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Medication or Hazardous Waste?

EPA's New Rule for Managing Unused Pharmaceuticals

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Overview of Presentation

- EPA's New Pharma Rule
- Background: Basic RCRA requirements
- RCRA vs. healthcare facilities (HCFs) and reverse distributors (RDs): Square Peg, Round Hole
- The Pharma Rulemaking Process
- The Final Pharma Rule
  - Health Care Facilities
  - Reverse Distributors
- Important Changes in Current Practices
- State Implementation and Interim Compliance
- How Best to Prepare

EPA's New Pharma Rule

- Hazardous pharmaceutical waste:
  - Pre-rule status: hazardous pharmaceutical wastes are subject to stringent management and disposal requirements under the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. §§ 6901 *et seq*.
  - On Feb. 22, 2019, EPA published comprehensive new rule with "relaxed" standards
    - *Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine*, 84 Fed. Reg. 5816

RCRA Background

- Federal “cradle to grave” regulation of hazardous waste
- EPA issues regulations (40 C.F.R. Parts 260-269) and all states with “delegated authority” must promulgate and implement regulations at least as stringent as the federal rule
  - Each state and EPA will enforce the state regulations
  - Exceptions: Iowa and Alaska, which directly implement the federal program
- 3 types of regulated entities: waste generators, waste transporters and facilities that treat, store or dispose of hazardous waste (TSDF)
  - All generators must determine whether each waste stream is a “hazardous waste,” and ensure that hazardous waste streams are disposed of at authorized facilities
    - Must track the waste with manifests, keep detailed records, file waste reports, etc.

How Does RCRA Work?

RCRA Generators

- **Large Quantity Generators (LQGs)** (generating ≥ 1000 kg/mo. or ≥ 1 kg./mo. of acute haz waste) are subject to many additional management requirements
- **Small Quantity Generators (SQGs)** (generating > 100 and < 1000 kg/mo.) may accumulate less waste
- **Very Small Quantity Generators (VSQGs)** (generating ≤ 100 kg/mo. and ≤ 1 kg/mo. of acute haz waste)

TSDFs

- Subject to stringent permitting, operational, recordkeeping, financial assurance and closure requirements

What Is Hazardous Waste?

- Two questions:
  1. Is it a "solid waste"?
     - A solid waste is any solid, liquid or gas that has served its intended purpose and is no longer wanted
     - Is it useless? Are you ready to discard it? → It's a waste
     - Or can it legitimately be reused or reclaimed? → May not be a waste
  2. Is it also a *hazardous* solid waste that falls into one of two categories:
     - Is the material specifically listed as a hazardous waste in the applicable state regulations ("*listed waste*")?
       - E.g., EPA waste codes: listed wastes will be assigned a four character code beginning with F, K, P or U
     - Is the material characteristically hazardous waste?
       - E.g., EPA has designated certain characteristics as hazardous
       - Substances that are ignitable, corrosive, reactive, or toxic

Is It a Hazardous Waste?

- Examples of relevant listed wastes
  - P and U waste codes refer to “unused commercial chemicals”
  - P codes are used for acutely toxic hazardous waste, such as warfarin, physostigmine, nicotine, arsenic trioxide and their packaging
    - Handling just 1 kg/mo. of acute P-listed waste triggers extensive LQG waste management requirements
  - U codes are for “discarded products” or mixtures w/ ≥ 10% U materials
    - E.g., cepastat lozenges, chloraseptic spray, resperine, selenium sulfide
  - F codes refer to wastes generated in common manufacturing and industrial processes
    - F-code waste in the healthcare industry are solvent wastes, typically generated in diagnostic labs
      - F003: spent non-halogenated solvents, such as xylene, acetone, ethyl acetate, n-butyl alcohol, cyclohexanone and methanol
      - F005: spent non-halogenated solvents, such as toluene, isobutanol and benzene
  - The K-list identifies hazardous wastes from specific sectors of industry and manufacturing and are considered source-specific wastes. To qualify as a K-listed hazardous waste, a waste must fit into one of the 13 categories (mostly manufacturing) on the list and the waste must match one of the detailed K list waste descriptions

Summary – Is It a Hazardous Waste?

