

# Navigating Federal Reform: IRA Financial Impacts and DSCSA Readiness in Retail Pharmacy

NACDS Regional 2026

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January 2026

# Session Objectives

- Quantify IRA financial and working-capital impacts
- Understand operational and compliance implications
- Review DSCSA impact to date on dispensers
- Frame implications for financial leaders, operations leaders, and policy stakeholders on federal policy changes
- Discussion

# Industry Context

Pharmacy margins under pressure for over a decade

## Key structural drivers:



PBM  
Consolidation



DIR fee  
expansion



Regulatory  
complexity



Shifts in front-end economics  
and changing consumer behavior

Since  
2015:



Brand  
Reimbursement



Generic  
Reimbursement

**The IRA does not land in  
a neutral environment**



## What is the Inflation Reduction Act?

- Enacted in 2022 to lower drug costs and patient burden
- Medicare reforms include:
  - Drug price negotiation
  - Maximum Fair Prices (MFPs)
  - \$2,000 Part D OOP cap
  - \$0 ACIP-recommended vaccine copays
  - Inflation penalties
- First negotiated prices effective January 1, 2026

**Discounts average to ~ 63% of the total WAC**



# Effectuation 2026 MFP:

## First 10 Medicare Part D drugs (141 NDCs) under negotiation



**Eliquis**  
Bristol Myers Squibb



**Jardiance**  
Boehringer Ingelheim/  
Eli Lilly



**Xarelto**  
Johnson & Johnson



**Januvia**  
Merck



**Farxiga**  
AstraZeneca



**Entresto**  
Novartis



**Enbrel**  
Amgen



**Imbruvica**  
AbbVie/Johnson & Johnson



**Stelara**  
Johnson & Johnson



**Novolog**  
Novo Nordisk

## Timeline

Impact grows annually and is cumulative.



**Source:** Inmar Intelligence historical filling patterns from 2024 and the first half of 2025.

# IRA Sales Dollars Subject to MFP

## Share of total sales dollars:



Variability by Medicare mix



Volume of transactions is low (1-4%)



High-cost drugs drive outsized financial exposure

**Source:** Inmar Intelligence historical filling patterns from 2024 and the first half of 2025.



## How MFP Changes Cash Flow

- Split payment model:
  - PBM payment at POS
  - Manufacturer MFP reimbursement later
- Manufacturer portion  $\approx$  63% of transaction value
- Additional 7–30 days to collect full payment
- Pre-IRA benchmark is 19.5 DSO

# Working Capital Impact

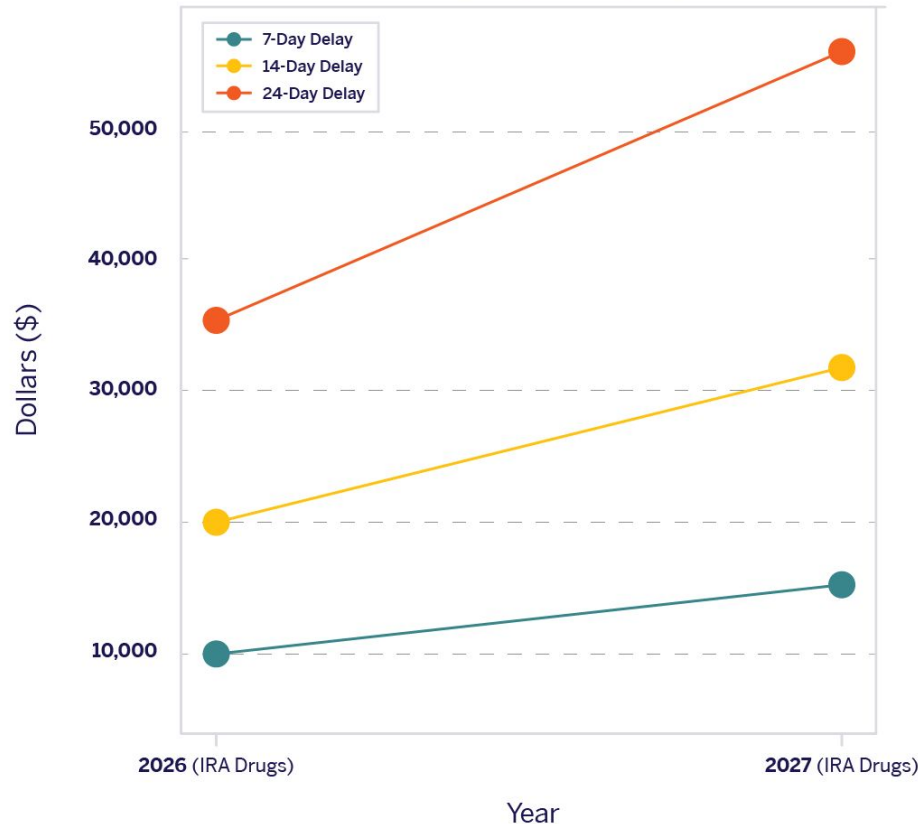
## Incremental working capital per pharmacy:

