

# Pharmaceutical Waste: The Latest from DEA and EPA

Practice Greenhealth

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# New Practice Greenhealth Guidance Document

## Best practices for disposal of controlled substances

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There is increased concern over pharmaceuticals in waterways. There are “no drugs down the drain” rules in certain states. And harm can come from unauthorized access to controlled substances and the resulting wastage. Health care facilities must address these issues and ensure alignment with Drug Enforcement Administration (DEA) and Environmental Protection Agency (EPA) regulations as well as local rules. So Practice Greenhealth and a team of stakeholders developed this guidance to support hospitals and clinicians in managing controlled substances and the resulting wastage.

This document summarizes and builds upon the September 2014 promulgation of the DEA rule on the

**Inventory:** Controlled substances that are part of stock and have not been dispensed or administered

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# Objectives

- Review the steps of Practice Greenhealth's guidance to help healthcare facilities and providers through the legal management of controlled substances that are no longer needed.
- Understand the changes in the DEA and EPA regulatory status of a controlled substance that is in inventory versus dispensed.
- Briefly review the EPA's new hazardous waste pharmaceuticals rule and how it will impact controlled substance wastage and returns.

# Introductions



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# Rationale for Development of Best Practices for Disposal of Controlled Substances

- Increased concern over pharmaceuticals in waterway as evidenced by “no drugs down the drain” rules in certain states
- Potential diversion risks by employees, patients, and visitors within the healthcare setting
- Compliance with the DEA’s Drug Disposal Regulations
  - Required and authorized by the Secure and Responsible Drug Disposal Act of 2010 to provide a pathway for the return and disposal of controlled substances from the ultimate user (patient)
  - DEA also included additional conditions regarding the management of controlled substances in inventory vs. wastage
- Ensuring compliance with EPA’s hazardous waste regulations as they apply to pharmaceutical waste
- Guidance document finalized prior to the publication of the EPA’s Final Rule: Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine

# The Controlled Substances Act

- Enacted in 1970 and enforced by the Drug Enforcement Administration (DEA)
- DEA resides within the Dept. of Justice
- Restricted access to controlled substances to those registered to manufacture, distribute, prescribe or dispense such products.
- All regulated substances are placed into one of five “schedules”



# Controlled Substance Schedules

- Schedule I: Drugs with no recognized medical use and high abuse potential (marijuana now in transition)
  - Heroin, LSD, methaqualone, peyote
- Schedule II: Medical use but high abuse potential
  - Hydrocodone/acetaminophen (Vicodin), cocaine, methamphetamine, methadone, hydromorphone (Dilaudid), meperidine (Demerol), oxycodone (OxyContin), fentanyl (Duragesic), dextroamphetamine (Dexedrine), (Adderall), and methylphenidate (Ritalin)
- Schedule III: moderate to low potential for physical and psychological dependence
  - Tylenol with codeine, ketamine, anabolic steroids, testosterone
- Schedule IV: low potential for abuse and low risk of dependence.
  - Alprazolam (Xanax), carisoprodol (Soma), propoxyphene (Darvon), (Darvocet), diazepam (Valium), lorazepam (Ativan), pentazocine (Talwin),
- Schedule V: drugs with lower potential for abuse than Schedule IV and consist of preparations containing limited quantities of certain narcotics.
  - Guafenesin & codeine( Robitussin AC), diphenoxylate & atropine (Lomotil)



# The DEA Disposal Regulation

- Published September 9<sup>th</sup>, 2014; took effect October 9<sup>th</sup>, 2014
- Requirements to govern the secure disposal of controlled substances by both DEA registrants and ultimate users
- Expands options for take-back events
- Creates mail-back programs and collection receptacle options

# The DEA Disposal Regulation

- Authorized manufacturers, distributors, reverse distributors, narcotic treatment programs, retail pharmacies and hospitals/clinics with on-site pharmacies to voluntarily participate
- Pharmacies (Retail and hospital/clinic) are authorized to maintain collection receptacles at long term care facilities
- Reorganizes and consolidates regulations on disposal and the role of reverse distributors

# Healthcare Sectors Impacted by DEA Changes

- **Registrant Disposal**
  - Hospitals, clinics, physicians, veterinarians, dentists
  - Retail Pharmacies including LTCF Provider Pharmacies
  - Reverse Distributors
- **Non-Registrant Disposal**
  - **“Ultimate User” collection programs, including law enforcement**
    - Mail-back
    - Receptacles (kiosks)
    - Single day events
  - **“Ultimate User” long term care facilities (LTCFs)**
    - Receptacles provided and managed by retail pharmacies

