# Hazardous Waste Federal Rules Alignment 2021

## Hazardous Waste Program

April 27, 2021
Virtual Meeting via Zoom

# OVERVIEW

- Welcome!
- Review Logistics and Expectations
- Agenda and Schedule
- Questions

# REVIEW: Considerations

| Impacts |
| --- |
| Businesses |
| Environment |
| HW Program |
| Other Programs |

| Other States |
| --- |
| Adopted |
| Not Adopted |
| Partial Adoption |
| Equivalent Adoption |

| Implementation |
| --- |
| Business Outreach |
| DEQ Staff Training |
| Enforcement |
| Systems Requirements |

# REVIEW

- Last meeting’s highlights
- Additional comments
- Anything else?

# Common Terms

- Resource Conservation and Recovery Act (RCRA)
- Hazardous and Solid Waste Amendments (HSWA)
- Code of Federal Regulations (CFR)
- Adopt by reference
- Program Authorization
- Less or More stringent
- Exemption
- Exclusion
- Treatment, Storage and Disposal Facility (TSDF or TSDs)

# Hazardous Waste Generator Improvements Rule

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# Generator Improvements Rule (GIR): Background

EPA evaluated generator program from 2004 to 2014

Goals:

- Improving effectiveness
- Reducing compliance costs
- Fostering improved relationships

GIR is based on feedback to EPA

# Generator Improvements Rule: Reorganization

- Conditionally Exempt Generator → Very Small Quantity Generator
- Generator requirements from 265 copied into 262
  (e.g. emergency preparedness and container management)

| Provision | Existing Citation | New Citation |
|---|---|---|
| **Generator Category Determination** | 261.5(c)-(e) | 262.13 |
| **VSQG Provisions** | 261.5(a), (b), (f)-(g) | 262.14 |
| **Satellite Accumulation Area Provisions** | 262.34(c) | 262.15 |
| **SQG Provisions** | 262.34(d)-(f) | 262.16 |
| **LQG Provisions** | 262.34(a), (b), (g)-(i), (m) | 262.17 |

# GIR: Satellite Accumulation Areas

262.15 Clarifications:

- Allows containers to **remain open temporarily** when necessary for safety
- “Three days” means **three consecutive calendar days** before moving to storage or off-site
- “**Under control of the operator**”
- **Labeling requirements** consistent with central accumulation areas: “hazardous waste”
- Subject to **incompatibility** and **emergency preparedness requirements**

# GIR: Hazardous Waste Determination (HWD)

- ✓Must be **accurate** and made **at the point of generation**
- ✓SQGs and LQGs **must maintain records**, including records which explain knowledge basis for determination
- ✓If testing, **must manage as hazardous until test results are received -** codifies prior guidance
- ✓**Must determine generator category**, based on amount generated per calendar month

# GIR: Exemption vs Independent Requirement

**Exemption conditions from permit requirement: 262.14-17**

- Container and tank standards
- Preparedness and prevention
- Training

**Independent requirements: 262.10(a)(1)**

- Hazardous Waste Determination
- Determining generator category
- Manifesting
- Most recordkeeping

**Note: States continue to retain discretion and authority**

# GIR: New Labeling Requirements

1. When generated, label containers and tanks with **hazard**

2. Prior to off-site shipment to TSDF, mark container with **waste codes** of contents

**Examples of Nationally Recognized Hazard Labels**


**Ignitable Liquid**
Department of Transportation (DOT) warning label or placard

**Toxic Substance**
Occupational Safety and Health Administration pictogram


**Reactive Liquid**
National Fire Protection Association hazard identification system

Source: EPA

# GIR: Emergency Preparedness

**Contingency Plan - Quick Reference Guide (QRG)**

**Requires eight elements**:

1. Types/names of hazardous waste, and associated hazards
2. Estimated maximum amounts of hazardous waste
3. Hazardous waste requiring **special treatment**
4. Map showing generation, accumulation or treatment
5. Evacuation facility map
6. Location of water supply
7. On-site notification systems
8. Emergency coordinator(s) contacts

- New LQGs must submit together
- Existing LQGs must include QRG when updating contingency plan