- 2026: \$10K–\$35K
- 2027: \$16K–\$57K

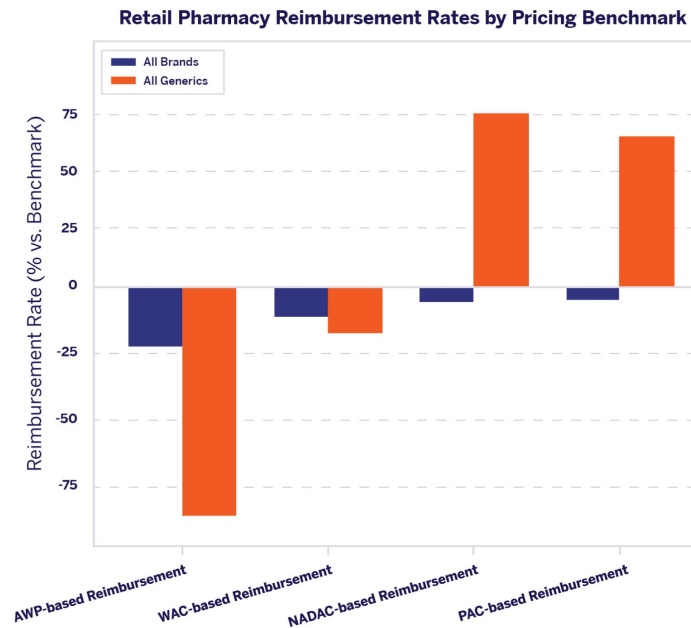
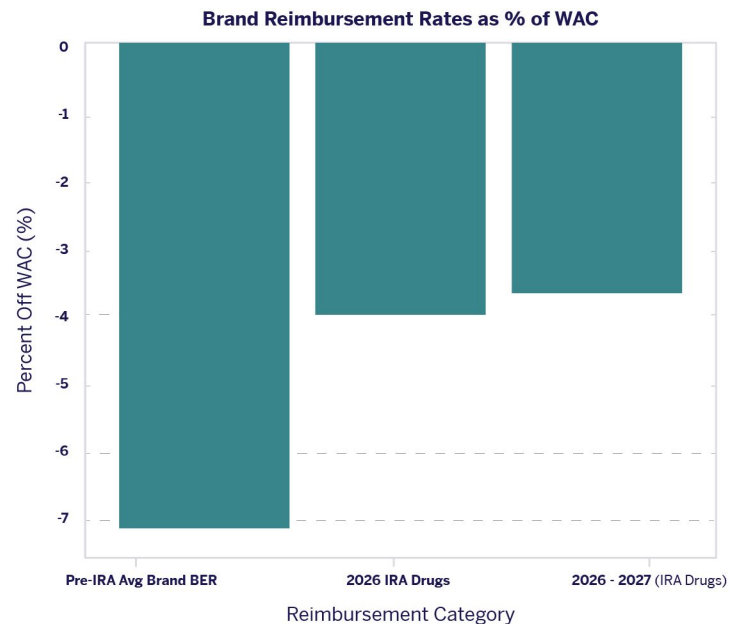
Driven by extended DSO  
and higher-dollar scripts

