Flushing of pharmaceuticals has become a commonly used disposal method by healthcare facilities which
  - Contributes to pharmaceuticals in surface and drinking water,
  - Has demonstrated risks to the environment and potential to present risks to human health
  - Are not being treated for by POTWs, except incidentally
- Flushing is allowed by current regulation

"There's not some sort of magic process that can remove everything we put down the drain"

David Sedlak, Director of the Institute for Environmental Science and Engineering at UC Berkeley

#6: Sewering Pharmaceuticals

Proposed Solution

- Rule bans the sewering of HW pharmaceuticals
  - Sewer ban applies to all healthcare facilities & RDs, including CESQGs
    - Otherwise CESQG healthcare facilities are not subject to the proposal
  - Prevents 6400 TONS of hazardous waste pharmaceuticals from contaminating the water per year
  - Sewer ban reinforces and highlights EPA's policy against flushing pharmaceuticals
    - At EPA's urging, DEA no longer allows sewering as a means of destroying controlled substances
    - Several federal agencies, including EPA, have been coordinating to educate consumers to stop flushing pharmaceuticals
  - EPA would join other jurisdictions with sewer bans for pharmaceuticals, including IL, NJ, DC and CT (proposed)

Problem Area #2

HCF

Potentially Creditable Pharmacy Drugs (20%)

Non-creditable Floor Waste & Pharmacy Drugs (80%)

1st RD

2nd RD

HW TSDF

Non-Compliant Disposal

≈40-50%

Sewer

6 Main Remaining Issues for Rulemaking

1. Regulatory status of creditable pharmaceuticals
2. LQG status due to P-listed hazardous waste
   - Warfarin & nicotine
3. Manufacturing-oriented framework of the generator regulations
4. Intersection of EPA & DEA regulations
5. Containers with P-listed pharmaceutical residues
6. Pharmaceuticals being flushed/sewered

#5: Containers with Residues

Problem

- If residues are acute/P-listed HW, then to be considered "RCRA empty," containers must be:
  - Triple-rinsed, or
  - Cleaned by another method shown in the scientific literature or by tests by generator, to achieve equivalent removal

- Current RCRA empty container rules apply to residues in very small containers used in healthcare setting, including:
  - Vials
  - Dixie cups
  - Soufflé cups
  - Blister packs, etc.

#5: Containers with Residues

Proposed Solution

1. Residues in unit-dose containers and dispensing bottles/vials would be exempt from RCRA
   - Unit-dose containers (e.g., packets, cups, wrappers, blister packs and unit-dose delivery devices) and
   - Dispensing bottles and vials up to 1 liter or 1000 pills
2. Dispensed syringes would be exempt from RCRA provided:
   - The syringe has been used to administer the pharmaceutical to a patient, and
   - The syringe is placed in a sharps containers that is managed appropriately
3. All other containers, including delivery devices, that once held listed or characteristic pharmaceuticals, must be managed as hazardous waste, including IV bags, aerosols, nebulizers, etc.

#4: Intersection of DEA & EPA Rules

Problem

- There are a few RCRA hazardous wastes that are also DEA controlled substances
  - Chloral hydrate (U034)
  - Fentanyl sublingual spray (D001)
  - Phenobarbital (D001)
  - Testosterone gels (D001)
  - Valium injectable (D001)
- These are dually regulated by EPA and DEA – must comply with both sets of regulations

#4: Intersection of DEA & EPA Rules

Proposed Solution

2 Conditional Exemptions:

1. Hazardous waste pharmaceuticals that are also DEA controlled substances would be exempt from RCRA regulation

- Conditions for exemption:
  - Must be managed in accordance with all DEA regulations
  - Must be combusted at a permitted/interim status:
    - municipal solid waste combustor or
    - hazardous waste combustor

#4: Intersection of DEA & EPA Rules
Proposed Solution

2. Authorized collectors of DEA controlled substances that co-mingle them with pharmaceuticals that are exempt household hazardous waste (HHW) would be exempt from RCRA regulation

- Conditions for exemption:
  - Must be managed in accordance with all DEA regulations
  - Must be combusted at a permitted/interim status:
    - municipal solid waste combustor or
    - hazardous waste combustor