# GIR: LQG Closure

Requires:

- Documentation of closure of waste accumulation area
- Notify DEQ when close facility
  - No later than 30 days prior to closure
  - Within 90 days after closure if can’t clean close **must close as a landfill**

# GIR: “Optional” Provisions

**Less stringent – adoption optional**

Three optional provisions:

- 50-foot property line rule – waiver option
- LQG Consolidation
- Episodic Generation

# GIR: LQG Consolidation

- VSQG ships HW, **without manifest**, to LQG **under control of same person**
- **No TSD permit required**

| LQG Responsibilities | VSQG Responsibilities |
|---|---|
| Notify: Site ID Form (8700-12) | Label containers: “Hazardous Waste” + hazards |
| Label containers: Accumulation start date | |
| Records: For each shipment, three-year retention | |
| Manage all waste as LQG waste | |

# GIR: Episodic Generation

Allows generator to **maintain existing generator category** provided compliance with streamlined requirements:

- **One event** per calendar year with opportunity to **petition for a second**
- **Notify DEQ prior** to **planned event** (proposing **60 days** prior in Oregon)
- **Proposing prior written approval from DEQ required for planned events**
- **Notify DEQ** by phone, fax or email **within 72 hours** of **unplanned event**
- **Complete event and manifest/treat** all waste within **maximum 60 days**
- Accumulation and records requirements

# GIR: Episodic Generation

**Short Term Generator**: One-time, non-recurring, temporary event that is not related to normal production processes.

Short-term generators produce hazardous waste from **a particular activity for a limited time** and then cease conducting that activity.

EPA Examples-(1) one-time highway bridge waste generation; (2) underground storage tank removals; (3) generation of off-specification or out-of-date chemicals at a site that normally doesn't generate hazardous waste; (4) remediation or spill clean-up at sites with no previous RCRA EPA Identification Number; and (5) site or production process decommissions by a new operator.

# GIR: Episodic Generation

| Episodic Event Type Options in EPA RCRAInfo | |
|---|---|
| **Planned Event** | **Unplanned Event** |
| Short-term Construction or Demolition | Act of Nature |
| Excess Chemical Inventory | Accidental Spill |
| Equipment Maintenance During Plant Shutdown | Product Recall |
| Tank Clean-out | Production Process Upset |
| Other | Other |

# GIR: Episodic Generation

**New OAR 340-102-0230**, **Episodic Generation**

- All episodic generators, including VSQGs, must:
  - Obtain a Department or EPA identification number
  - Report to DEQ
  - Pay hazardous waste generation fees
- Unplanned events: Submit written notification within five days of initial 72-hour notification
- Planned events:
  - Notify DEQ 60 days in advance of initiating a planned episodic event.
  - Planned events require prior written Department approval to qualify as episodic.

# GIR: Episodic Generation

| DEQ New OAR 340-102-0230 | |
|---|---|
| **EPA GIR** | **DEQ More Stringent** |
| 30 day notification for planned event | 60 day notification for planned event |
| 72 hour initial notification for unplanned event with follow-up 8700-12 Site ID notification | 72 hour initial notification for unplanned event with follow-up DEQ Site ID notification within 5 days of initial 72 hour notification |
| Written approval for second petitioned event | Written approval for first event and second petitioned event |
| Biennial Report for LQGs. No report fees | Annual report for all episodic events. Generation and management fees |