- Are you, the Health Care Facility or Reverse Distributor, ready to discard it?
- Can it be reused or reclaimed in an appropriate manner?
  - If yes, it may not be a waste or hazardous waste
  - If no, then it's a waste
- Is it listed under a state (EPA) hazardous waste code? or
- Does it exhibit a characteristic of hazardous?
  - If yes to either, it's a hazardous waste
- Key point: It becomes a waste when the decision is made to discard it (the "point of generation")

EPA's Pharma Rule – the Big Picture

- What it's not: The Pharma rule does not address "medical waste," which is separately regulated by states (including "dual wastes" subject to RCRA and state medical waste requirements)
  - E.g., discarded blood, sharps, microbiological cultures, human or animal tissue, bandages, gloves, etc.
- Pharma rule: pills, liquids, creams, ointments and their containers
- Applies to a broad range of "healthcare facilities" (HCFs) and "reverse distributors" (RDs)

EPA's Pharma Rule – The Big Picture

Generally Applies to 13+ NAICS Enterprises

Drug Wholesalers	Supermarkets and Other Grocery (except Convenience Stores)
Pharmacies and Drug Stores	Warehouse Clubs and Supercenters
Veterinary Services	Physicians' Offices
Dentists' Offices	Other Health Practitioners (e.g., Chiropractors)
Outpatient Care Centers	Other Ambulatory Health Care Services
Hospitals	Nursing Care Facilities (e.g., in assisted living facilities, nursing homes)
Continuing Care Retirement Communities (e.g., assisted living facilities with on-site nursing facilities)	Reverse Distributors (various NAICS Codes)

EPA's Pharma Rule – The Big Picture

- **Prescription pharma waste management system:**
  - Step One: Codifies Minnesota's position that ***all prescription* (Rx)** pharmaceuticals ***become waste*** when decision is made to dispose or to send Rx to RD, first triggering waste management standards ***at the HCF*** making the decision
  - Step Two: Creates *streamlined* handling, disposal and reporting requirements for ***all hazardous waste*** pharmaceuticals that would otherwise be subject to the full suite of RCRA requirements
    - 40 CFR Part 266, "Subpart P"
- **Non-Prescription Off-Ramp from RCRA and Subpart P:**
  - Step Three: Codifies prior EPA guidance and allows HCFs to send reusable ***non-Rx non-hazardous pharmaceuticals*** to reverse logistics center as products, not "waste"
    - *But only if there is a legitimate expectation for reuse (donation) or reclamation*
    - E.g., over-the-counter (OTC) and homeopathic drugs and dietary supplements

EPA's Pharma Rule – The Big Picture

- EPA bans the flushing/sewering of all hazardous pharmaceutical hazardous waste in all states, effective Aug. 21, 2019
- EPA also amends the Nicotine Listing (P-75), no longer considering FDA-approved OTC nicotine replacement therapies to be "hazardous waste"
  - Used and unused gums, patches and lozenges can be disposed with trash
  - e-cigarettes, e-liquids still regulated as hazardous waste pharmaceuticals
- The Pharma Rule effective date is Aug. 21, 2019
  - Takes immediate effect on Aug. 21 in Iowa and Alaska
  - In all other states, the Subpart P requirements will not take effect until each state adopts rules implementing the federal rule
  - Compliance "gap"

History of Pharmaceuticals and RCRA

- Certain pharmaceuticals (e.g., warfarin, nicotine), considered "acute" haz waste when decision is made to discard; > 1kg./mo. triggers onerous Large Quantity Generator ("LGQ") standards
  - In 1981, EPA guidance to pharmaceutical manufacture: for product *returns (credit)*, the decision to dispose (point of generation) is made at the manufacturer's plant (RCRA Online 11012)
    - Thus, pharma is not a waste when it leaves the HCF; standards don't apply at HCF, even if pharma is hazardous
    - Alternatively, point of generation is the RD processing for credit
  - In 1991, additional guidance clarified that to remain "commercial chemical products," (i.e., not waste), pharmaceuticals must have a "reasonable expectation of recycling" (RCRA Online 11606)
- Connecticut, Washington, and Minnesota adopted state policies for pharmaceuticals under RCRA

Compliance Conundrums for HCFs and RDs under the RCRA System

- Does it make sense for HCFs and RDs disposing of warfarin and nicotine to be classified as LQGs (generating > 1kg/mo. of acute haz. waste)?

  → subject to full suite of management requirements

- How to manage non-Rx hazardous meds when shipped to RD for reuse or reclamation?
  - What is point where material is "discarded" and needs to be characterized?
- How best to manage used containers with residual medication?
  - Impractical "RCRA empty" rule
- Should chemotherapy agents be regulated as "toxic" under RCRA?

