

# 340B Drug Program Threats and Reimbursement Concerns

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# Agenda

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OPPS Medicare Part B Payment Policy

Contract Pharmacy Issues

Manufacturer Developments and Drug Exclusions

Compliance Trends

# History of OPPS Medicare Part B Cuts

- Background: *American Hospital Association, et al v. Becerra*
  - CMS 2019 OPPS Final Rule
  - Medicare reimbursement for certain outpatient drug at the ASP -22.5% (reduction of nearly 30%) for certain 340B Covered Entities
  - Prior to 2018, Medicare paid ASP +6% (same rate as non-340B hospitals)
- AHA and hospital co-plaintiffs filed suit challenging the 340B payment policy
  - Hospitals argued that Medicare statute does not authorize HHS to vary payment rates by hospital group unless HHS first surveys hospitals to determine drug acquisition costs
  - Hospital challenged 2018 payments cuts and in subsequent filing, challenged 2019 payment cuts
- Federal District Court of Appeals held payment cuts illegal
- Federal Circuit Court of Appeals held payments cuts authorized
- Hospitals appealed to U.S. Supreme Court

# U.S. Supreme Court Holding: Implications

AHA v. Becerra

- Court's holding did not address the remedy to make 340B hospitals whole for payment reduction due to unlawful policy
- Court's holding also limited to 2018 and 2019 payment policies
  - Court did not address the same payment policy for 2020-2022
- Court noted that Medicare statute authorizes CMS to vary payment rates by hospital group if agency first surveys hospital acquisition costs
- 2020 CMS attempted a survey
- 2021 OPPS Proposed Rule proposed to further reduce payment rates based on survey results but never finalized

# Improvements Ahead

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- OPPS 2023 Final Rule
- End of 30% cut in 2023
- Claims Modifier Mandate
- Reductions for Non-Drug Items and Services
- CMS Plan for Past Cuts/Remedies
- Future Acquisition Cost Surveys

# Contract Pharmacy Issues

# 340B Contract Pharmacy Restrictions

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18 drug companies  
are restricting  
340B discounts to  
CEs for drugs  
dispensed at  
contract  
pharmacies

9 implemented  
policies in 2022

12 out of 18 say  
they will offer  
340B discounts for  
multiple contract  
pharmacies if CEs  
submit claims data

Median annualized  
340B hospital  
losses have more  
than doubled since  
the end of 2021

# Restrictions Added In The Past Year

Basic Overview of 2022 Manufacturer Restrictions				
Manufacturer	Allows for single CP if no retail pharmacy	Conditions access to 340B at CPs by requiring claims data	Applies to Hospitals	Applies to Other CEs
AbbVie	✓	✓	✓	
Amgen	✓	✓	✓	
Bausch Health	✓	✓	✓	All grantees
Bristol Myers Squibb	✓		✓	All grantees
Exelixis	✓	✓	✓	
Gilead	✓	✓	✓	
GlaxoSmithKline	✓	✓	✓	
Johnson & Johnson	✓	✓	✓	
Pfizer	✓	✓	✓	



