



NJDEP Subpart P Implementation

December 13, 2022

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Agenda

Subpart P Rule Summary

NJDEP Timeline – Implementation
of Subpart Rule

Inspections at Healthcare facilities

Violations at Healthcare facilities

Inspector's Experiences

Challenges / What's Next



Hazardous Waste Pharmaceuticals & Amendment to the P075 Listing for Nicotine

- Final rule was signed by EPA on 12/11/18 and published in the Federal Register on 2/22/19. [View the final rule in the FR](#)
- Establishes standards for handling of hazardous waste (HW) pharmaceuticals (Pharma) in the healthcare sector.
- Prohibits all facilities from disposing of HW Pharma in the sewer.
- FDA-approved, over-the-counter nicotine replacement therapies (i.e., nicotine patches, gums and lozenges) will no longer be considered HW when discarded.



PREPARATION PRIOR
TO
IMPLEMENTATION
OF RULE

March 2019 -
Internal Review of
pre-publish rule
Enforcement
Checklist created

EDUCATION
AND
OUTREACH

Internal training with staff
and seminars provide by US
EPA

8/1/2019 - NJDEP
published Compliance
Advisory in website

10/9/19 - US EPA provided
in-person seminars to staff
and the regulated
community

IMPLEMENTATION
OF
RULE

8/21/19 - NJDEP
incorporated Subpart P
rule prospectively

Late August 2019 - Began
processing RCRAInfo
notifications by healthcare
facilities (HFs)

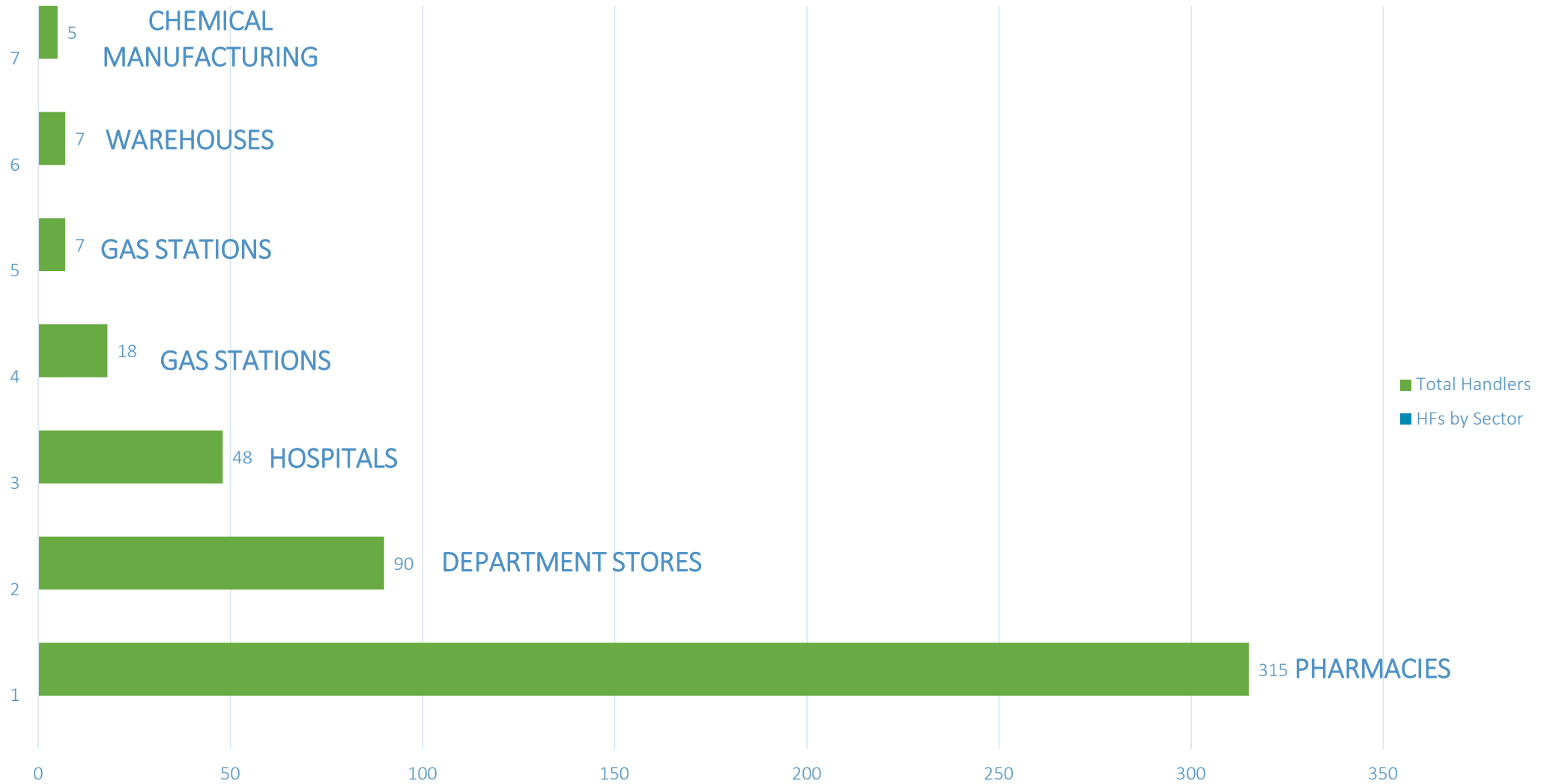
9/1/19 - Inspections began
at HFs but suspended in
March 2020 because of
COVID 19 Pandemic

