Drug Shortages and the Pursuit of Sustainability and Supporting Safe Drug Disposal in Your Community Moderator: Michigan Representative Brenda Carter, Women In Government State Director

> Monét Stanford, Director of Public Policy, Association for Accessible Medicines

Irina Butler, MPP, Deputy Executive Director and Vice President of Compliance, Pharmaceutical Product Stewardship Working Group



NATIONAL LEGISLATIVE

Drug Shortages – A Reflection of Challenges to Generic Sustainability



Your Generics & Biosimilars Industry

Why Now?

- Drug shortages hit crisis proportions in 2010-2011
- Shortages have become rarer because of aggressive efforts but these measures did not eliminate the problem
- News reports now suggest a rise in shortages due to post-COVID shifts in supply chain, reduced reimbursement and chilled investment



On The Ground

- "Akorn filed Chapter 7, stopped all business and recalled 75 products, of which 6 were sole-source"
- "Lannett Company, Inc. enters into restructuring support agreement"
- "Teva plans to cut back generic drug production even as shortages intensify"

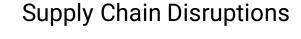




The Causes Of Shortages Vary, But Fall Into Several Categories

Unexpected Surge in Demand





Limited Supply







Sustainability Can Also Be Impacted By Pricing Factors and Policy Miscues

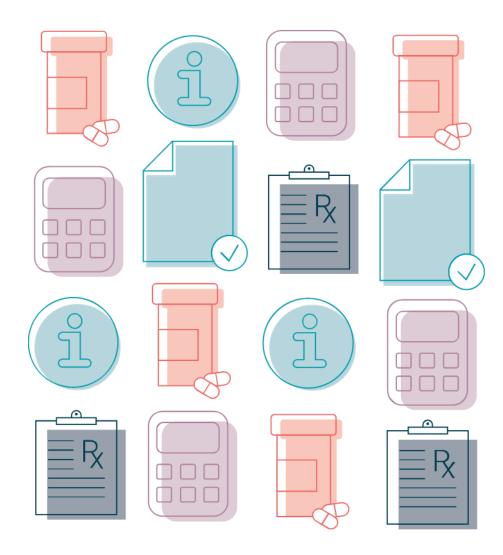
- Supply Chain Purchasing
 Power
- High Generic Price Deflation
- Slower Adoption Of New Generics

- Government Payment Policies
- State Regulatory Burdens
- Recent or proposed policies (IRA and changes to 180-day)



The Path to Reduce Drug Shortages Requires A Comprehensive Plan

Address Regulatory Challenges	Increase Reserves	Improve Manufacturing Capacity	Pursue Sustainability
 Fund FDA's Drug Shortage Staff Improve transparency and processes within FDA Engage DEA on quota requirements Review shelf-life extension programs 	 Create reserve capacity supply modeled after Strategic National Stockpile Update Essential Medicines List Incentivizes hospitals to purchase to utilize fixed price contracts 	 Provide direct assistance to utilize excess manufacturing capacity 	 Align Medicaid Inflation Penalty with IRA Enhance patent and regulatory environment to continue generic entry Encourage use of new generics Exempt generics from 340B program



Supporting Safe Drug Disposal in Your Community

Irina Butler, MPP Deputy Executive Director and Vice President, Compliance

> **PPSWG** Pharmaceutical Product Stewardship Work Group

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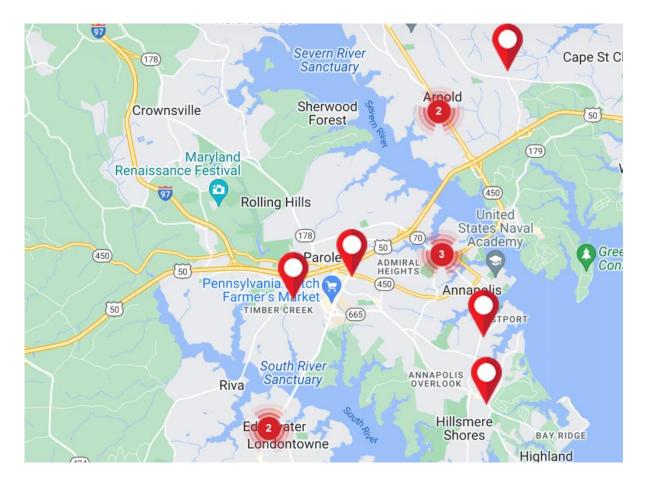
Do you know...

How many medicine disposal locations are available in your community?

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Did you know...

