



ASTSWMO Joint Hazardous Waste & Materials Management Training
August 2019

PHARMACEUTICAL WASTE REGULATIONS:

Practical Impacts of the New EPA Pharma Rule & Home Generated Pharmaceutical Drug Take Back Programs

Selin Hoboy

Vice President, Government Affairs and Compliance Global
Stericycle, Inc.

Practical Implications of Subpart P

What to work on with generators & understanding how the rule applies to them

Overview – Practical Implications of New Subpart P

- Ways to Help Healthcare
- Handling Empty Containers/Residue
- Changes in Storage and Labeling
- Other Issues To Look For
- Nicotine Waste Rule

Ways to Help Healthcare – Applicability

- Health care facilities that are small quantity or large quantity generators of hazardous waste (SQG or LQG)
 - Mandatory to follow Subpart P
- Very small quantity generators (VSQGs) do NOT have to follow Subpart P
 - With the exception of the sewerage ban
 - Can “opt-in” to some parts of the rule that will be helpful or choose to follow the whole subpart
- Those that do not meet the EPA’s definition of “health care facility”
 - Pharmaceutical manufacturers
- Does NOT apply to Pharmaceutical wastes that are NOT a hazardous waste
- Rule does not apply to management of hazardous wastes that are **NOT** pharmaceuticals
 - Lab waste/solvents
 - Expired chemicals
 - Cleaning and sterilization products
 - Universal wastes – batteries, lamps

Handling Empty Containers/Residue

- 4 categories described in rule (applies to VSQG not following Subpart P)
- Stock, dispensing, and unit dose containers – includes vials, blister packs, dispensing bottles (not to exceed 1 liter or 1000 pills). These items are empty when contents removed by normal means and can go in the trash, even if they held P-listed waste.
- Syringes – considered empty and not regulated as hazardous waste when the plunger is fully depressed.
- Intravenous bags (IVs) – full administered IV bags are considered empty and/or those that meet current definition of RCRA empty.
- Other containers, including delivery devices – inhalers, ointments, gels, creams are empty when current definition of RCRA empty is met.

Changes in Storage and Labeling

- Current Rule – satellite accumulation area and central accumulation areas had different requirements.
 - Under Subpart P - Storage requirements are the same no matter where the container is located.
- Under Subpart P the following apply wherever the container is located:
 - One year of storage time
 - Container must be labeled “Hazardous Waste Pharmaceuticals”
 - Container must be closed at all times and secured in a manner that prevents unauthorized access to its contents
 - Waste must be compatible with container and other contents and in good condition

Other Issues To Look For

- Changes to E-Manifest – adding “PHARMS” to Section 13
- Changes for Long Term Care Facilities
- State by State adoption – will be important for generator and the state waste is being shipped for disposal.
- VSQG's have options

Nicotine Waste Rule

- Nicotine and empty containers from these items are P075 waste today
- EPA edited P-listing to exclude FDA-approved over-the-counter nicotine replacement therapies:
 - Patches
 - Gums
 - Lozenges
- Does not include:
 - Prescription nicotine therapies (inhalers)
 - E-cigarettes/liquids

The above would apply to ALL generators of hazardous waste, not just health care as this is a modification of the P-listed waste rules, NOT part of Subpart P



Drug Take Back Programs for Safe Medication Disposal – Program Overview & Regulatory Best Practices