NJDEP Implementation of Subpart P Rule

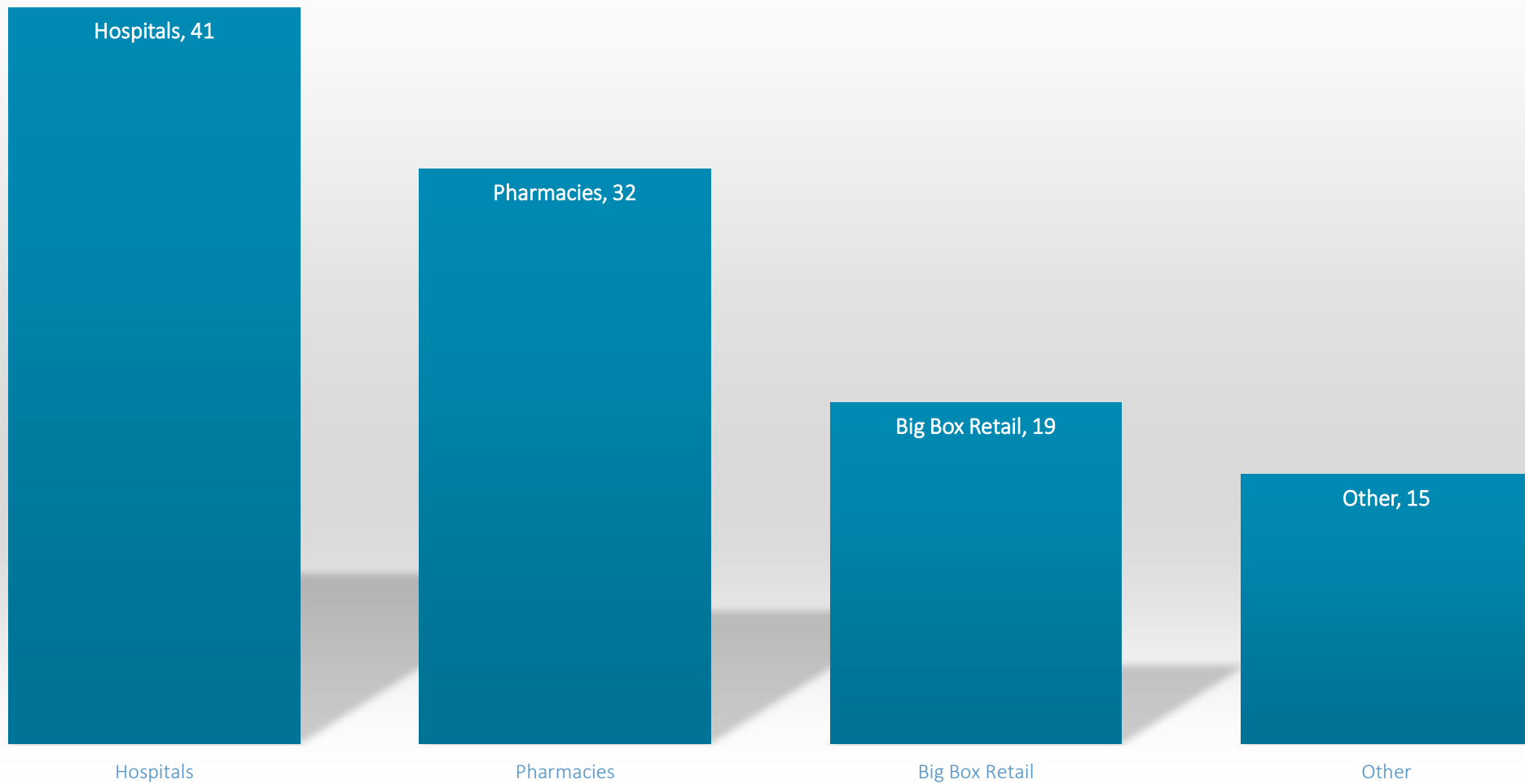


- Since the 8/21/2019, 624 sites have notified as HFs in RCRAInfo.
- NJ has two (2) sites notified in RCRAInfo as a Reverse Distributors
- NJDEP Bureau Hazardous Waste Compliance & Enforcement (BHWCE) has conducted 107 Subpart P related inspections since 9/1/19
- BHWCE suspended inspections at HFs March 2020 because of COVID-19 Pandemic
- Since restarting in January 2021, BHWCE has conducted 76 Subpart P related inspections