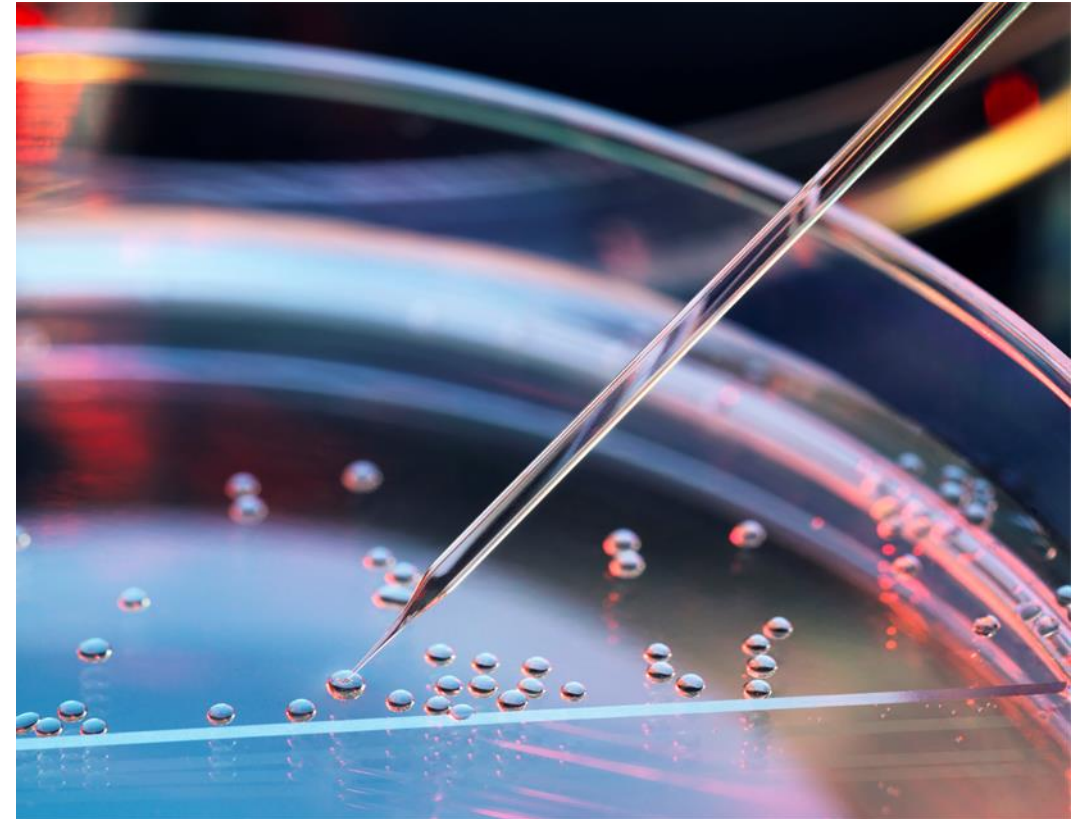
# Mitigation Strategies

## Optimizing Pharmacy Options

- Increase number of contract pharmacy arrangements
- Open and operate more in-house or wholly owned retail pharmacies
- Educate patients and providers about the availability of in-house pharmacies
- Evaluate contract pharmacy arrangements with specialty pharmacies to access drugs that hospitals otherwise cannot purchase

# Mitigation Strategies, Continued

- Applying for an exception
  - Single Contract Pharmacy if no in-house pharmacy
  - Designation of pharmacies wholly owned by the Covered Entity or under common ownership
- Data Submission to 340B ESP Platform



# Claims Data Submission: Financial Pressure

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- Pros/Cons
- Individual Decision for each Covered Entity
- Various Results In Recovering Revenue
- Price Restoration Delays at Contract Pharmacy

# Long Term Concerns

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Manufacturers requiring data submission on commercial claims to avoid paying voluntary rebates under Pharmacy Benefit Manager(PBM) Agreements

Data may be used by payers or PBMs to lower reimbursement and/or remove Covered Entities and their pharmacies from payer networks

# Legal Issues

- Lack of HRSA oversight
- Concerns Relating to Berkeley Research Group
- HIPAA Compliance
- 340B ESP's Terms of Use



# Future of Contract Pharmacy

- Ongoing litigation
  - Nine manufacturers sued HRSA with three cases in appellate courts
- Most likely will be decided by U.S. Supreme Court
- HRSA issuing more enforcement letters to manufacturers and referrals to OIG
- OIG action still pending

# Manufacturer Developments: Purchase Restrictions

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# New Manufacturer Policy



- Cosette Pharmaceuticals and Woodward Pharma Services LLC announced that Covered Entities must purchase some of their products through a company-designated vendor to access 340B pricing
- Both using Direct Customer Solutions
- Policy took effect in January 2023



