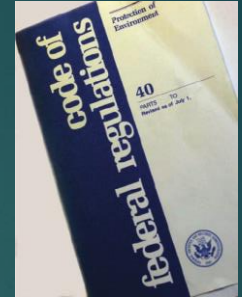




Federal (Hazardous Waste) Pharmaceutical Rule



Compliance Assistance for Briefing for RegForm

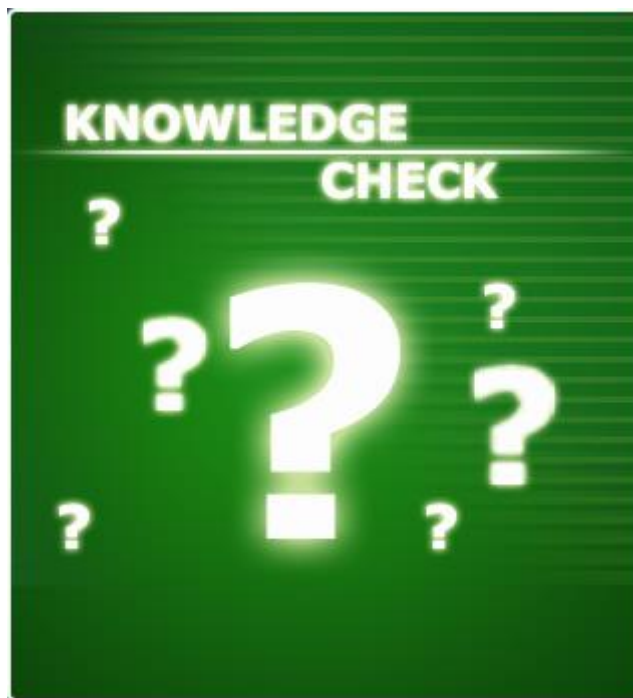
Marcus Rivas

Hazardous Waste Program, EPA Region 7

9.40a, 07 November 2019



Learning aid



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



“Pharma”
Rule

Pharma Rule Overview Summary

- ▶ Why it's a big deal & effective dates
- ▶ Sewer prohibition
- ▶ Impacted (& **NOT** included) classes
- ▶ Key rule elements
- ▶ Planned Outreach



Pharma Rule Overview Summary

This is a quick and broad overview.

The 'deep dive' occurs in the lowa workshops (more on those in a bit).



Pharma Rule

6

A big deal for RCRA...

- ▶ Relax definitions of P075 (nicotine)
- ▶ Re-defines “empty” container for HWP
- ▶ Dispositions for HHWP & DEA collection programs



Why the Pharma Rule?

Part 266 subpart P

- ▶ Better **regulatory fit** for healthcare sector
- ▶ **Eliminate sewerage** hazardous waste pharmaceuticals
- ▶ Reduce overlapping regulations (e.g., DEA, FDA)

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Part 266 subpart P

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Subpart P & RL

- Provide **clarity and consistency** for reverse distribution & reverse logistics

Why the Pharma Rule?

Part 266 subpart P

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Subpart P & RL

- Provide **clarity and consistency** for reverse distribution & reverse logistics

Part 261

- **Reevaluate nicotine** replacement therapies as acute hazardous waste

Pharma Rule Effective Date

- ▶ Signed 11 December 2018
- ▶ Promulgated 22 February 2019
[84 Federal Register 5816](#)
- ▶ **Effective 21 August 2019** in Iowa, Alaska, Indian Country & Territories

December 2018						
S	M	T	W	T	F	S
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31					

February 2019						
S	M	T	W	T	F	S
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28		

August 2019						
S	M	T	W	T	F	S
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

Timeline - Dates & Adoption

Feb 22
2019

August 21
2019

July 1
2020

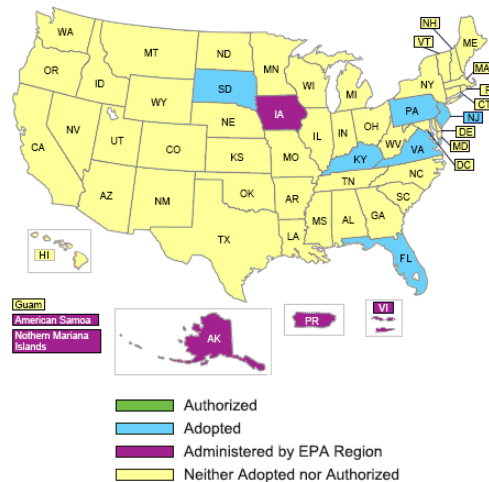
July 1
2021

Federal Register
publication
[84 FR 5816](#)

- **Nicotine amendment** effective in Iowa, AK, & Indian Country
- **Subpart P** effective in Iowa, AK, & Indian Country
- **Sewer Prohibition** effective in ALL States