OVERVIEW

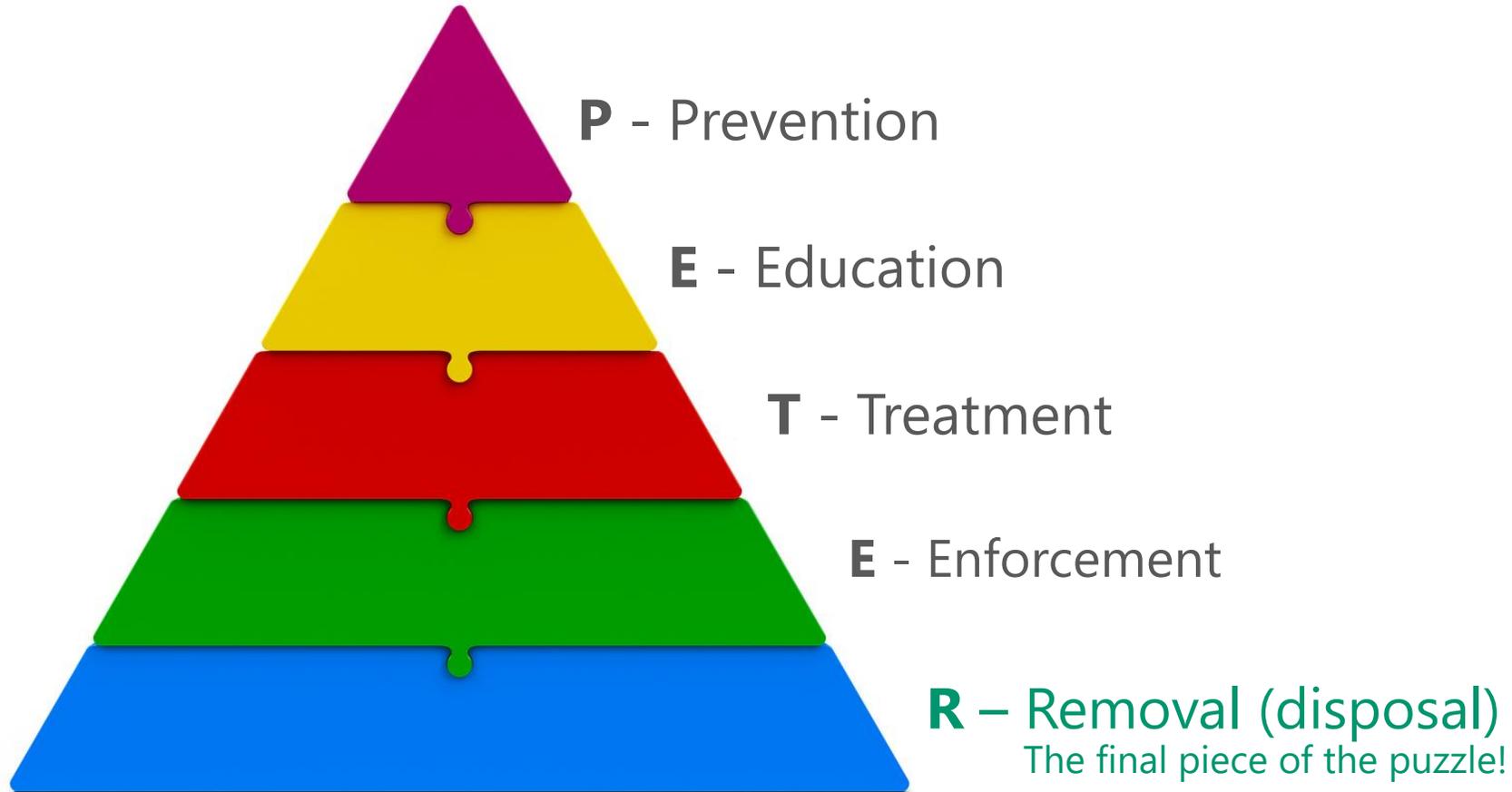
- 1. Why drug take back?**
- 2. Regulatory requirements**
- 3. Program development best practices**

Why Drug Take Back? Public & Environmental Health Impacts



- In 2018 for the first time, Americans **were more likely to die from an opioid overdose than a car crash** *(National Safety Council)*
- **3 in 4** heroin users start by misusing prescription drugs *(National Institute on Drug Abuse)*
- **2 in 3** teens who misuse prescription painkillers for the first time report obtaining the drugs from friends or relatives *(Substance Abuse & Mental Health Services Administration)*
- A vast array of pharmaceuticals have been found in the drinking water supplies of at least **41 million Americans** *(Associated Press, 2008)*

PETER – A DEA Response to Opioid Abuse



Safe Medication Disposal?

Most methods of consumer drug disposal are not safe:

- Storing unused drugs in the medicine cabinet (diversion risk)
- Flushing drugs down the toilet or sewer (environmental risk)
- Mixing drugs with kitty litter or coffee grounds and throwing in the trash (diversion & environmental risk)
- Returning unused drugs to pharmacies or medical offices and leaving them with staff (diversion & compliance risk)

Drug Take Back – The Safest Solution

Safe & Convenient Collection:

- Via secure kiosks hosted at pharmacies, hospitals, and law enforcement agencies (DEA registrants)

Compliant Processing & Transportation:

- Packaged and transported via common carrier per DOT Special Permit requirements
- Requires proper closure of the container
- Cannot inspect or remove any contents
- Both self-service and technician-assisted models available (cost savings vs. convenience)
- Waste processed at DEA regulated facilities

Safe & Sustainable Destruction:

- Waste anonymously incinerated for destruction meeting DEA and EPA requirements
- Tracking capabilities allow for program utilization reporting

Medication Mail Back Programs:

- Can be distributed by anyone to anyone (no DEA registration required)
- Tracking capabilities allow program utilization reporting to justify expense
- Waste is diverted from landfills



Growing in Popularity

Though awareness and adoption of drug take back programs has been slow in the past, many organizations have become industry leaders by being the first to implement them in recent years, including:

- **Retail Pharmacies** – Walgreen's, CVS, & others
- **Large Hospital Networks** – Kaiser Permanente, TriHealth, & others
- **Law Enforcement Agencies** – localized kiosks at police stations
- **Regional Hospitals, Clinics, & Long-Term Care Facilities** – Many sprinkled throughout the country
- **State & Local Governments** – 8 states (MA, VT, CA, WA, NY, CO, MO, OR) and 16 counties in CA and WA have either passed laws requiring drug manufacturers to fund drug take back programs OR have put government funded programs in place at pharmacies and law enforcement agencies

How is Drug Take Back Regulated?