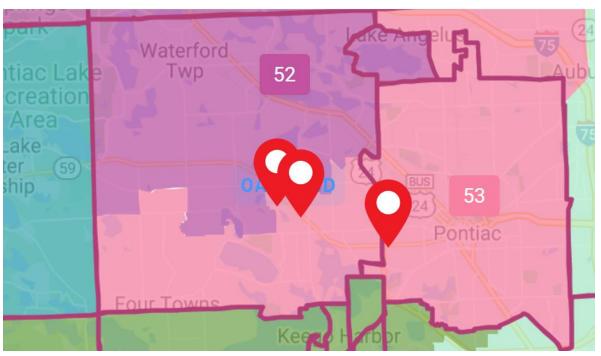


There are twelve disposal options within 5 miles of this hotel...



Did you know...

53rd House District, Michigan





...and 3 disposal options in Representative Carter's district!

Map source: michigan.mydistricting.com

Why is Proper Disposal of Household Medicine Important?



of Americans take over-the-counter medication



2/3 of Americans rely on prescription medication While these medications can be necessary, and

can be necessary, and even life-saving, improper disposal can lead to accidents or misuse.

To keep our communities safe and healthy, we all need to do our part to increase awareness of proper medicine disposal.

PPSWG[®] Pharmaceutical Product Stewardship Work Group

About PPSWG

- The Pharmaceutical Product Stewardship Work Group (PPSWG) is a **non-profit membership association**.
- Our mission is to provide infrastructure, guidance, and subject matter expertise to:



Support producer compliance with extended producer responsibility (EPR) laws Improve awareness of existing pharmaceutical disposal options

Supporting Producer Compliance





Support producer compliance with extended producer responsibility (EPR) laws We were the **first organization** to develop and implement pharmaceutical take-back programs to address pharmaceutical EPR laws in the U.S.

On behalf of our **397 member companies**/participating producers, we provide reliable collection and compliance programs in all jurisdictions with mandated producer-funded pharmaceutical take-back programs.

Our program operator currently services more than 20 take-back programs covering **more than 80 million people across the U.S.**

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Mandated Extended Producer Responsibility for Pharmaceutical Products

Extended Producer Responsibility (EPR): An environmental policy approach in which a producer's responsibility for a product is extended to the post-consumer stage of a product's life cycle.

Source: <u>oecd.org</u>

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In 2012, Alameda County, CA became the nation's first jurisdiction to enact legislation requiring producers to operate and fund an unused medicine take-back program.

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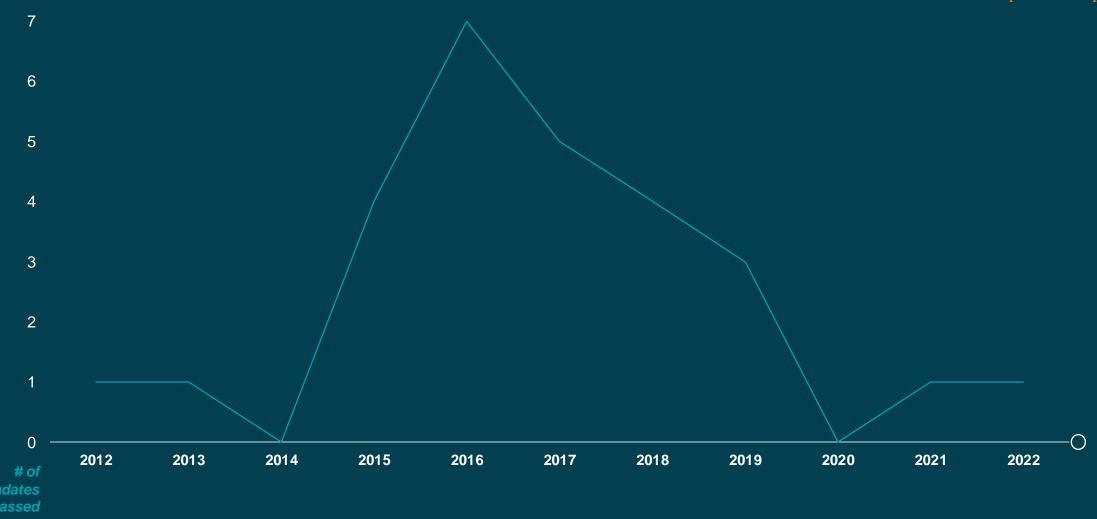


A decade later, the landscape has changed...