Compliance Conundrums for HCFs and RDs under the RCRA System

- What to do about contamination in wastewater treatment plant effluent due to sewering of unused pharmaceuticals?
- Is the “household waste” exemption for long-term care facilities appropriate?
- Complex DEA – EPA overlap: certain narcotics are DEA-scheduled and must be disposed of pursuant to regulations to ensure destruction and avoid diversion.

Pharma Rulemaking Process and Lingering Concerns

- 2008 – EPA proposed to include hazardous waste pharmaceuticals under the Universal Waste program (e.g, fluorescent lights, batteries)
  - Concerns regarding diversion of DEA compounds
  - Not finalized by EPA
  - But adopted by Florida and Michigan
- State, federal and industry partnership to provide guidance: *Managing Pharmaceutical Waste – A 10-Step Blueprint for Healthcare Facilities in the United States*, Aug. 2008

Pharma Rulemaking Process/Lingering Concerns

- 2010-2015 –further EPA evaluation of the sector and potentially unsafe management practices (including IG Report)
- Texas: *Study on the Methods for Disposing of Unused Pharmaceuticals*, Dec. 2010
- 2016: EPA released Retail Strategy, where it committed to developing a policy for reverse distribution for the entire retail sector, and to completing pharmaceutical rule.

Pharma Rulemaking Process

- 2015 – EPA proposed Pharma rule, 80 Fed. Reg. 58,014 (Sep. 25, 2015)
- 200+ comments filed, focusing on
  - Broad definition of “healthcare facility”
  - Detailed recordkeeping requirements
  - Lack of clarify on what constitutes creditable pharmaceuticals
  - How to manage small-scale pharmacies?

Final Rule – Key Definitions

- "*Health Care Facility*" means 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) Distributes, sells or dispenses Rx or OTC pharmaceuticals, dietary supplements or homeopathic drugs

- Includes hospitals, pharmacies, clinics, physician and dental offices, **long-term care facilities**, surgical centers, wholesale distributors and veterinary clinics, but <u>not</u> manufacturers or RD
- Includes veterinary clinics, but not ranchers or farmers

Final Rule – Key Definitions & Outcomes

- "*Long-term Care Facility*" – licensed entity that helps with daily activities, incl. administering pharmaceuticals
  - E.g., skilled nursing and hospice, but not group homes or assisted living facilities
- *"Potentially Creditable Hazardous Waste Pharmaceutical" – hazardous* ***Rx*** med waste with potential for manufacturer credit that is
  - In original packaging,
  - Undispensed, and
  - Unexpired or less than one year past expiration
    - **HCF may ship these wastes to RD for credit and ultimate disposal, or directly to licensed TSDF for disposal**

Final Rule – Key Definitions & Outcomes

- *"Non-creditable Hazardous Waste Pharmaceutical"* – either
  - a *Rx* hazardous pharmaceutical with no reasonable expectation for manufacturer credit, or
  - a *non-Rx* hazardous pharmaceutical with no reasonable expectation for reuse or reclamation
    - E.g., investigational drugs, free samples, residues remaining in empty containers, contaminated PPE, floor sweepings and med spill cleanup material
    - i.e., obviously a waste
  - **For these waste meds, the HCF is the waste "generator" and must ship directly to a licensed TSDF for disposal**
    - **Prohibited from sending to RD**

Final Rule – Definitions & Outcomes

- "*Pharmaceutical Reverse Distributor*" means
  - Any person that receives and accumulates potentially creditable ***Rx*** waste pharmaceuticals for the purpose of facilitating or verifying manufacturer's credit *(hazardous or non-hazardous)*
  - RD can be any forward distributor, third-party logistics provider and drug manufacturer that accepts hazardous meds for processing credits
    - EPA assumes that almost all Rx meds ultimately will be disposed of, rather than reused or reclaimed
- Compare to "Reverse Logistics" –
  - HCF may ship unused ***non-Rx non-hazardous*** waste pharmaceuticals as "product" to a reverse logistics center if there is reasonable expectation of reuse
  - Not covered by Subpart P

HCFs – Generator Requirements

- HCF must categorize all unused meds
  - Creditable or not; reasonably reusable or not
- HCF must determine whether the unused med, if not creditable or reusable, qualifies as a RCRA listed or characteristic hazardous waste
- HCF need not count monthly quantity of HW meds toward facility's generator status if meds are managed under Subpart P
- Hazardous waste pharmaceutical monthly quantities will not trigger "generator" categories of SQG or LQG
- Very Small Quantity Generators only subject to 40 CFR § 262.14