- **DEA Regulations**

- DEA regulations effective September 2014
- Primary goal is to eliminate diversion
- Different requirements for collection kiosks vs. mail back envelopes

- **DOT Regulations**

- Safety of transportation of potential hazardous materials
- Requires adherence with DOT SP- 20225

- **EPA**

- Consumer drugs are exempt from RCRA and other EPA regulations that apply to waste generated from businesses

- **State & Local Regulations**

- Can significantly vary from state to state
- Can impact the way collected waste must be managed

DEA Regulations

- Specifies how and where kiosks can be located at hospitals and pharmacies (requires visibility of pharmacy staff, secure bolting to the floor, locked when not supervised, etc.)
- Authorized collectors easy registration process – add to current registration via online process DEA website
- Waste must be removed with two people for secure removal – inspection of waste is not allowed
- Mail back envelopes don't require host site DEA registration for distribution – returned envelopes must be destroyed on site at return facility that is registered

DOT Regulations

- Providers of kiosk waste packaging their own waste for shipment must apply for DOT Special Permit 20255
- Service providers supporting hospitals, pharmacies, or law enforcement for packaging and shipping of waste must have DOT Special Permit
- Can be shipped via common carrier
- Containers should be packaged using DOT Special Permit conditions and containers

EPA Regulations

- EPA considers this material exempt home generated waste
- EPA new regulations under “**MANAGEMENT STANDARDS FOR HAZARDOUS WASTE PHARMACEUTICALS**” require proper management of waste
 - Must be DEA approved method (in writing)
 - Incineration options
- Waste weights do not count towards generator status

State & Local Regulations

- State and local regulations can vary and be different from Federal EPA regulations
- Board of Pharmacies (BOP) at the state level can have restrictions for pharmacies, hospitals, rehab programs, or long term care facilities
- **State or local regulation impacts:**
 - Regulations and ordinances can make an impact on cost and operations – consistency is key
 - Destruction – consistent destruction requirements, provide broad options to reduce cost
 - Tracking – consistent tracking, using tracking still enable efficiency; cannot separate waste
 - Reporting – reporting that provides flexibility for different systems, some reporting requirements can be very onerous and complicates making it difficult and costly to comply
 - Encourage engagement with the regulated community – CA SB212 Case Study
 - Several regulatory reviews with the stakeholders in meetings
 - Review of pre-regulations – comments on proposed draft
 - Ongoing regulatory development

Real & Perceived Program Challenges

Challenges and concerns of facilities:

- Non-retrievable definition
- Compliance risk and fear
- Staff availability & training
- Cost

Reality of costs to operate program:

- Finding funding support
- Justifying program ROI

Overcoming regulatory challenges:

- Haz waste generator status impacts
- DOT special permit required
- EPA household exemption regulations – states may not accept
- Challenges with patchwork of regulations state by state
- Final destruction location concerns

Choosing the Right Disposal Program

Drug take back kiosks:

1. Best for high-volume collection
2. Lowest cost per lb drug disposal solution
3. Various kiosk features
4. Multiple waste processing service options
5. Utilization tracking & program reporting

Drug mail back envelopes:

1. Great supplement to drug take back kiosk programs
2. Discounts available for large volume orders
3. Low cost & lower barrier-to-entry for drug take back pilot programs
4. Utilization tracking & program reporting
5. Better alternative to drug neutralizing disposal pouches

Drug Take Back Program Setup

1. Kiosk delivery & installation coordination
 - Placement (w/supervision)
 - Securely bolted to floor
2. Staff process & compliance training
3. Service initiation with program partner
4. Public awareness & education

Closing

Subpart P and New Changes to RCRA

- Very helpful for healthcare waste management
- Ideally regulations would be adopted consistently over the states
 - Will be key to follow for generator state vs destruction state

Drug Take Back Programs

- Drug take back/medication mail back programs provide best options for management of left over medications
- Drug take back programs are already heavily regulated
- Programs being adopted for pharmacies are taking traction, but consistency in regulations will encourage better participation
- Drug take back programs with law enforcement has opportunity, however tend to be less popular with consumers
- As legislation is adopted at state and local levels for take back programs there is an opportunity for ASTSWMO to advise on best practices and promote consistency and cost/convenience optimization

Q&A

Thank you.

Selin Hoboy

Vice President, Government Affairs
and Compliance, Global at Stericycle, Inc.

shoboy@stericycle.com
847-456-8889 (m)

