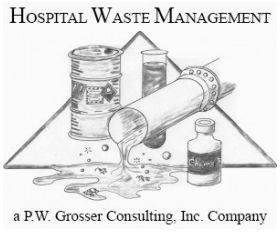
Volume 17, Number 4

HOSPITAL WASTE MANAGEMENT



Winter 2015

Special points of interest:

- **EPA's New Hazardous Pharmaceutical Waste Rule is complicated, but useful**
- **Local Wastewater treatment districts moving rapidly to ban sewering pharmaceutical waste**

Inside this issue:

Hospital Waste

EPA Proposed Rule on Hazardous Pharmaceutical Waste Management

The U.S. EPA published its new proposed rule on managing pharmaceutical waste in the September 25, 2015 issue of the Federal Register. The proposed rule will be within 40 CFR §266, Subpart P—Management Standards for Hazardous Waste Pharmaceuticals, but will probably not take effect for one to two years. The new proposed rule is 267 pages as published.

One notable aspect of the new proposed rule is that as a result of comments, EPA is *not* proposing to manage pharmaceutical waste as Universal Waste. There were a number of objections to provisions of the Universal Waste Rule, including the lack of sufficient waste tracking protocols.

The proposed new rule will impact healthcare facilities including hospitals, pharmacies, clinics, physician offices, veterinary clinics, surgical centers, long-term care facilities and reverse distributors (vendors which take back unwanted pharmaceuticals for credit by the manufacturer). It will *not impact* facilities that are Small Quantity Generators or drug manufacturers. Most hospitals will want to manage their hazardous pharmaceutical waste under the proposed rule as it eliminates much of the frustration of the old regulations.

The first goal of the new rule is to reduce the amount of pharmaceutical waste that is disposed of down the drain. The DEA has agreed that sewering hazardous controlled substance pharmaceutical waste will no longer be acceptable. The second goal is to reduce the burden of regulatory overlap between EPA's rules on hazardous waste and DEA's rules on controlled substances.

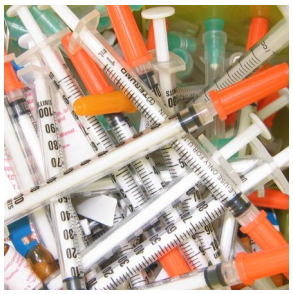
EPA will create two different pharmaceutical waste protocols: one for waste that can be returned via a reverse distributor (creditable) and one for waste which cannot be returned (non-creditable).

One difficult aspect of the proposed rule will be identifying which drugs are hazardous and which are not. For example, multidose flu vaccines designate as hazardous waste, but single dose flu vaccines do not. Under the new rule, residues in unit-dose containers will be exempt from the Resource, Conservation & Recovery Act (RCRA). Hospitals and pharmacies will want to assess their formularies as part of compliance.

What is considered empty has been made easier under the new rule. A vial, bottle or ampoule of less than 1 liter or 1,000 tablets will be empty and the contents *not regulated* if:

- As much pharmaceutical has been removed as is possible using normal dispensing protocols;
- The original dispensing container is

(Continued on page 2)



(Continued from page 1)

destroyed (e.g., crushed) so as to be unusable and prevent diversion (the container can then be disposed of as non-hazardous waste);

- The pharmaceutical residues in a syringe are not regulated if:
  - ° The syringe has been used to administer the pharmaceutical to a patient; and
  - ° The syringe is placed into a sharps container and managed as medical waste.

All other containers, including delivery devices, that once held listed or characteristic hazardous pharmaceuticals must be managed as hazardous waste. This includes IV bags and tubes, inhalers, aerosols, nebulizers and tubes of ointment, gels or creams.

A welcome aspect of the new rule is that used nicotine patch envelopes and warfarin packs can be disposed of in the trash (these are P-list wastes that once required triple rinsing to be considered empty).

The new rule recognizes that very little, if any, redistribution of expired pharmaceuticals is taking place. It puts the onus of declaring expired pharmaceuticals as waste directly onto the healthcare facility, not the reverse distributor.

The proposed rule does not identify any new listed hazardous pharmaceuticals or change the criteria for listed or characteristic wastes. It does include all dose forms including tablets, capsules, gums, lozenges, liquids, ointments, lotions, IVs, antiseptics and patches.

Expired pharmaceuticals must be managed differently. They will be considered solid waste the day that they expire, although they may still be returned to the manufacturer via a reverse distributor. The new rule has a waste tracking protocol that requires (1) the hospital or pharmacy to notify the reverse distributor of the shipment of waste and (2) must receive notice from the reverse distributor within seven days that the shipment was received at its destination. These tracking records must be available for inspection.

Under the new rule healthcare facilities must declare to the EPA that they will operate under the new protocol. Here in Washington that will translate to notifying the Washington Dept. of Ecology. It is likely that the rule will not take effect until late 2016 or even early 2017 because of the comment period and a six month grace period.

Because the new rule is stricter than current rules, all states will be required to adopt the new federal rule, if not make it even more stringent. Some states (Florida and Michigan) will have to rescind some portion of their laws which manage pharmaceutical waste as Universal Waste. As with Washington Ecology's *Interim Enforcement Policy*, healthcare facilities managing their pharmaceutical waste under the new rule will not have to count their pharmaceutical waste towards their generator status or report volumes annually.