**Source:** Inmar Intelligence historical filling patterns from 2024 and the first half of 2025.

Incremental Working Capital Impact per Pharmacy



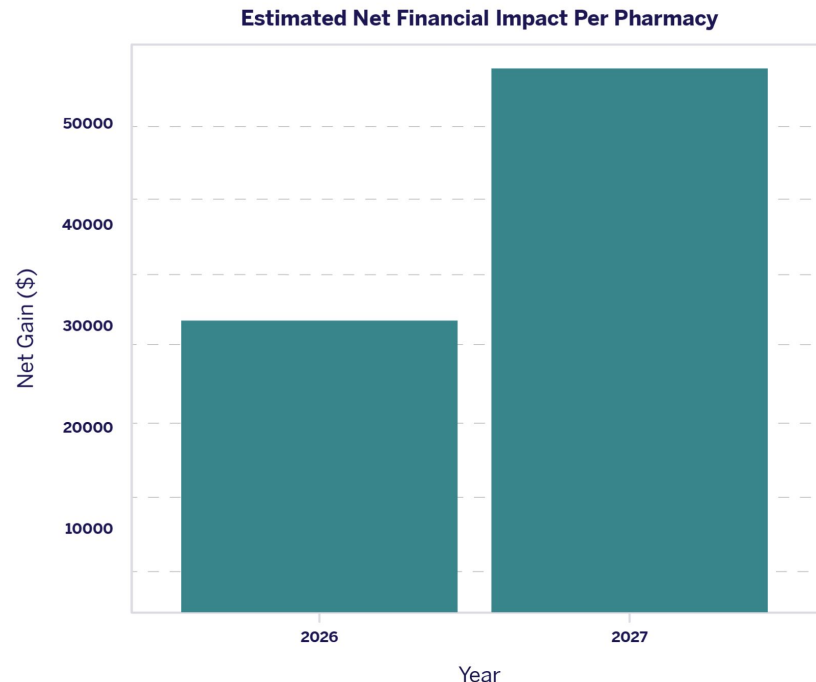
# Reimbursement Relative to WAC



**Source:** Inmar Intelligence historical filling patterns from 2024 and the first half of 2025.

# Net Financial Impact

- IRA reimbursement closer to full WAC
- Financing costs partially offset gains
- Estimated net gain per pharmacy:
  - 2026: ~\$33k
  - 2027: ~\$55k
- Only achievable under optimal conditions
- Watchout: shrinking gap between WAC and the manufacturer's net price



Source: Inmar Intelligence historical filling patterns from 2024 and the first half of 2025.



# Operational & Compliance Complexity



- Increase in receivable records and transactions
- More manufacturers remitting payments directly
- Expanded reconciliation, exception handling, and audit exposure
- PBM audits remain active despite new payment models
- IRA financial benefits could decline if manufacturers cut brand name list prices to align more closely with MFP

# 340B Interaction Challenges

- Manufacturers pay lower of MFP or 340B price
- No standard 340B flag at adjudication
- Risk of retroactive clawbacks
- Additional reconciliation between covered entities and contract pharmacies
- Medicare Part D prescriptions that are 340B ~10%\*
- A federal judge blocked the Health Resources and Services Administration (HRSA) from implementing its 340B Rebate Pilot Program

\*Source: <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2811898>



## Important to protect patient loyalty:

- On average, a retail pharmacy serves 211 IRA patients, grows to 290 in 2027
- Each representing approximately \$6,156 in annual revenue (including both IRA and non-IRA drugs)

## For IRA drugs:

- Only 0.02% fully patient-paid
- Average copay ~\$80-\$88

Pharmacies serve as access point and financial intermediary

**Source:** Inmar Intelligence historical filling patterns from 2024 and the first half of 2025.

# Drug Supply Chain Security Act (DSCSA) Timeline

## Overview



\* FDA issues exemption for Connected Trading Partners on Oct 9, 2024

\*\*\*\* Small dispenser exemption - 25 or fewer FTE licensed pharmacists and/or pharmacy technicians

## Data/Connections

- Highways are “open” and data is moving
- Position by the MFG and Wholesaler to require the dispensing entities to initiate or be a part of the request for connection

## Authorized Trading Partners

- Continued challenges in the industry to confirm correct GLNs
- **GLN verification of who enumerated you, Wholesaler, GPO or did you self support**

## Verification

- Desire for single scan solutions to support inventory systems, and DSCSA compliance
- **Education on the importance of compliance within sites & clarity on what is not covered by DSCSA**

## Reporting/Inspections

- Stabilization of workflows continue to be a topic of conversation and discussion as dispensers work through troubleshooting
- **SOPs in place to support all process and procedures, including those that outline how to handle outlier product (WEE)**

# Be Prepared



- Jan 12 marked the first the first DSCSA-focused 483 the FDA has issued to a dispenser
- Review Policies and Procedures (P&Ps)
- Perform ongoing record reviews to evaluate gaps and areas for improvement
- Prepare the records or documents that will be needed for your on-site visit and develop a plan to access them efficiently
- Conduct a mock inspection or survey

Individually, each policy reform carries the potential for significant disruption. Collectively, they may redefine the economic foundation of retail pharmacy—shifting the sector toward a model where high-quality patient care and service delivery become both essential and financially sustainable.

- Inflation Reduction Act (IRA) new drugs in 2028, including Part B
- **Proposed Pharmacy Benefit Reform Act of 2025 (PBM Reform Act)**
- Most Favored Nation (MFN) Pricing Policy
- Potential 340B Program Reform
- **Proposed Ensuring Community Access to Pharmacist Services Act (ECAPS)**
- GENEROUS, GLOBE, and GUARD



# Key Takeaways

- Drug-margin dependence continues to erode (WAC, DTP, Cost-Plus)
- Liquidity pressure will intensify with IRA and other potential rebate models
- Federal reforms are interconnected with PBM Reform and ECAPS as the strongest potential stabilizers with cost-based reimbursement and service payment streams
- Success requires:
  - Strong working-capital strategies
  - Automation and compliance investment
  - Growth in clinical and service revenue



*Glad To Be Here!*



# Discussion

# Thank You!



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