#3: Manufacturing Framework

Problem

- Healthcare facilities that generate hazardous waste are currently regulated the same as any industrial facility that generates hazardous waste

- Healthcare facilities differ from industry
  - Thousands of drugs in their formularies, which vary over time
  - Lots of healthcare workers involved in generation of waste in lots of locations throughout facility
  - Healthcare workers and pharmacists have little expertise with RCRA yet are critical in getting the hazardous wastes directed to proper waste management

- Hazardous waste pharmaceuticals are unique among hazardous wastes:
  - Street value
  - Potential for diversion/theft

#3: Manufacturing Framework
Proposed Solution

- Part 262 generator regulations are replaced by sector-specific management standards for the management of hazardous waste pharmaceuticals at healthcare facilities and pharmaceutical reverse distributors
  - Part 266 Subpart P

- The Part 262 generator regulations do not apply to hazardous waste pharmaceuticals, including:
  - SQG and LQG generator categories
  - Satellite accumulation area (SAA) regulations
  - Central accumulation area (CAA) regulations

#3: Manufacturing Framework
Proposed Solution

Accumulation on-site at healthcare facility:

- One-time notification as HCF (as opposed to as a generator)
- Performance-based training for healthcare workers
- No Biennial Report for hazardous waste pharmaceuticals

- Potentially Creditable HW pharmaceuticals
  - No specific labeling or accumulation time limits proposed

- Non-creditable HW pharmaceuticals
  - Similar to simplified Universal Waste standards
  - "UW Plus"

#3: Manufacturing Framework

Proposed Solution

Shipments off-site from a healthcare facility:

- Potentially Creditable HW pharmaceuticals can go to a Pharmaceutical Reverse Distributor:
  - Written, advance notice of shipments to RD
  - Confirmation of receipt of shipment by RD
  - Recordkeeping of shipments to RD
  - Common carrier allowed
  - HW codes not required during shipment
- Non-creditable HW pharmaceuticals must go to a TSDF
  - HW transporter required
  - Manifesting required
  - HW codes not required on manifest
  - "Hazardous waste pharmaceuticals" in Box 14 of manifest

#2: LQG Status Due to Acute HW
Problem

- LQG status for healthcare facilities & pharmacies due to exceeding 1 kg acute HW/month, which results in highest level of regulation, including:
  - Shorter accumulation time
  - Biennial Reporting
  - More training requirements and documentation
  - Higher costs for generators
  - Higher costs for states who must inspect LQGs more frequently

#2: LQG Status Due to Acute HW
Proposed Solution

- HW pharmaceuticals do not have to be counted toward the healthcare facility's generator status when they are managed under Part 266 Subpart P
  - No SQG or LQG status for HW pharmaceuticals
  - All HW pharmaceuticals are managed the same
  - Don't have to keep track of monthly generation for hazardous waste pharmaceuticals
  - Don't have to accumulate acutes and non-acutes separately
  - Reduces incidences of episodic generation

Problem Area #3

Potentially Creditable Pharmacy Drugs (20%)

Non-creditable Floor Waste & Pharmacy Drugs (80%)

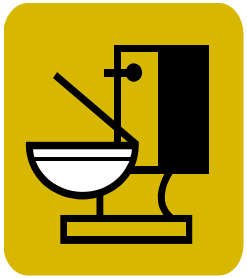
HCF

1st RD

2nd RD

HW TSDF

Non-Compliant Disposal



Sewer

6 Main Remaining Issues for Rulemaking

1. Regulatory status of creditable pharmaceuticals
2. LQG status due to P-listed hazardous waste
   - Warfarin & nicotine
3. Manufacturing-oriented framework of the generator regulations
4. Intersection of EPA & DEA regulations
5. Containers with P-listed pharmaceutical residues
6. Pharmaceuticals being flushed/sewered

#1: Status of Creditable Pharmaceuticals
Problem

- Current guidance allows point of generation of creditable pharmaceuticals to be at reverse distributor, based on the assumption that some pharmaceuticals will be redistributed
  - Creditable pharmaceuticals are not regulated as wastes even though they are being discarded after manufacturer's credit is processed by reverse distributor
  - Current guidance creates concern about lack of tracking and the potential for diversion (theft)