HEALTHCARE FACILITIES THAT NOTIFIED BY SECTOR

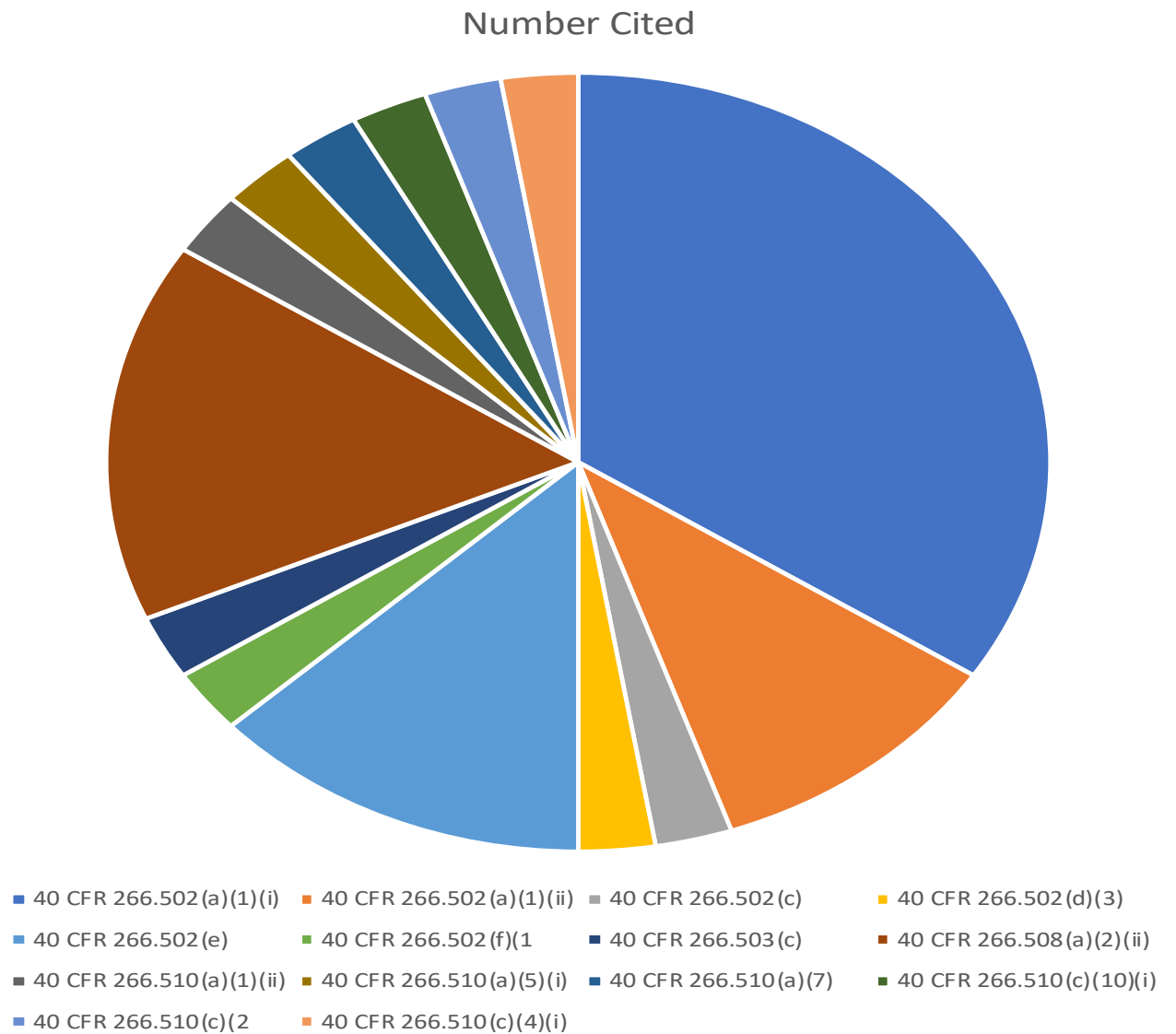


Inspections - Subpart P



Citation	Number Cited
40 CFR 266.502(a)(1)(i)	13
40 CFR 266.502(a)(1)(ii)	4
40 CFR 266.502(c)	1
40 CFR 266.502(d)(3)	1
40 CFR 266.502(e)	5
40 CFR 266.502(f)(1)	1
40 CFR 266.503(c)	1
40 CFR 266.508(a)(2)(ii)	6
40 CFR 266.510(a)(1)(ii)	1
40 CFR 266.510(a)(5)(i)	1
40 CFR 266.510(a)(7)	1
40 CFR 266.510(c)(10)(i)	1
40 CFR 266.510(c)(2)	1
40 CFR 266.510(c)(4)(i)	1
	38

**Subpart P
Violations
cited
(11/22/22)**



Top Three Subpart P Violations Cited



1. **40 CFR 266.502(a)(1)(i)** – Failure of HF that has an EPA ID number to notify that the facility is a HF.
2. **40 CFR 266.508(a)(2)(ii)** – Failure of HF to write the word “PHARMS” in Item 13 of the manifest when shipping non-creditable pharmaceuticals.
3. **40 CFR 266.502(e)** – Failure of HF to label or clearly mark each container of non-creditable hazardous waste pharmaceuticals with the phrase “Hazardous Waste Pharmaceuticals.”



Compliance Assistance

Compliance Advisory (8/1/19)

<https://www.nj.gov/dep/enforcement/advisories/2019-04.pdf>

Subpart P Seminar (10/9/19)

<https://www.state.nj.us/dep/enforcement/docs/HW%20Pharms%20Final%20Rule%20-%20NJ%20Training.pdf>

Compliance Assistance Packet

<https://www.nj.gov/dep/enforcement/docs/compliance-assistance-packet-2020-v20-3.pdf>

Subpart P Inspection Checklist

Inspectors Experiences



Challenges...

Challenges...

- Using PHRMS code as well as HW code on manifests
- Data issue that impacted the BR 2021 cycle
- HFs not using PHRM code
- Notification as HF in RCRAInfo. Only 624 have notified.

What's Next...

- Additional Subpart P Seminars / Webinars
- Use targeting platforms (Region 2 & RITA) to identify sites that have notified as HFs
- Continue to inspect HFs

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Thank you!

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