# Registrant Disposal Concerns Expressed to DEA

- Definition of “non-retrievable” limited to incineration
- Ability to render a drug “non-retrievable” in an institutional setting
- Ability to transfer drug wastage to a reverse distributor for incineration from an institutional setting
- Requirement to double witness the destruction of the CS until it is rendered non-retrievable

# DEA Clarification Letter: October 17, 2014

- “...once a controlled substance has been dispensed to a patient by an institutional practitioner on the basis of an order for immediate administration to a patient at the registrant's registered location, the substance is no longer in the practitioner's inventory. For example, after a pre-filled syringe or a single-dose vial or syringe is administered to a patient, any remaining substance in the syringe or vial is not required to be destroyed in accordance with new Part 1317.”
- Such wastage cannot be disposed in a receptacle for ultimate user collection (take-back kiosk)
- Controlled substances from the pharmacy’s inventory cannot be disposed in a receptacle for ultimate user collection (take-back kiosk)
- All destruction must be in accordance with Federal, State, tribal, and local laws and regulations

# DEA Clarification Letter: October 17, 2014

- “Although Part 1317 does not apply to pharmaceutical wastage, the DEA strongly encourages all practitioners to continue to adhere to security controls and procedures that ensure pharmaceutical wastage is not diverted. For example, most institutional practitioners have implemented policies that require two persons to witness and record destruction of pharmaceutical wastage.”
- [http://www.dea diversion.usdoj.gov/drug\\_disposal/dear\\_practitioner\\_pharm\\_waste\\_101714.pdf](http://www.dea diversion.usdoj.gov/drug_disposal/dear_practitioner_pharm_waste_101714.pdf)

# PGH Guidance: Definitions

- **Controlled substances:** drugs/chemicals identified in Title 21 USC Controlled Substances Act
  - Schedules I through V in decreasing order of abuse potential
- **Registrant:** A person who has applied to DEA and received from DEA a specific registrant number enabling specific authorization for various functions, including ordering, stocking, dispensing, or administering controlled substances
- **Inventory:** controlled substances that are part of stock, have not been dispensed or administered, and for which tight security controls should be implemented



# PGH Guidance: Definitions

- **Wastage:** A controlled substance which has been removed from inventory in accordance with a physician's order for administration to a patient and which has not been entirely administered to the patient
- **Destruction:** The standard of destruction established in the DEA rule is to render the controlled substance to a non-retrievable state
  - Applies to controlled substances within the registrant's inventory
  - Does not apply to controlled substances "wastage"
- **Non-retrievable:** Permanent alteration of the controlled substance's physical or chemical condition or state through irreversible means, thereby rendering the controlled substance unavailable and unusable for all practical purposes.

# PGH Guidance: Definitions

- **Reverse distribute:** To acquire controlled substances from another registrant or law enforcement for the purpose of return or destruction
  - Credit may also be allocated based on the manufacturer's return policy
- **Reverse distributor:** Any person registered by the DEA and appropriate state boards of pharmacy as a reverse distributor and allowed to acquire controlled substances from another registrant or law enforcement for the purpose of return or destruction

# The Cycle of Controlled Substances

- Inventory: Receipt and storage
  - Ordered in accordance with DEA requirements from a drug wholesaler or manufacturer
  - Quantities verified upon receipt
  - Entered into an inventory maintenance recordkeeping system
  - Stored in a highly secured manner with limited employee access e.g. Pyxis CII Safe
  - May also be securely stored in the nursing unit in an automated dispensing cabinet
  - Outdated controlled substances should be returned to pharmacy for appropriate management

# The Cycle of Controlled Substances

- Inventory: Removal
  - Dispensed to a patient upon the order of an appropriately licensed practitioner
  - Outdated or unwanted controlled substances must be rendered “non-retrievable”
  - Based on statements by DEA, the only method accepted at this time is by incineration
    - Transfer between DEA registrants to a reverse distributor for potential credit and witnessed incineration
    - OR if an appropriately permitted incinerator is geographically available
      - Two authorized employees witness the incineration and complete the Form 41: Registrant Record of Controlled Substances Destroyed

# The Cycle of Controlled Substances

- Special case, unintended consequences:
  - Outdated compounded IVs containing controlled substances
  - Included in the pharmacy's inventory
  - Must be managed as inventory and either sent through reverse distribution or undergo witnessed destruction through a DEA-authorized destruction method that meets the non-retrievable standard
  - Exceptions to incineration authorized by regional DEA personnel should be documented in writing