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Number of pharmaceutical EPR laws passed per year, 2012 - 2022

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Improving Awareness



Improve awareness

of existing pharmaceutical disposal options

- We are committed to promoting public awareness of the **existing network of drug disposal options** available nationwide.
- We invest in outreach to **educate consumers** on the proper usage, storage, and disposal of medication.
- MyOldMeds.com, the nation's most comprehensive database of existing drug disposal options, is funded by our association's 397 members.

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Did you know?



drug disposal options are available across all 50 states



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Did you know?

Here in Maryland, **around 88% of residents are within a 10-minute drive** from a disposal option listed on MyOldMeds.com **Resident Drive Time to Nearest Disposal Option**

State	10 Minute Coverage	20 Minute Coverage	Kiosks	Take Home Locations
Maryland	87.8%	97.3%	258	122

Drive time data determined using data from MyOldMeds.com and GIS mapping tools

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Improving Awareness

- **The drug disposal options exist** the next step is public awareness.
- Consumers need to know that they can **easily access free and convenient options** to safely dispose of their old medicine.
- Education and outreach **including at a community level** - can help keep people safe and healthy by preventing accidents or misuse by others.



MyOldMeds.com



MyOldMeds.com provides consumers with 24/7 access to information on **safe, free, and convenient disposal options** for unwanted or expired household medicine.

Checked for accuracy twice annually, MyOldMeds.com has **an easy-to-use locator tool** that lists **more than 22,000 drug disposal options in all 50 states**.

MyOldMeds.com also has educational information on the safe usage and storage of household medications.



Safe Disposal Options

The locations listed on MyOldMeds.com include **kiosks** as well as locations offering **in-home disposal kits** and **mail-back** packages.

- Disposal options are conveniently located in pharmacies, law enforcement agencies, government offices, and healthcare facilities.
- MyOldMeds.com also provides educational information on the safe usage and storage of household medications.





How do we promote safe disposal options?

- **Facebook and Twitter**, including periodic paid content to reach a wider audience.
- Press releases and media pitches.
- Content provided to our **membership** for promotion via their networks.
- Content provided to **legislators** to educate their constituents.



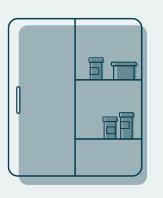


What message do we promote?

Our message is simple and straightforward, and follows the guidance provided by government agencies such as the U.S. Food & Drug Administration, Drug Enforcement Administration, National Institutes of Health and the Centers for Disease Control and Prevention.



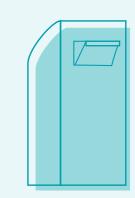
Follow the **instructions exactly as provided** including labeling information and Medication Guides accompanying the medicine.



In particular, follow any storage instructions as provided on the medicine label and on the patient information accompanying the medicine.



Keep the medicine in a **secure** location, either in a medicine cabinet or safely away from people or pets that might come in contact with it.



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When medicine is unwanted, unused, or expired, **dispose** of it immediately and properly, including in a kiosk site.

How can you promote safe disposal options?

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To keep our communities safe and healthy, we can all play a part in increasing awareness of proper medicine disposal.

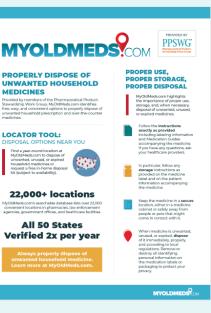
We've seen legislators leverage information from MyOldMeds on their:

- Newsletters
- Websites
- Social Media

Many communities also participate in the DEA's bi-annual National Rx Drug Take-Back Days in April and October.



How can you promote safe disposal options?



Fact sheet/ infographic

One-page/letter-sized format – great to share as a PDF or distribute as printed flyers



Public Service Announcement

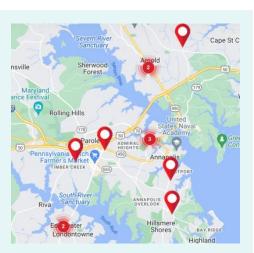
30-second video; perfect for sharing via social media



Social content

Includes graphics and suggested text for posts

Graphics can also be leveraged in newsletters, on websites, or other digital formats as needed



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Locator tool

Screenshot and share maps on your website or in your newsletters; provide lists of locations in your area



Do you know?



How many medicine disposal options are available in your jurisdiction?

To find a kiosk site near you click on the map or enter information below:



Radius

 \checkmark

FIND MY LOCATION

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Next Steps

Use MyOldMeds to find disposal options in your jurisdiction

Reach out to us for free content/educational materials Educate your communities! – via social media, newsletters, websites, events

Thank you!

Irina Butler, MPP Deputy Executive Director and Vice President, Compliance ibutler@ppswg.org 202//495-3125





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