Some pharmaceuticals are considered to be both hazardous and controlled substances, including:

- Chloral hydrate (U034)
- Fentanyl sublingual spray (D001)
- Phenobarbitol (D001)
- Testosterone gels (D001)
- Valium injectable (D001)

These waste pharmaceuticals will be exempt from RCRA regulations when they are:

- managed in accordance with DEA regulations, and
- combusted at a permitted municipal or hazardous waste incinerator.

Healthcare facilities will be prohibited from sewering any hazardous waste pharmaceuticals, although non-hazardous controlled substance waste can still be sewered under DEA rules. In Washington, however, Ecology is expected to ban

(Continued on page 4)

Bedside Controlled Substance Pharmaceutical Waste Disposal

The convergence of EPA's proposed Part P rule, Ecology's *Interim Enforcement Policy* and DEA regulations have prompted some Washington wastewater treatment districts to force the issue of sewering controlled substance waste. Healthcare facilities and caregivers are being squeezed in the resulting dilemma.

EPA, Ecology and wastewater experts agree that wastewater treatment facilities cannot adequately neutralize most pharmaceuticals, which end up fully active in our community surface waters. Yet presently healthcare givers commonly waste extra controlled substance that has been assigned to a patient but cannot be all administered by squirting it into the sink. Historically, DEA has allowed this means of wasting and Ecology quietly accepted it.

Under EPA's proposed Part P rule, sewering any hazardous (RCRA) pharmaceutical waste will be banned and Ecology is expected to enforce that ban for all pharmaceutical waste when it adopts the federal rule. However, some Washington wastewater treatment districts either already have or are preparing to prohibit the sewering of any controlled substance waste very soon. These collective actions are complicating efforts by healthcare givers to comply with competing local, state and federal regulations.

If a local wastewater treatment district preemptively bans the sewering of controlled substance waste there are few obvious options for caregivers.

> *Once again, competing local, state and federal regulations are complicating efforts by healthcare givers to do their jobs and yet comply with regulations*

A seemingly logical alternative to sewering controlled substance waste at the bedside is to squirt it into a pharmaceutical waste capture product that will render the drug unrecoverable. Two such products are the Cactus Smart Sink® and Rx Destroyer®. The former polymerizes the drug waste and the latter immobilizes the drug waste in activated charcoal. Both use a gastric irritant to promote vomiting if someone attempts to divert the drug waste. Both can be sent to an incineration facility after use at the bedside.

Unfortunately, the use of either of these products presently constitutes *Treatment by Generator* in the opinion of Ecology and is not compliant with the *Interim Enforcement Policy*. As a result, all pharmaceutical waste thus treated must count towards the facility's dangerous waste generator status and must be reported on the Dangerous Waste Annual Report. The use of either product could well cause some healthcare facilities to jump to Large Quantity Generator (LQG) status, triggering higher fees and more extensive training and planning requirements.

Everyone wants to do the right thing, but presently there is no "right thing." When EPA's Part P rule becomes effective some day, sewering any pharmaceutical waste in Washington will no longer happen. But in both the interim and long-term something has to give way. It will either be a hodge-podge of different local wastewater district regulations or a common, statewide solution from Ecology. If the latter is to happen, it will have to take place quickly.

HOSPITAL WASTE MANAGEMENT

a P.W. Grosser Consulting, Inc. Company

17629 NE 138th Street
Redmond,
Washington 98052-1226

Phone: 425-883-0405
Fax: 425-895-0067
E-mail: ajones@pwgrosser.com

www.hospitalwastemgmt.com

Hospital Waste is published quarterly for hospital, clinical and medical laboratory waste and hazardous material managers to assist them in managing these materials.

You can download past issues (since the Summer of 1999) of Hospital Waste from our website http://www.hospitalwaste mgmt.com. There is a searchable index of articles at the website and all issues are downloadable as portable document format (.pdf) files.

If you wish to receive this free quarterly newsletter, please notify us by telephone, fax or e-mail (contact information is shown adjacent). You will receive the newsletter as an e-mail on your smartphone and with a hyperlink to a .pdf file on our website that you can download.

(Continued from page 2)

the sewering of any pharmaceutical waste., which will apply to Small Quantity Generators.

When a drug waste is subject to both RCRA and DEA regulations, the waste is exempt from RCRA regulations and only DEA regulations will apply. I.e., controlled substance waste.

The new rule means that hazardous pharmaceutical waste will no longer be managed in the same fashion as other hazardous waste. This is in recognition of the great variety of pharmaceuticals, their small volumes and their potential for abuse. Specifically:

- A healthcare facility (HCF) must only notify one time, not annually;
- Workers will be required to have performance-based training;
- There will be no annual reporting required (as is the case now in Washington under the *Interim Enforcement Policy*);
- Hazardous pharmaceutical waste can be accumulated for 1 year; and
- Containers must be labeled "Hazardous Waste Pharmaceuticals."

Potentially creditable hazardous waste pharmaceuticals can be shipped offsite to a reverse distributor via common carrier; e.g., the USPS, UPS or FedEx. However, non-creditable hazardous waste pharmaceuticals must go to a Treatment, Storage & Disposal facility, a hazardous waste transporter must be used, and a manifest is required.