# GIR: Oregon Impacts

**DEQ**:

- Implementation
- Staffing

**Regulated community**:

- Education
- Increased management flexibility

# GIR: Fiscal Impacts

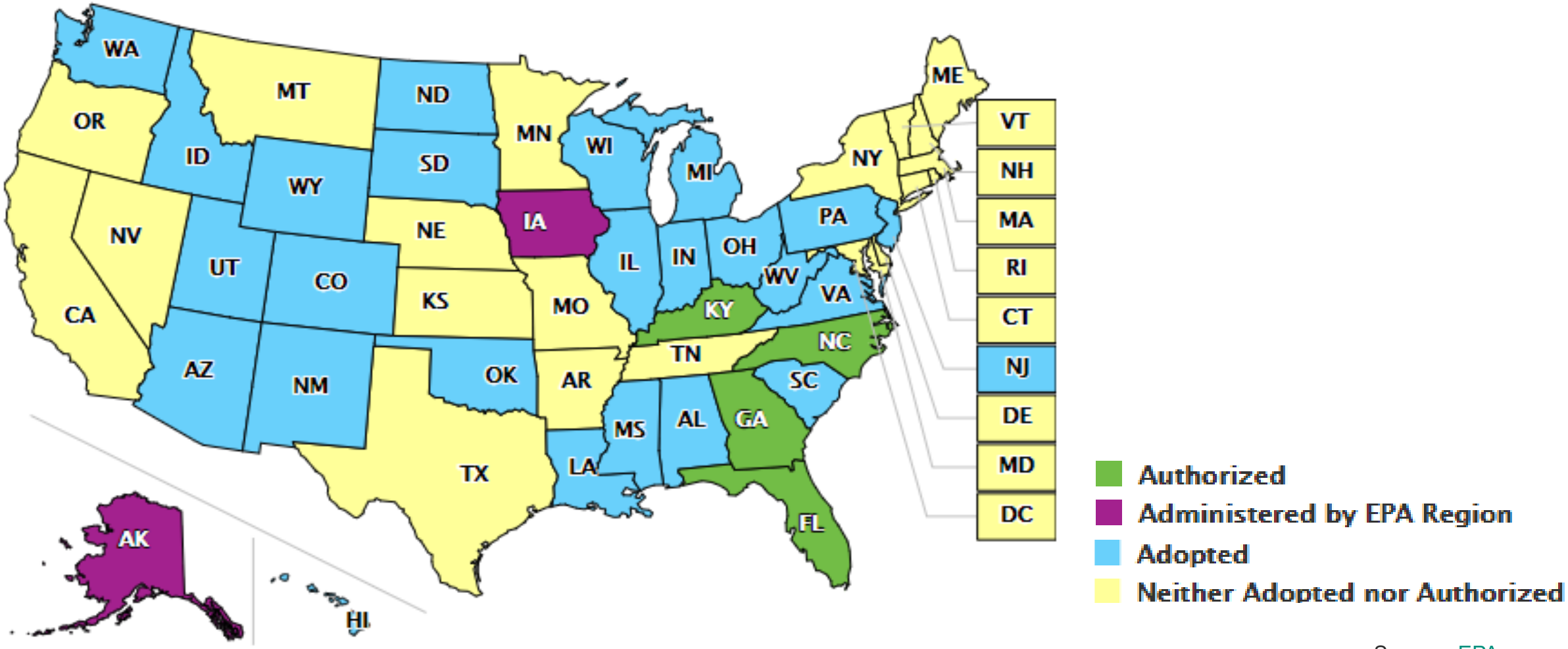
**DEQ:**

- Minimal impact to fee revenue

**Regulated community:**

- Potential savings

# GIR: State Adoption




Source: EPA

# GIR: Recommendations

- ✓ Adopt all mandatory provisions by reference
- ✓ Adopt optional provisions:
  - Episodic Generation, with amendments
    - Planned-60 day notification/unplanned-initial 72 hr then 5 day notification, written approval, report and fees
  - LQG Consolidation, by reference
  - 50-foot property line waiver, by reference

# Generator Improvements Rule

Questions?

# Generator Improvements Rule

As with any rulemaking advisory committee, DEQ must ask:

- Will the proposed rule have a fiscal impact?
  - If so, what will the extent of that impact be?

- Will rule changes have a significant adverse impact on small businesses?
  - If so, what can DEQ do to mitigate that impact?

# Division 12 Enforcement

Sarah Wheeler, Environmental Law Specialist
Office of Compliance and Enforcement

# Division 12: Review

**Oregon Administrative Rules (OAR) Chapter 340, Division 12**

OAR 340-012-0026 – 340-012-0170

– Rules that direct how DEQ issues penalties.

– Division 12 rules do not impose requirements on regulated facilities.

# Division 12: Review

Revisions to Division 12 included in this rulemaking to:

- Ensure DEQ can issue fair and appropriate civil penalties for noncompliance with the adopted rules.
- Meet the goals of enforcement.

