

# SPEND MEND



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**Statement of Disclosure**  
**We have no conflicts of interest.**

# OBJECTIVES

Identify the  
Medications

Impacts to  
the 340B  
Program

Strategies  
and Tools

# QUESTION #1

# WHY??



Reduce Medicare Part B



Reduce Medicare Part D



Applicable to High Dollar Single Source Drugs



# OBJECTIVES

Identify the  
Medications

# MEDICARE MODIFIERS

Effective January 1, 2024, all CEs had to submit a “JG” or “TB” modifier for 340B drugs administered to patients and subsequently billed to Medicare Part B.



“JG” modifier no longer accepted.



Starting **January 1, 2025**, Hospitals and Grantees must submit a “**TB**” modifier for 340B drugs administered to patients and subsequently billed to Medicare Part B.

# MEDICARE MODIFIERS

Enacted in August 2022, establishes  
a Maximum Fair Price (MFP)

(<https://www.congress.gov/117/plaws/publ169/PLAW-117publ169.pdf>)



340B Covered Entities are  
entitled to the lower of the  
340B Ceiling Price or MFP



# INFLATION REDUCTION ACT

## Pricing Negotiations

- 10 drugs 2026
  - BMS Eliquis: \$231
  - BI Jardiance: \$197
  - J&J Xarelto: \$197
  - Merck Januvia: \$113
  - AZ Farxiga: \$178.50
  - Novartis Entresto: \$295
  - Amgen Enbrel: \$2,355
  - AbbVie Imbuvia: \$9,319
  - J&J Stelara: \$4,695
  - Nov.Nord. NovoLog: \$119



Pricing to take effect  
January 2026 for first  
10 drugs

CMS Fact Sheet:  
<https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdf>



Additional 15 drugs  
selected for 2027, again  
for 2028. Additional 20  
drugs each subsequent  
year.

# IRA UPDATE

## Future Outlook for 340B Providers:

- Budget impact – anticipate loss of 340B savings for select drugs
- Access to MFP – draft guidance proposes retrospective rebate via a Medicare transaction facilitator (MTF)
- Deduplication strategy – How will duplicate discounts between 340B and MFP be prevented (draft guidance calls for voluntary use of claim-level modifier)

Drug Name	Participating Drug Company	Commonly Treated Conditions	Agreed to Negotiated Price for 30-day Supply for CY 2026	List Price for 30-day Supply, CY 2023	Discount of Negotiated Price from 2023 List Price
Januvia	Merck Sharp Dohme	Diabetes	\$113.00	\$527.00	79%
Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill	Novo Nordisk Inc	Diabetes	\$119.00	\$495.00	76%
Farxiga	AstraZeneca AB	Diabetes; Heart failure; Chronic kidney disease	\$178.50	\$556.00	68%
Enbrel	Immunex Corporation	Rheumatoid arthritis; Psoriasis; Psoriatic arthritis	\$2,355.00	\$7,106.00	67%
Jardiance	Boehringer Ingelheim	Diabetes; Heart failure; Chronic kidney disease	\$197.00	\$573.00	66%
Stelara	Janssen Biotech, Inc.	Psoriasis; Psoriatic arthritis; Crohn's disease; Ulcerative colitis	\$4,695.00	\$13,836.00	66%
Xarelto	Janssen Pharms	Prevention and treatment of blood clots; Reduction of risk for patients with coronary or peripheral artery disease	\$197.00	\$517.00	62%
Eliquis	Bristol Myers Squibb	Prevention and treatment of blood clots	\$231.00	\$521.00	56%
Entresto	Novartis Pharms Corp	Heart failure	\$295.00	\$628.00	53%
Imbruvica	Pharmacyclics LLC	Blood cancers	\$9,319.00	\$14,934.00	38%