# The Cycle of Controlled Substances

- Wastage
  - Removed from inventory and dispensed to a patient but not entirely used
    - e.g. partial morphine IV, partial vial, etc.
  - Required security, recordkeeping and reporting protocols
  - “Such remaining substance must be properly recorded, stored, and destroyed in accordance with DEA regulations (e.g., § 1304.22(c)), and all applicable Federal, State, tribal, and local laws and regulations, although the destruction need not be recorded on a DEA Form 41.” 79 Fed. Reg. 53521\*.
  - 1304.22(c) Name of drug, strength, number of units or volume, name, address of patient, name or initials of person administering

\*<https://www.govinfo.gov/content/pkg/FR-2014-09-09/pdf/FR-2014-09-09.pdf>

# The Cycle of Controlled Substances

- Wastage
  - DEA does not designate or require any specific method for managing wastage other than to prevent diversion and maintain compliance with Federal, State, tribal, or local environmental rule, regulation, or statute
  - EPA currently designates several controlled substances as hazardous waste
    - Chloral hydrate CIV U034
    - Fentanyl Sublingual Spray (Subsys®) CII D001
    - Diazepam (Valium®) 5mg/ml injection CIV D001
    - Testosterone Gel CIII D001



# Diversion Prevention

- Pharmacy inventory:
  - Tight controls on receipt and dispensing quantities
  - Restricting access to the smallest number of employees feasible
  - Regular physical audits to ensure accuracy and to detect diversion
  - Monitoring of on-site reverse distribution personnel

# Diversion Prevention

- Wastage in the nursing unit:
  - Double witnessing of disposal method at the time of disposal
  - Follow up of any discrepancies noted in electronic wasting records
  - Identification of wasting “partners”
  - Provision of convenient sequestration devices
    - Activated carbon
    - Denaturation
- If hazardous waste controlled substances are dispensed, sequestration devices should be managed as hazardous waste
- DO NOT place unsequestered CS wastage in any waste containers, including red sharps! Too much opportunity for diversion throughout the storage, transport and disposal chain of command
- Drain disposal highly discouraged although still allowed in some states - new EPA rule will impact that practice

# Decision Tree for Controlled Substance Disposal

- The controlled substance in the pharmacy's inventory...
  - **EITHER** send through reverse distribution as a transfer between registrants
    - All outdated controlled substances
  - **OR** have two employees witness incineration if a permitted incinerator is conveniently located and complete Form 41 Registrants Inventory of Drug Surrendered
    - Cannot **CURRENTLY** use this option for any of the controlled substances that become a hazardous waste, due to hazardous waste regulations