# Division 12 Amendments: GIR

**Proposed Class I Change to OAR 340-012-0068(1)**

(a) Failing to make or document a complete and accurate hazardous waste determination of a residue as required; ~~by OAR 340-102-0011~~

….

(u) Failing to accurately determine generator status.

# Division 12 Amendments: GIR

## Proposed Class II Change to OAR 340-012-0068(2)

(b) Failing to label tanks or containers ~~a tank having a capacity of 100 gallons or more, or containers equaling more than 110 gallon capacity~~ used for accumulation or storage of hazardous waste with "hazardous waste," hazards of the contents, or waste codes;

(v) Failing to timely notify DEQ of LQG closure;

(w) Failing to comply with episodic generation conditions, not otherwise classified; or

(x) Failing to notify, keep records, or other requirements for consolidation of VSQG waste at LQG owned by the same person, by the LQG;

# Division 12 Amendments: GIR

Questions?

# Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine

Bart Collinsworth, Hazardous Waste Technical Assistance Specialist, Western Region
Chris Bayham, Hazardous Waste Inspector, Western Region
Mary Fritzmann, Hazardous Waste Reporting & Invoicing Coordinator, Headquarters

# Pharmaceutical Rule and P075 Amendment

**P075:** less stringent, adoption not mandatory

- Very specific listing amendment
- Waste specific
- Not sector specific

**Pharmaceutical Rule:** more stringent, adoption mandatory

- Waste specific
- Sector Specific
- Applies to LQGs, SQGs, Reverse Distributors and VSQGs that opt-in
- VSQGs are subject to **sewer ban**, container standards, and optional provisions, without opting in

# P075: Nicotine Replacement Therapies

Nicotine Replacement Therapies
P075 Amendment


Lozenges


Gum


Patches

P075[1]54-11-5 Nicotine & salts
Does not include patches, gums and lozenges that are FDA-approved over-the-counter nicotine replacement therapies.

# Pharmaceutical Rule: What? Who?

**Pharmaceuticals:**

- Dietary supplements
- Prescription and OTC drugs
- Homeopathic drugs
- Investigational new drugs
- Pharmaceutical residues in nonempty containers
- PPE-contaminated with pharmaceuticals
- Cleanup material from spills of pharmaceuticals

- **Facilities subject to 266 subpart P:**
- Healthcare Facilities (regarding their HW pharma)
  - LQGs, SQGs, and VSQGs that opt-in
- Reverse Distributors

**Still P075** – but may go out as PHARMS at a healthcare facility:

--*Electronic nicotine delivery systems*

--*Nicotine e-liquid and e-juices packaged for resale*

# Pharmaceutical Rule

**Healthcare Facilities:**

- Wholesale distributors
- Military medical logistics facilities
- Hospitals and psychiatric hospitals
- Health clinics, physicians' offices, chiropractors
- Optical and dental providers
- Pharmacies
- Long term care facilities
- Veterinary clinics

**Types of Pharma waste:**

- Non-creditable
- Potentially creditable
- Evaluated

**Not Healthcare Facilities**

- Pharma manufactures
- Reverse distributors

-Sewer ban
-Non-haz pharm
-Determs. and (incentive)
-LDR
-Count all waste determ gen. size
-Once in don’t count HW pharm
-No size category for HCF or RDs