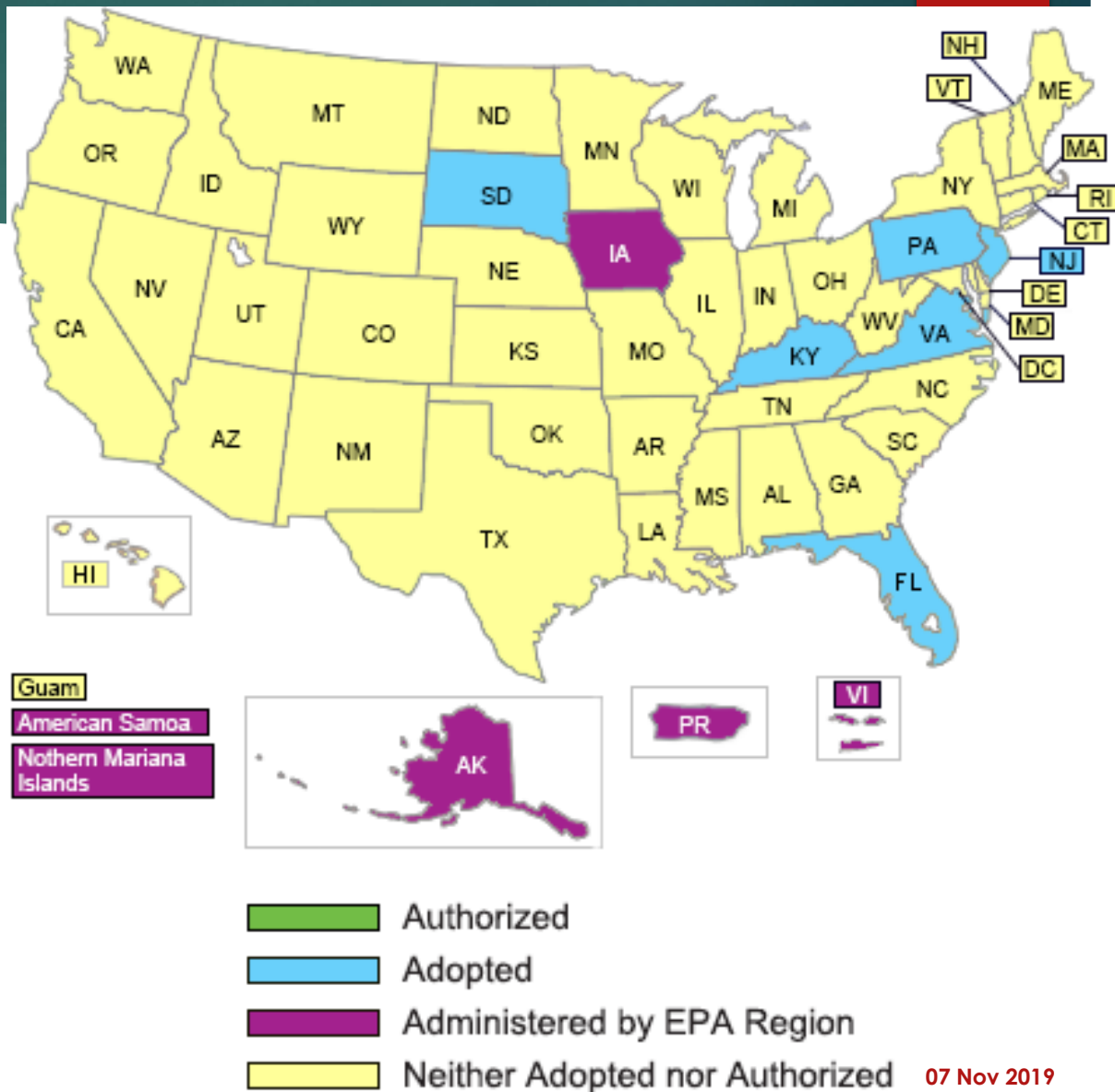
Authorized States must adopt subpart P

Authorized States that require a **statutory amendment** must adopt subpart P



Map

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



Pharma Rule

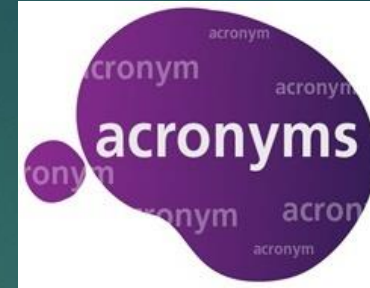
Sewer Prohibition

- ▶ Effective **21 August 2019** in all States, Indian Country and Territories
- ▶ Coordinated with DEA
- ▶ Applies to HWP, but ripples



Reference

14



- ▶ Hazardous Waste Pharmaceutical (HWP)
- ▶ Healthcare Facility (HCF)
- ▶ Household HWP (HHWP)
- ▶ Reverse Distributor (RD)

Pharma Rule Impacted Class

- ▶ Distribute or sell wholesale or retail
- ▶ General merchandisers
- ▶ Veterinary services
- ▶ Practitioners

continued

Pharma Rule Impacted Class

continued

- ▶ Non-residential care centers -
hospitals & clinics
- ▶ Residential care centers -
nursing homes, long-term, & hospice
- ▶ Reverse Distributors