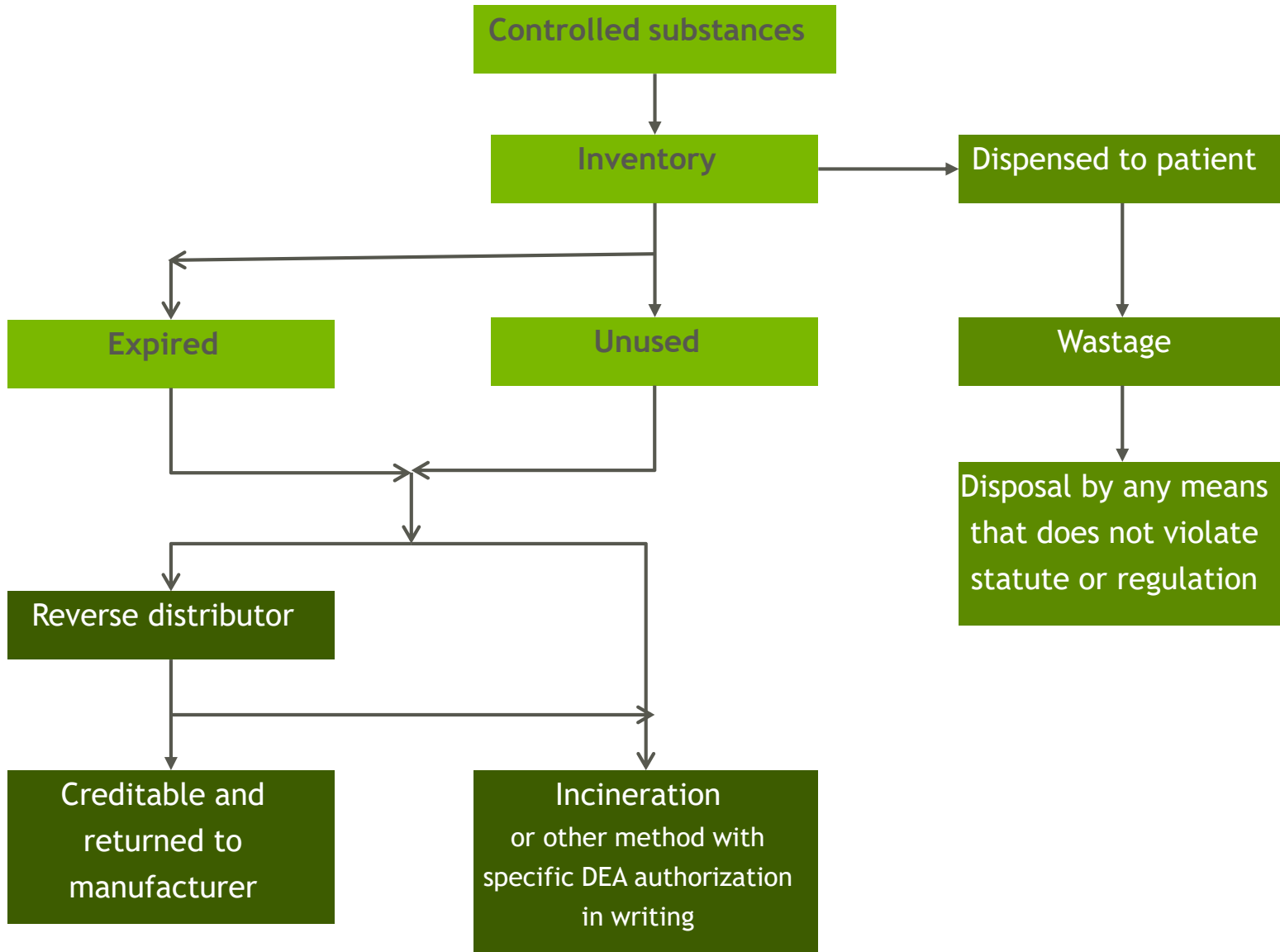
# Decision Tree for Controlled Substance Disposal

- The controlled substance has been charged out to the patient (i.e. no longer in the pharmacy's inventory, including stocking in the automated dispensing machine (ADM))
- Any remaining drug left after administration is considered “wastage” and is out of the DEA closed loop system
- The requirement of DEA is to prevent diversion and the recommendation is to document and ensure destruction

# Summary of Controlled Substance Disposal in Healthcare Facilities

- If in the pharmacy's inventory, the controlled substance must be sent to a reverse distributor or disposed through witnessed incineration.
- If the controlled substance has been dispensed to a patient, any remaining drug can be sequestered in a device and the device placed in either the white/blue non-hazardous waste container or the black hazardous waste container and managed by the appropriate waste vendor

# Controlled Substance Management Flow Chart



# EPA's Final Rulemaking: Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine

- Prepublication edition released December 11, 2018
- Official publication in the Federal Register February 22, 2019
- Largest change in the proposed management of hazardous waste pharmaceuticals since RCRA regulations were finalized in 1980
- Applicable in federally managed states and territories August 21, 2019 (Iowa, Alaska, Puerto Rico)
- **Sewer prohibition of hazardous waste pharmaceuticals nationwide August 21, 2019**
- All other states must adopt stricter aspects; may choose not to adopt less strict aspects



# WHY Part 266 Subpart P?

- Healthcare entities differ from pharmaceutical industry
  - Determination at point of generation by healthcare workers is difficult
  - Waste stream categorization and accuracy is challenging
  - Volume of pharmaceuticals is large and changing continuously
  - Number of individuals (healthcare workers) involved is also large
- Hazardous waste pharmaceuticals are different from hazardous waste
  - Potential for diversion
  - Street value
- Therefore, management of hazardous waste pharmaceuticals at Healthcare (HC) Facilities and Reverse Distributors (RD) are now addressed appropriately in Part 266 subpart P (not Part 262)

# EPA's Final Rule Tackles these Issues

- Defining LQG status of healthcare facilities on acutely hazardous waste generation (> 1 kg per month), P-listed pharmaceuticals responsible for this volume of generation were mainly warfarin and nicotine
- Recognition that original RCRA regulations were designed for manufacturing and heavy industry, not healthcare
- **Confusion around the intersection of EPA and DEA regulations - a few drugs are both controlled substances and hazardous pharmaceutical waste**
- Management of “empty” containers of P-listed drugs such as warfarin and nicotine as a hazardous waste
- Sewering of hazardous waste pharmaceuticals
- Reverse distribution of outdated hazardous waste pharmaceuticals returned for credit