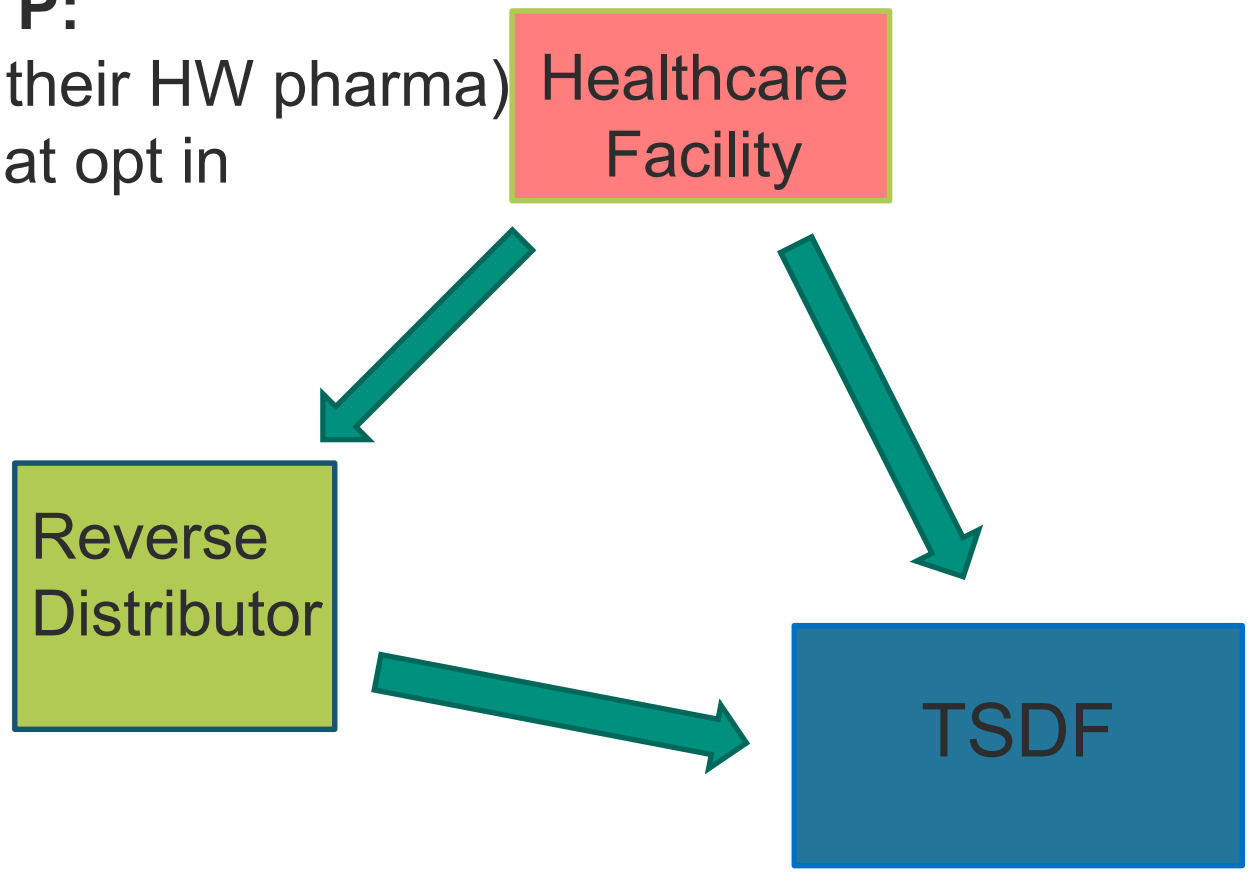
# Pharmaceutical Rule: Types of Facilities & Waste

**Facilities subject to 266 subpart P:**

- Healthcare Facilities (regarding their HW pharma)
  - LQGs, SQGs and VSQGs that opt in
- Reverse Distributors