# 2027 PRICING NEGOTIATIONS

## Pricing Negotiations Begin for 2027

- 15 drugs
  - Novo Nordisk - Ozempic; Rybelsus; Wegovy
  - GSK - Trelegy Ellipta
  - Pfizer and Astellas - Xtandi
  - BMS- Pomalyst
  - Pfizer - Ibrance
  - BI - Ofev
  - Allergan - Linzess
  - AZ - Calquence
  - Teva - Austedo; Austedo XR
  - GSK - Breo Elipta
  - Lilly - Tradjenta
  - Salix - Xifaxan
  - Allegra - Vraylar
  - Merck - Janumet; Janumet XR
  - Amgen - Otezla



## Pricing to take effect January 2027

\*CMS Fact Sheet:  
<https://www.cms.gov/files/document/factsheet-medicare-negotiation-selected-drug-list-ipay-2027.pdf>

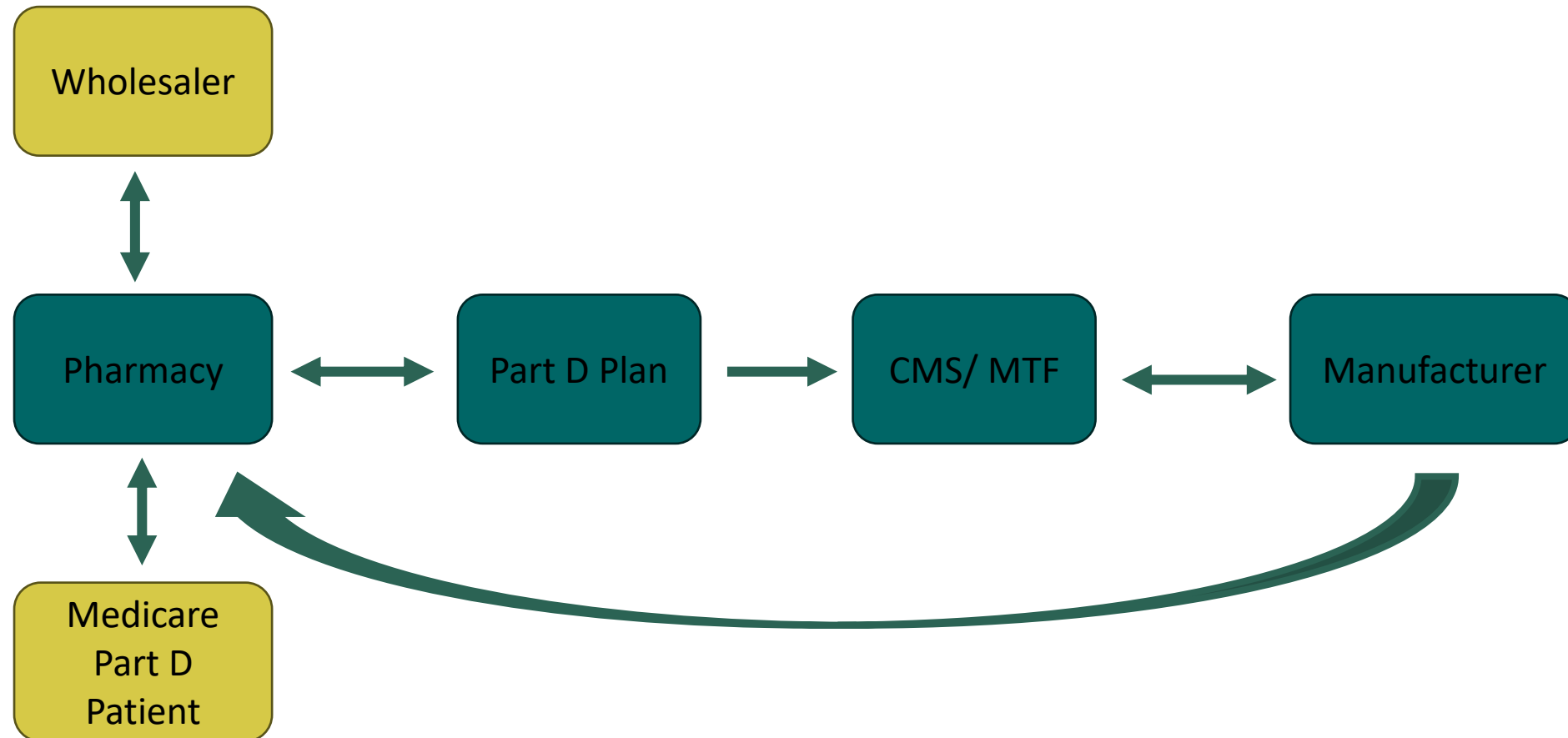
# OBJECTIVES

340B Program  
Impact

# POLL QUESTION #2

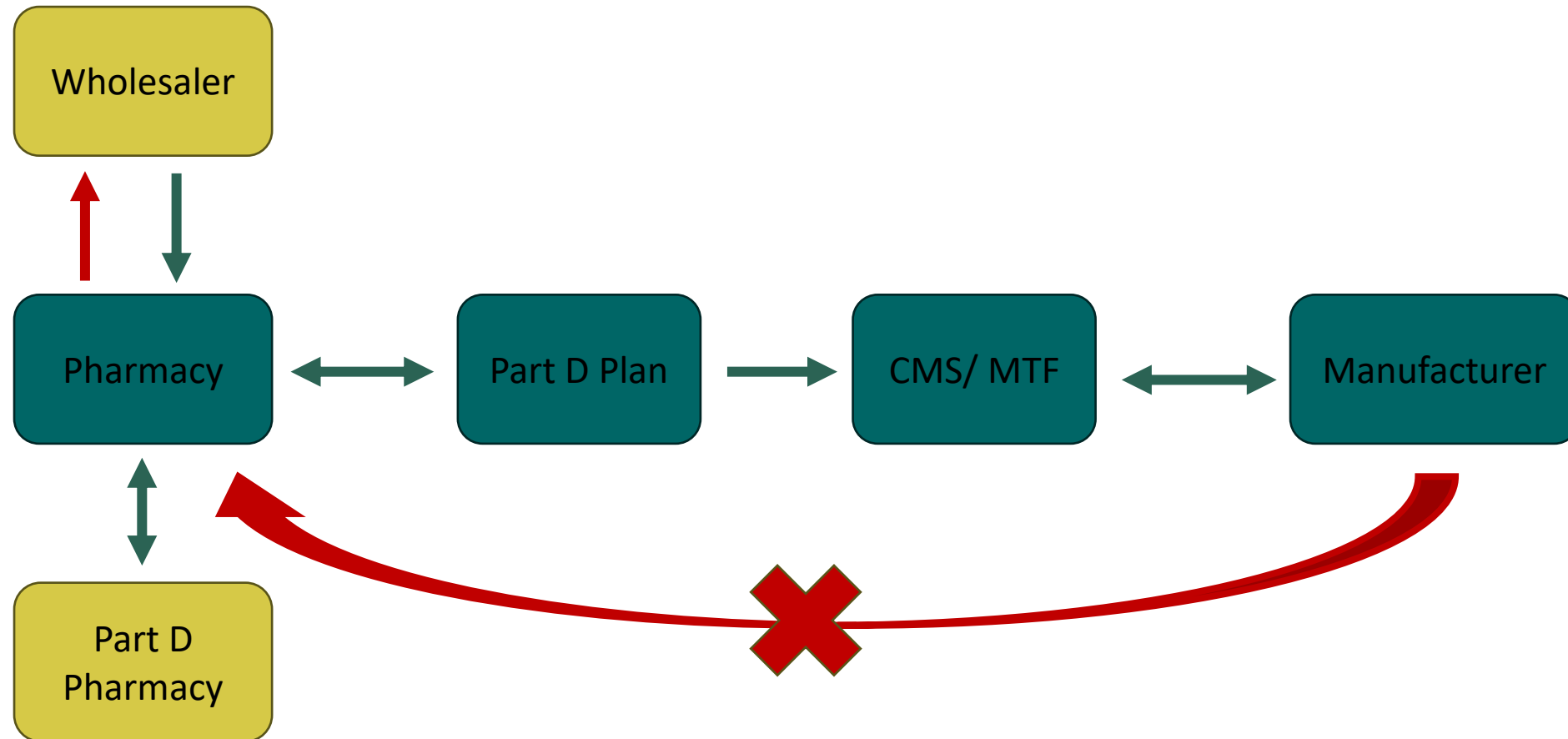
# CMS IMPLEMENTATION PLAN

CMS MFP FINAL GUIDANCE <https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf>