HCFs – Standards for Handling Non-Creditable Hazardous Waste Meds

- Training – for all personnel that "manage" non-creditable HW meds re: handling and emergency procedures
- Container Labeling – "Hazardous Waste Pharmaceuticals"
- One year accumulation limit, tracked by inventory, container labeling, or record in accumulation area
- Shipping:
  - manifest (with "PHARMS" code instead of EPA waste code)
  - Packing, labeling and marking per DOT requirements

Reverse Distributor Requirements

- RDs receive potentially creditable Rx hazardous waste, and must
  - Maintain an ongoing inventory of all potentially creditable hazardous waste pharmaceuticals on-site
  - "Evaluate" the creditability of pharmaceuticals within 30 calendar days of receipt
    - If evaluation is completed and pharmaceutical is ready to be shipped for disposal, it's deemed an "*evaluated hazardous waste*"
    - Otherwise, pharmaceutical may be shipped to another RD for further evaluation, and then shipped for disposal as an evaluated hazardous waste

Reverse Distributor Requirements

- Accumulation time limited to 180 days
- Separate 180 day limit for expired pharmaceuticals
- Designated accumulation area, weekly inspections, compatible storage requirements, and training program
- Facility security requirements to avoid diversion
- Contingency plan and emergency procedures
- Recordkeeping: maintain inventory of all pharmaceuticals on-site, confirmation of delivery from HCF, and US DOT shipping papers

Recordkeeping & Notifications

- Must notify EPA that operating under Subpart P
- RDs must confirm receipt of shipments, and HCFs must notify RDs if no confirmation is received
- RDs must maintain for three years details on each shipment of *potentially creditable hazardous* waste received
- Records must be maintained longer if an enforcement action is initiated
- Potentially-creditable HW meds not subject to biennial reporting

Important Changes in Current Practice: Ban on Disposal by Sewering

- Rule bans disposal of HW pharmaceuticals by sewering
  - Applies to all health care facilities and reverse distributors
  - Ends prior practice of using sewering as a means of destroying DEA-scheduled (controlled) substances

Important Changes in Current Practice: RCRA Empty Requirements for Pharma

- Rule exempts certain containers from "RCRA empty" requirement that containers be triple-rinsed, or cleaned by another method to achieve equivalent removal
  - Unit-dose containers (*e.g.*, packets, cups, wrappers, blister packs and unit-dose delivery devices)
- Dispensing bottles and vials up to 1 liter or 10,000 pills
- Dispensed syringes placed in sharps containers
- All other containers that once held listed or characteristic pharmaceuticals must be managed as hazardous waste

Important Changes in Current Practice: Overlapping DEA/EPA Regulation

- Two conditional exemptions
  - DEA controlled substances
  - DEA controlled substances comingled with exempt household hazardous waste (HHW) pharmaceuticals under take-back programs
  - Must be managed in accordance with all DEA regulations
  - Must be incinerated at a permitted facility (municipal or hazardous waste incinerator)

State Implementation

- For all states other than Iowa and Alaska, states have delegated RCRA regulatory authority
- States will need to draft, propose and adopt implementing regulations for Part 266, Subpart P compliance
- Because the nicotine redesignation is considered to be less stringent than current law, states are not required to adopt that change into their codes
- However, sewering ban takes effect nationally for all states
- Potential result is a patchwork for state-by-state compliance

Interim Compliance

- Mind the (compliance) gap—immediate noncompliance issue that states must cure with new rules
  - ". . . EPA's revised interpretation that the point of generation for prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals is at the healthcare facility, not the reverse distributor . . . " (84 Fed. Reg. at 5917)
  - BUT, Subpart P protections will only apply in 48 states *after* state adoption of new regulations, after months or years of process
- Will states exercise enforcement discretion?

Interim Compliance

- Many states mirrors federal policy regarding when a valuable product becomes hazardous waste
  - Preamble to final rule states that waste determination is made by the HCF, not by the RD.
  - Technically means that numerous HCFs are in noncompliance until new rules are adopted
- "Gap" period after federal rule finalized and before state rule package put into effect, when non-prescribed pharmaceuticals technically "hazardous waste" without revised process
  - Uncertainty for regulated facilities
  - Enforcement discretion memorandum?