**Types of Pharma waste:**

- Non-creditable
- Potentially creditable
- Evaluated



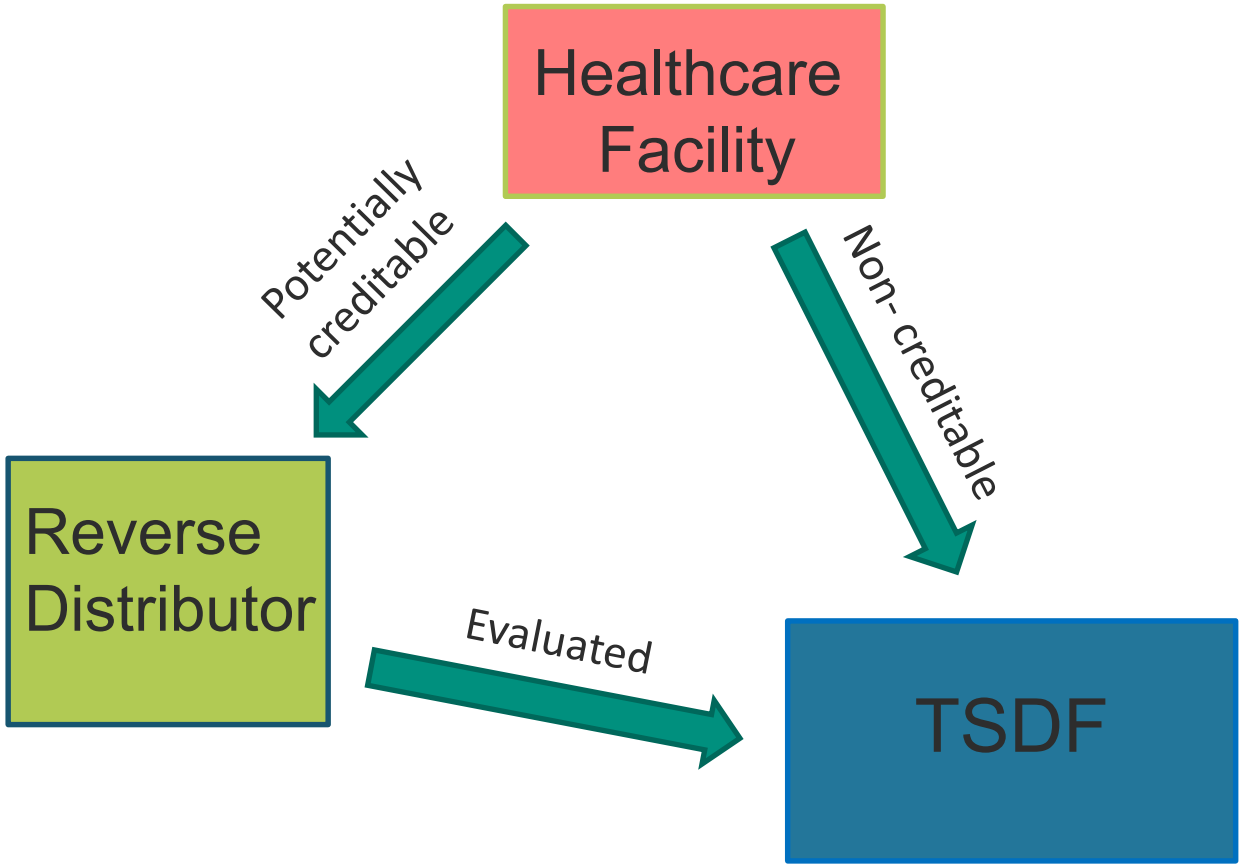
# Pharmaceutical Rule: Types of Pharma Waste

**Non-Creditable**
Broken or leaking
Repackaged
Dispensed
Expired over a year ago
Investigational new drugs
Contaminated PPE
Floor sweepings
Clean-up material

**Potentially Creditable**
Original manufacturer packaging (except recalls)
Undispensed
Unexpired or less than one year past expiration

**Evaluated**
No further evaluation or verification of manufacturer credit is necessary

# Pharmaceutical Rule: Waste Flow



# Healthcare Facilities Management Standards

| | Non-creditable HW Pharms | Potentially creditable HW Pharms |
|---|---|---|
| Notification | ✓ **HCFs Notify** | |
| Labeling | **HW Pharmaceuticals** | None |
| Container standards | ✓ | None |
| Max accumulation time | 1- year (UW like) | None |
| Biennial reporting | None* | None |
| Employee training | ✓ | None |
| Weekly inspections | None | None |
| Manifest | ✓ PHARMS | None |

*No reporting – just notify; *VSQGs opt-in/withdraw*

# Reverse Distributor Management Standards

| | Potentially creditable HW Pharms | Evaluated Pharms |
|---|---|---|
| Notification | ✓ | **RDs Notify** |
| Labeling | None | "HW Pharma" during accumulation |
| Container standards | None | ✓ |
| Max accumulation time | 30 days to evaluate | 180 days |
| Contingency Plan | Yes | Yes |
| Employee training | None | Yes – LQG like |
| Biennial reporting | None | Yes* |
| Weekly Inspections | None | ✓ |
| Manifest | None | ✓ |