Pharma Rule Impacted Class

NOT included

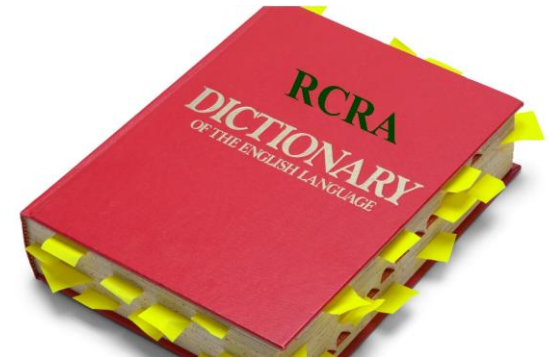
- ▶ Pharmaceutical manufacturers – unless as Reverse Distributor
- ▶ Farmers, Ranchers, & Fisheries
- ▶ Household usage [household hazardous waste]

Pharma Rule

Key rule elements

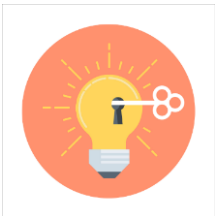


- ▶ Pharmaceutical (& HWP)
- ▶ Potentially creditable HWP
- ▶ Non-creditable HWP
- ▶ Evaluated HWP

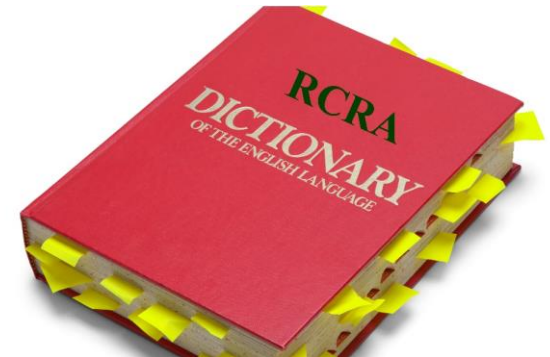


Pharma Rule

Key rule elements



- ▶ Healthcare Facility
- ▶ Long-term Care Facility
- ▶ Reverse Distributor
- ▶ Reverse Logistics



Pharma Rule On-going Outreach



▶ My contact info in the final slide

▶ National web support

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

Pharma Rule On-going Outreach



Compliance Assistance Website
www.epa.gov/ks/Pharma-Rule

- ▶ FAQs
- ▶ Key guidance documents
- ▶ Presentations
- ▶ Inspection checklists
- ▶ Fact Sheets
- ▶ Other? [what do YOU want?]

DEA Controlled Substances

(Take Back Day)

The next **National Prescription Drug Take Back Day** will likely be in April 2020. To find an authorized collector near you, go to

<https://apps2.dea.diversion.usdoj.gov/pubdispsearch/spring/main?execution=e1s1>

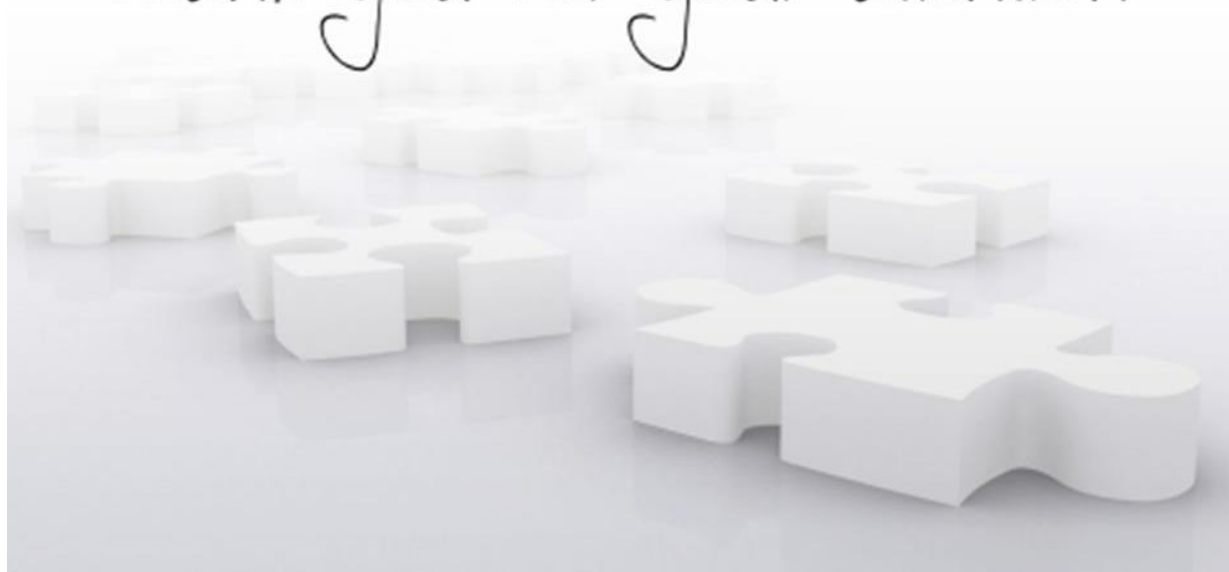


<https://takebackday.dea.gov/>

...a safe, convenient, and responsible way for households to dispose of unused or expired prescription drugs.

THANKS! ...

thank you for your attention



Questions/Clarify