# EPA's Response

## 40 CFR Part 266 Subpart P Management Standards for Hazardous Waste Pharmaceuticals

- Mandated for all current LQGs and SQGs; VSQGs may participate voluntarily
- EPA has created “sector-specific” standards for the management of hazardous waste pharmaceuticals for:
  - Healthcare facilities/pharmacies, and
  - Pharmaceutical reverse distributors
- Defines regulatory status of potentially creditable outdated pharmaceuticals
- Addresses LQG status due to P-listed hazardous waste
- **Exempts hazardous waste pharmaceuticals that are also a controlled substance (intersection of EPA and DEA regulations)**
- New definitions of “empty” depending on dosage form
- **Prohibits sewerage of hazardous waste pharmaceuticals**

# Sewer Prohibition for all Hazardous Waste Pharmaceuticals (HWPs)

- Sewering of HWPs will be PROHIBITED
  - All healthcare facilities (VSQG (fka CESQG), SQG, LQG)
  - Pharmaceutical Reverse Distributors
  - Sewer ban reinforces and highlights EPA's policy against flushing pharmaceuticals
    - DEA no longer allows sewerage as a means of destroying controlled substances (in inventory)
    - Several federal agencies educating consumers to stop flushing pharmaceuticals
- HSWA Provision: effective in all states upon the effective date for the rule, August 21, 2019
  - (HSWA provisions - elements of the Federal RCRA program that are implemented pursuant to the Hazardous and Solid Waste Amendments of 1984.)

# EPA and DEA Intersection: Controlled Substances that are also HW Pharmaceuticals

- Examples of the very few CS that are HWPs
  - Diazepam 5mg/ml injection (D001)
  - Fentanyl sublingual spray (D001)
  - Testosterone gel (D001)
  - Chloral hydrate (U034)
- Requirements for EPA conditional exemption from hazardous waste regulations
  - Managed in accordance with DEA regulations
  - Incinerated by one of five types of permitted combustors or destroyed by another method that has been publicly approved in writing by DEA
    - Municipal waste, regulated medical waste, hazardous waste incinerators
  - Cannot be sewerred (inventory or wastage)

# Operational Impact of the New EPA Rule on Controlled Substance Disposal

- Operationally, while DEA still enables sewerage of “wastage,” if the facility stocks controlled substances that are hazardous waste, EPA prohibits drain disposal of these drugs
- Not possible to train nurses on which controlled substances to drain dispose and which to place into sequestration devices and have incinerated
- Therefore, drain disposal is not feasible if hazardous waste controlled substances are stocked by the facility under the new EPA Hazardous Waste Pharmaceuticals Rule
- This aspect of the Rule takes effect August 21, 2019 nationwide

# Summary

- The DEA's 2014 Final Rule (Part 1317) differentiates between controlled substances in the pharmacy's inventory vs any wastage remaining after dispensing or administering
- Outdated, unused, and unwanted controlled substances in the pharmacy's inventory must be reverse distributed as a transfer between DEA registrants or managed in accordance with regional DEA authorization, including witnessed incineration
- DEA requirements for wasting: two witnesses, specific documentation, efforts to prevent diversion
- Both environmental and security concerns must be considered
- Representatives of all relevant stakeholders should be included in policy and procedure development for each stage
- The new EPA Hazardous Waste Pharmaceuticals Rule (HWPs) will most likely operationally preclude drain disposal for facility's stocking HWP controlled substances.



# References

## DEA Drug Disposal Rule and Industry Clarification Letter:

- [https://www.deadiversion.usdoj.gov/fed\\_regs/rules/2014/2014-20926.pdf](https://www.deadiversion.usdoj.gov/fed_regs/rules/2014/2014-20926.pdf)
- <http://www.aha.org/advocacy-issues/letter/2014/141006-let-disposal.pdf>
- [https://www.deadiversion.usdoj.gov/drug\\_disposal/dear\\_registrant\\_disposal.pdf](https://www.deadiversion.usdoj.gov/drug_disposal/dear_registrant_disposal.pdf)

## EPA Hazardous Waste Pharmaceuticals Rule:

- <https://www.epa.gov/hwgenerators/final-rule-management-standards-hazardous-waste-pharmaceuticals-and-amendment-p075>

## WMSS PharmEcology Services

- [www.pharmecology.com](http://www.pharmecology.com)

FAQs, state and federal waste regulations, subscription search engine

# Questions?

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