# Pharmaceutical Rule: Empty Containers

| Type of Container | RCRA Empty: Non-Acute HWP | RCRA Empty: Acute HWP |
|---|---|---|
| Stock/Dispensing Bottles (1 liter or 10,000 pills) & Unit Dose Containers | Remove Contents | Remove Contents |
| Syringes | Fully Depress Plunger | Fully Depress Plunger |
| IV Bags | Fully Administer Contents or Meets 40 CFR § 261.7(b)(1) | Fully Administer Contents |
| Other Containers (includes, but is not limited to: inhalers, aerosols, neutralizers, and tubes or ointments, gels or creams) | Meets 40 CFR § 261.7(b)(1) or (2) | Cannot be RCRA Empty |

# Pharmaceutical Rule: VSQG Optional Provisions

## VSQGs - for both HW Pharma & Non-pharma HW:

- May send potentially creditable pharma to Reverse Distributor
- May send "*HW Pharma" to another Healthcare Facility
  - Meets 266.502(l), 503(b)
- May send HW Pharma to an LQG
  - VSQG meets 262.14(a)(5)(viii), LQG meets 262.17(f)

## Long Term Care Facilities that are VSQGs:

- May dispose HW Pharma, with exceptions, in onsite receptacle of a Drug Enforcement Agency authorized collector
- With 20 beds or less is presumed to be a VSQG

# Pharmaceutical Rule: Fiscal Impacts

**Reduces compliance costs:**

- Over-the-counter products be disposed as solid waste
- No LQG-like training requirements for HCFs
- Provides flexibility for HW determinations for Pharms
- Exemption for DEA-controlled substances
- Clarifying RCRA empty for HW Pharms containers

**Small Businesses:**

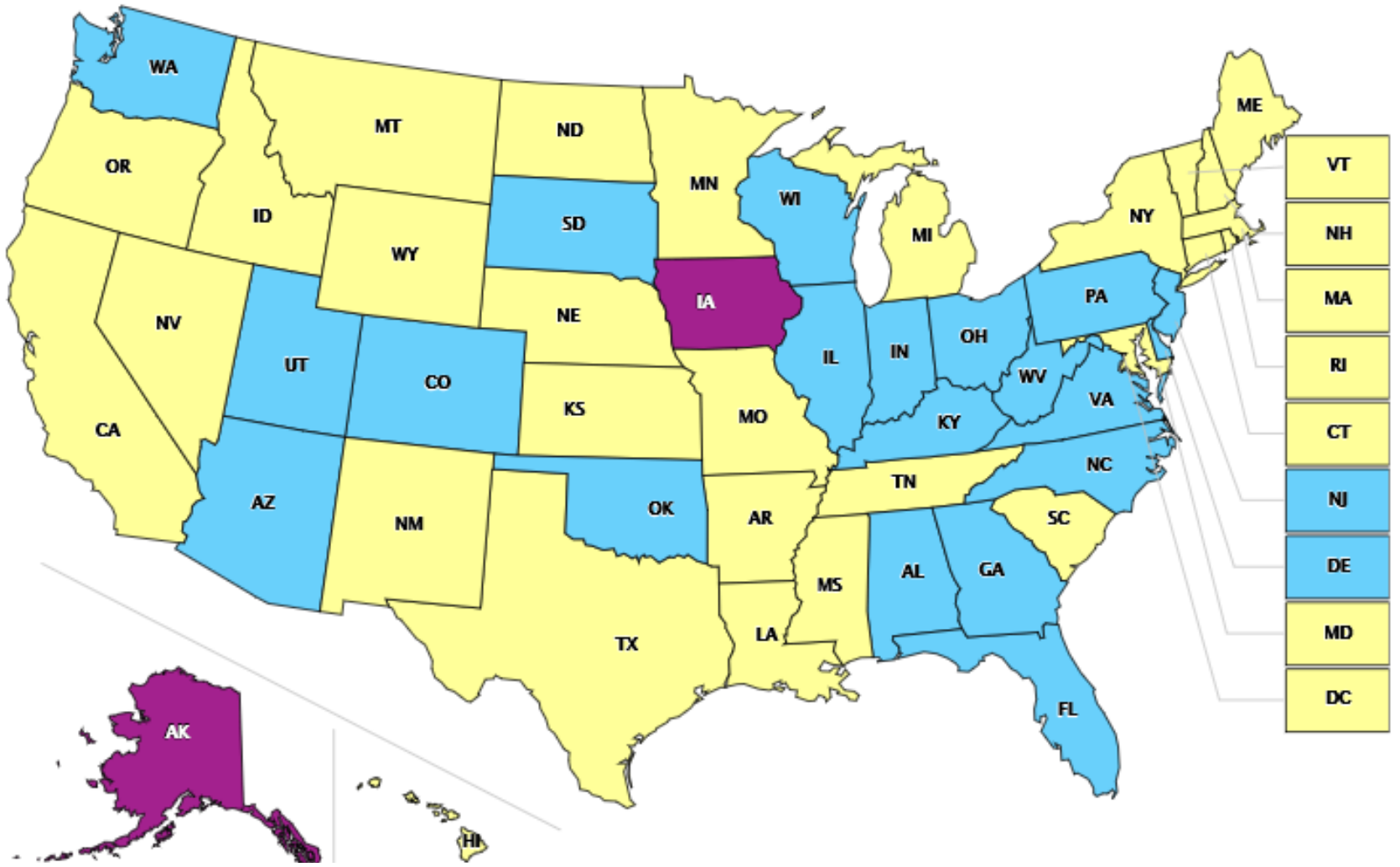
- 0.13% of HCFs' and 0.002% of Hospitals' revenue
- $5,300 annually for small Reverse Distributors