Regional Implementation

- Michigan and Florida:
  - Currently include pharmaceuticals under their universal waste regulations
  - They will be required to revise their programs to adopt Subpart P requirements
- Wisconsin and Illinois:
  - No current state programs addressing haz waste pharmaceuticals
  - Enforcement discretion pending adoption of Subpart P?

California

- Hazardous vs. Medical Waste
  - DTSC – hazardous waste under the Hazardous Waste Management Act and RCRA
  - CDPH – medical waste under Medical Waste Management Act
- Reverse Distribution considerations
  - History of enforcement – from 2009 through 2015 DTSC targeted retail chains with pharmacies related to reverse distribution
  - Strong comments on draft rule
- Prohibitions on “sewering” already in place
  - Lindane
  - Certain counties have programs in place (Alameda, Contra Costa, Sacramento)
- DTSC has a more stringent interpretation of containers – containers with residues make the entire container (not just the residue) subject to treatment as a hazardous waste, which impacts tonnage and fee calculations
- DTSC guidance considers, and rejects, 2011 U.S. EPA guidance, taking the position that California’s RCRA program is more stringent than federal law requires

Texas

- Generally mirrors federal program for pharmaceuticals
- Texas Commission on Environmental Quality's current plan for adopting Subpart P is unclear
  - One package of miscellaneous RCRA "fixes" tentatively scheduled for proposal in fall of 2019; adoption in June 2020
    - May include Subpart P
  - But Subpart P relies on certain RCRA terms and provisions that are expected to be amended in the miscellaneous package
    - Must Subpart P wait for a second package?
    - 3 year deadline
  - Discussions concerning industry guidance, enforcement discretions, other potential compliance strategies

How Best to Prepare?

- Expansive definition of HCFs may include entities who are caught unaware:
  - Long term care facilities (LTCFs): previously treated as exempt under the household waste exclusion are now HCFs (except assisted living)
  - "[I]ncludes, but is not limited to, wholesale distributors, third-party logistics providers that serve as forward distributors, military medical logistics facilities, hospitals, psychiatric hospitals, ambulatory surgical centers, *health clinics, physicians' offices, optical and dental providers, chiropractors, LTCFs*, ambulance services, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of pharmaceuticals, and veterinary clinics and hospitals."
- Future enforcement actions?

How Best to Prepare

- Who owns compliance?
  - Who handles and sorts waste materials?
  - Who maintains waste inventory records?
  - Who prepares hazardous waste shipping records?
  - What training do staff have regarding disposal of warfarin/Coumadin and other hazardous meds?
- Audit compliance against hazardous waste regulatory checklist
- Identify and address gaps; audit again
- Consider state audit disclosure immunity programs

Longer Term

- Upgrade HCF Internal Procedures and Training
  - HCFs need to implement recordkeeping to flag when shipments to RDs are not acknowledged
  - Directly contract with TSDFs for “non-potentially creditable” hazardous waste pharmaceuticals
  - Develop process to avoid mis-shipment of non-creditable materials to RDs
  - Ensure that selected RDs are qualified and reputable
- LTCFs must determine generator status, plan to comply with rule requirements

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Sarah divides her time between development/redevelopment work, environmental compliance counseling, transactions and environmental litigation. Sarah has extensive experience on the cutting edge of Clean Air Act, Clean Water Act, Superfund, and RCRA enforcement, as well as citizen suit litigation, settlement strategies, and related cost recovery, insurance coverage, and indemnity disputes. Sarah also provides counsel to clients regarding air emissions, waste management, underground storage tank compliance, water discharge permitting and compliance, and on a variety of compliance matters related to chemicals and chemical usage, including under California's Proposition 65.

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Environmental lawyer Laura Whiting, a partner in Foley Gardere's environmental practice group, brings to the table over 27 years of experience assisting clients with all aspects of environmental regulatory compliance and permitting for heavily regulated industries and real estate developments. She focuses her practice on state and federal enforcement and compliance counseling under the Clean Air Act, RCRA, CERCLA, Clean Water Act, incident investigations, regulatory advocacy, and product stewardship requirements, as well as the ongoing need to conduct thorough due diligence and cost-effective remediation and cost recovery.

Laura is committed to achieving clients' goals through leadership, teamwork, advocacy and precise documentation, particularly in the environmental and process safety areas for chemical manufacturing, oil and gas production, pipeline, airline and real estate clients. She is a trusted advisor, who is adept at communicating effectively at all levels of the client organization and with outside stakeholders.

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Thank you!

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