- Some states are questioning our interpretation
  - Regulatory uncertainty exists for reverse distributors and the healthcare facilities that use them

#1: Status of Creditable Pharmaceuticals
Proposed Solution

- EPA now understands that little to no redistribution of pharmaceuticals is actually occurring during reverse distribution and we are proposing to revise our interpretation such that
  - A decision to send a pharmaceutical to a reverse distributor is a decision to discard
  - The point of generation for pharmaceuticals sent to a reverse distributor is at the healthcare facility, not the reverse distributor
    - Allows better tracking of shipments of creditable HW pharmaceuticals to reverse distributors
    - Allows better oversight of reverse distributors through notification

#1: Status of Creditable Pharmaceuticals
Proposed Solution

- A Pharmaceutical Reverse Distributor would be considered a new type of hazardous waste management facility
  - Can only accept "potentially creditable hazardous waste pharmaceuticals"
  - No RCRA storage permit required
  - All RDs are regulated the same for hazardous waste pharmaceuticals
    - No CESQG, SQG or LQG categories for hazardous waste pharmaceuticals
  - Standards similar to LQGs, with additions
    - "LQG Plus"

What is "Potentially Creditable"?

- The proposed definition of *Potentially Creditable Hazardous Waste Pharmaceutical* is:

  A hazardous waste pharmaceutical that has the potential to receive manufacturer's credit and is:

  1. Unused or un-administered; and
  2. Unexpired or less than one year past expiration date
  3. The term does not include:
     - Evaluated hazardous waste pharmaceuticals
     - Residues of pharmaceuticals remaining in containers
     - Contaminated personal protective equipment, and
     - Clean-up material from the spills of pharmaceuticals

What is NOT "Potentially Creditable"?

- Since manufacturers set the policies of when a pharmaceutical receives credit, a healthcare facility does not always know when credit will be given
- However, if there is no reasonable expectation of credit, the hazardous waste pharmaceutical can not go to an RD, for example if the pharmaceutical:
  - Is a sample
  - Is a generic
  - Is more than 1 year past expiration
  - Has been removed from original container and re-packaged for dispensing
  - Was generated during patient care, or refused by a patient

Flow of HW Pharmaceuticals

HCF/Pharmacy

- Diagram shows maximum number of transfers allowed
- 90-days maximum allowed at each RD