# Pharmaceutical Rule: Fiscal Impacts

**Impacts to DEQ**

- P075-Nicotine: Loss of activity verification (LQG/SQG) fees ~$8,500-$14,200 from big box store pharmacies
- Pharmaceuticals: Loss of activity verification (LQG/SQG) fees ~$14,300 from hospital and medical center pharmacies
- Pharmaceuticals: Loss of generation fees ~$10,000
- Possible total loss of fees ~$40,000, about 1.86% of 2019 total generator fees
- Other costs: outreach and education, updating webpages and documents, training

# Pharmaceutical Rule and P075: State Adoption




Authorized

Adopted

Administered by EPA Region

Neither Adopted nor Authorized

Source: EPA

# Pharma & P075: Recommendations

**P075:** Less stringent, optional adoption: Adopt by reference

## Pharmaceutical Rule:

- Adopt mandatory rule by reference, **except**:
  - Notification on Oregon Site Identification form for all Healthcare facilities and Reverse Distributors **within 60 days of being subject to the rule**
  - **Do not adopt** less than 20-bed Long Term Care Facility VSQG presumption
  - **Do not adopt** more flexible options for proving one-year accumulation
    - **use only option for labelling each container**
  - Reverse Distributors **report annually to DEQ**, not biennially to EPA
  - For empty container residuals **follow 110 gals not 119 gals** per DEQ definitions

# Pharmaceutical Rule and P075 Amendment

Questions?

# Pharmaceutical Rule and P075 Amendment

As with any rulemaking advisory committee, DEQ must ask:

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# Division 12 Amendments: Pharmaceutical Rule

**Summary of proposed changes** – Classifications

New Class is in 0068(1)(v)-(aa):

- Failing to notify or withdraw for Healthcare Facilities (HCF) or Reverse Distributors (RD)
- Sewering hazardous waste pharmaceuticals
- Transportation of HW other than potentially creditable hazardous waste pharmaceuticals to a RD
- Failing to submit an unauthorized waste report
- Accepting HW pharma at a facility not authorized to manage it
- Failing to provide confirmation that shipment arrived at RD

# Division 12 Amendments: Pharmaceutical Rule

**Summary of changes** – Classifications and Penalty Matrix

- Added categories of hazardous waste pharmaceuticals, healthcare facilities, and reverse distributors to existing I, II, and III classifications (e.g. closure plan, spills, labeling, inspections, storage)

- Penalty Matrix for Reverse Distributors ($8,000)

# Division 12 Amendments: Pharmaceutical Rule

Questions?

- Timeline and next steps
- Questions?