# DSH Eligibility Protection

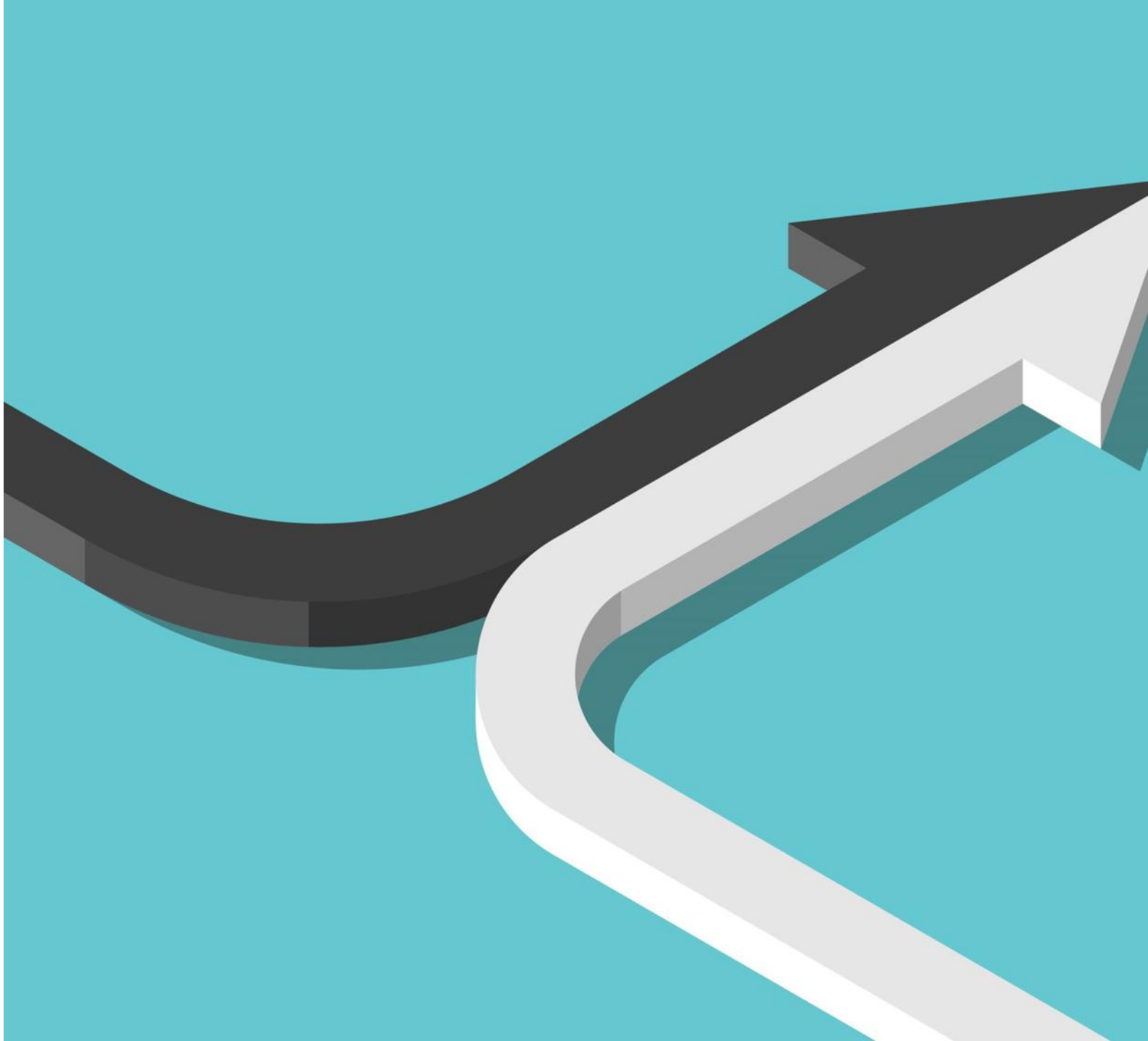
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Public Health Emergency legislation protecting hospitals from losing 340B eligibility due to changes in patient mix from COVID-19

Exemption applies to DSH hospitals that lost eligibility or anticipate losing eligibility