1st RD can be a manufacturer

2nd RD can be a manufacturer

3rd RD must be a manufacturer

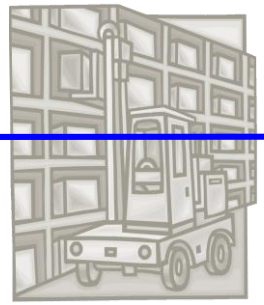
HW TSDF

Flow of HW Pharmaceuticals

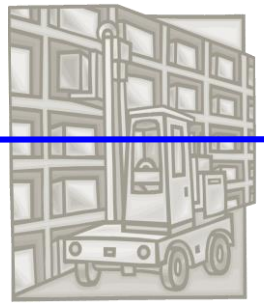
HCF/Pharmacy

- **Not all steps occur in every case**

1st RD can be a manufacturer



2nd RD can be a manufacturer



3rd RD must be a manufacturer

HW TSDF

Flow of HW Pharmaceuticals

HCF/Pharmacy

- The same steps may not occur in every case

1st RD can be a manufacturer

2nd RD can be a manufacturer

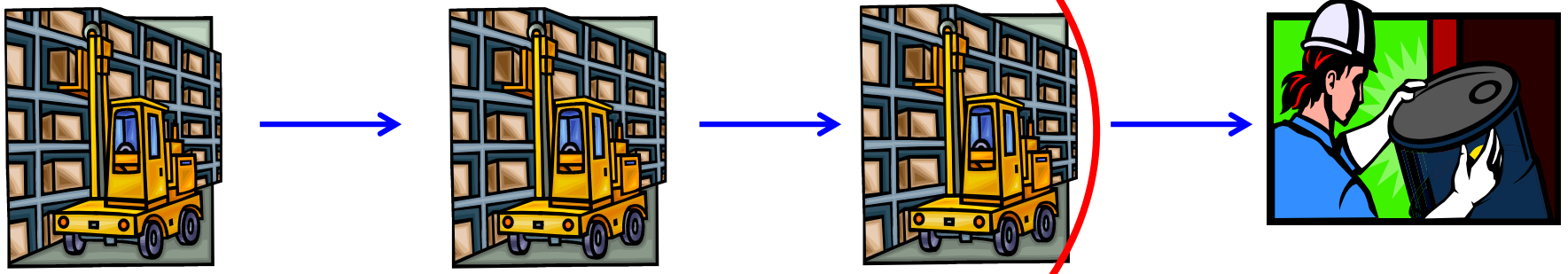
3rd RD must be a manufacturer

HW TSDF

Flow of HW Pharmaceuticals

HCF/Pharmacy

As long as manufacturer's credit is being determined/verified, and pharmaceuticals are destined for an RD, they are still considered **"Potentially Creditable HW Pharmaceuticals"**



1st RD can be a manufacturer

2nd RD can be a manufacturer

3rd RD must be a manufacturer

HW TSDF

Flow of HW Pharmaceuticals

HCF/Pharmacy

Once manufacturer's credit has been determined/verified, and pharmaceuticals are destined for a TSDF, they are considered

"Evaluated HW Pharmaceuticals"

1st RD can be a manufacturer

2nd RD can be a manufacturer

3rd RD must be a manufacturer

HW TSDF

#1: Status of Creditable Pharmaceuticals
Proposed Solution

- An RD must evaluate each potentially creditable hazardous waste pharmaceutical within 21 calendar days of arrival to determine whether it is destined for:
  - Another pharmaceutical reverse distributor for further evaluation/verification of manufacturer's credit, or
  - A permitted/interim status TSDF

- If an RD receives hazardous waste, other than potentially creditable hazardous waste pharmaceuticals, it must:
  - Prepare an "unauthorized waste report" and send it to the shipper and to EPA
  - Manage the waste appropriately

#1: Status of Creditable Pharmaceuticals

Proposed Solution

Accumulation on-site at reverse distributor:

- 90 days total accumulation time at each reverse distributor

- Potentially Creditable HW pharmaceuticals
  - No specific labeling or container standards proposed

- Evaluated HW pharmaceuticals
  - Must designate an on-site accumulation area and conduct and keep a log of weekly inspections
  - LQG training for personnel handling evaluated HW pharmaceuticals
  - Closed containers, if holding liquids or gels
  - Wastes that can't be incinerated must be accumulated separately (e.g., P012)
  - HW codes required prior to transport off-site
  - Label as "Hazardous Waste Pharmaceuticals"
  - Biennial Report

#1: Status of Creditable Pharmaceuticals

Proposed Solution

Shipments off-site from an reverse distributor:

- Potentially Creditable HW pharmaceuticals can go to another Pharmaceutical Reverse Distributor:
  - Written, advance notice of shipments to next RD
  - Confirmation of receipt of shipment by next RD
  - Recordkeeping of shipments to RD
  - Common carrier allowed
  - HW codes not required during shipment
- Evaluated HW pharmaceuticals must go to a TSDF
  - HW transporter required
  - Manifesting required
  - HW codes required on manifest

Part III: What's Ahead?

- Proposed rule was published in Federal Register
  - September 25, 2015; 80 FR 58014
- 60-day public comment period
  - Ends Tuesday, November 24, 2015
  - Several requests for extension have been submitted
- EPA reviews public comments
- EPA commences work on final rule
- EPA decides whether to proceed on additional proposed or final rules related to:
  - Expanding what pharmaceuticals are hazardous
  - Nicotine

Pop Quiz


TRUE or FALSE?
The public comment period ends on October 30th

Your Role in Rulemaking

- Comment on the proposed rule during the public comment period
  - Indicate aspects you support
  - Indicate aspects you do not support
  - Explain your reasons
  - Provide examples and/or data to support your comments
  - Provide alternative ideas

QUESTIONS??

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  - Fitzgerald.Kristin@epa.gov
- Josh Smeraldi
  - 703-308-0441
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- Resources

  http://www2.epa.gov/hwgenerators/proposed-rule-management-standards-hazardous-waste-pharmaceuticals

  http://hwpharms.wikispaces.com