Exemption period ends no later than December 2023

# Compliance Update

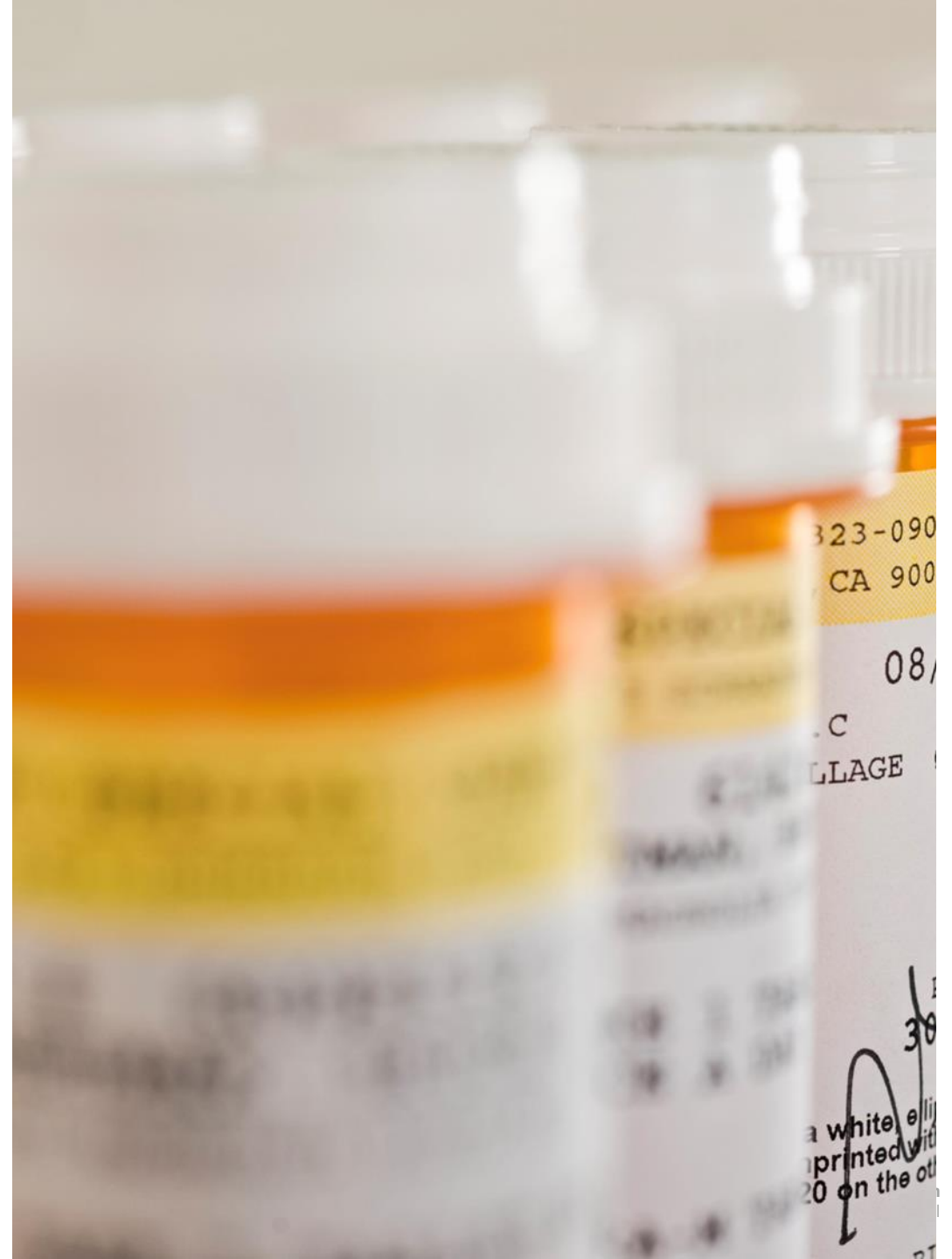


# Hospital Audit Findings, 2015-2022

	FY15	FY16	FY17	FY18	FY19*	FY20	FY21	FY22
Diversion	54%	54%	52%	40%	16%	6%	9%	6%
FFS Duplicate Discount	20%	22%	24%	29%	26%	17%	16%	12%
Inaccurate Medicaid Exclusion File	6%	5%	5%	8%	3%	6%	8%	7%
Inaccurate Database	48%	28%	29%	31%	25%	21%	49%	49%
GPO Exclusion	11%	6%	4%	1%	3%	<1%	2%	<2%

# HRSA's 2019 Audit Enforcement Changes for Retail Scripts

- De-emphasized location where prescriptions originated
- Continue focus on script written by health professional credentialed or employed by hospital OR by professional to whom patient was referred
- Emphasis on supporting documentation of patient's health record related to the script



# Genesis Case: Future of Patient Definition

- Litigation Status
- HRSA asking for regulatory authority to issue binding regulations
- HRSA could issue enforceable regulations relating to 340B statute so long as interpretation not contrary to statute





# Questions and Comments

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