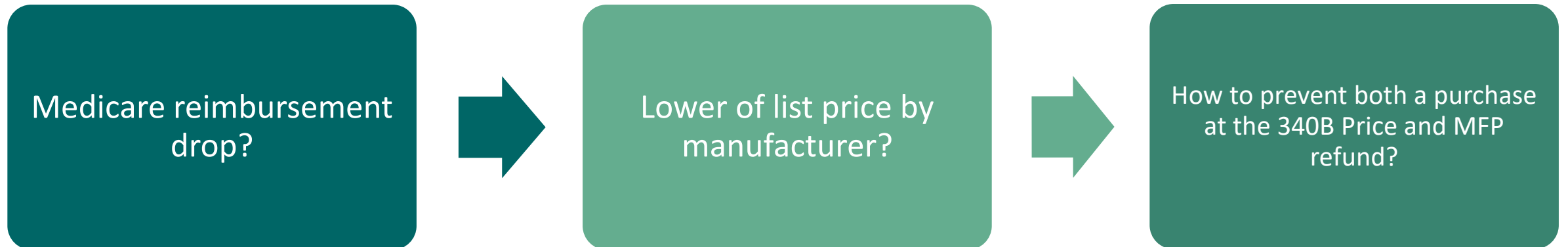




# CMS PLAN AND THE 340B PURCHASED DRUG



# POTENTIAL IMPACT ON THE 340B PROGRAM



# NEXT STEPS



Manufacturer De-duplication Plans



CMS to conduct audits of plans they feel will not impact the MFP



Monitor List prices and changes



Data required for transparency



Calculate the Estimated Impact

# POLL QUESTION #3

# OBJECTIVE

## Strategies and Tools

# THINGS TO CONSIDER-STRATEGY





# WEBINARS AND ARTICLES TO ASSIST

340B Health Webinar "Inflation Reduction Act Assessing Financial and Operational Challenges"



Craneware News "How the Inflation Reduction Act Could Affect 340B Covered Entities and Contract Pharmacies"



340B Report "Compliance with the Inflation Reduction Act and Associated Maximum Fair Price Rules for 340 B Covered Entities"



340B Unscripted Podcast  
Ep 4 Inflation Reduction Act's 340B...  
  
Ep 46 Revisiting the Intersection of the IRA Medicare Drug Pricing Program and 340B - Jeff Davis  
  
Ep 65 IRA Impact on 340B

# IRA 340B CLEARINGHOUSE DISCUSSION

- Data Computer Corporation of America (DCCA)
  - Awarded a \$60 million contract by CMS to develop the Medicare Transaction Facilitator Data Module (MTF-DM) to support the Medicare Drug Price Negotiation Program.
  - The MTF-DM will facilitate the exchange of certain claim-level data elements and payment-related data elements for selected drugs to enable drug manufacturers to complete timely implementation of negotiated drug prices.

# 340B Health IRA Tool

- IRA-2026-Calculator.xlsx

	A	B	C	D	E	F
1	<b>Results</b>					
2	<b>By Drug</b>	<i>Scroll down to see results by payer</i>				
3	<b>NDC</b>	<b>Label Name</b>	<b>Current Savings</b>	<b>2026 Savings</b>	<b>Change In Savings</b>	
4	00003089321	ELIQUIS 2.5 MG TABLET	\$ -	\$ -	\$ -	
5	00003089331	ELIQUIS 2.5 MG TABLET	\$ -	\$ -	\$ -	
6	00003089421	ELIQUIS	\$ -	\$ -	\$ -	
7	00003089431	ELIQUIS 5 MG TABLET	\$ -	\$ -	\$ -	
8	00003089470	ELIQUIS 5 MG TABLET	\$ -	\$ -	\$ -	
9	00003376474	ELIQUIS	\$ -	\$ -	\$ -	
10	58406001004	ENBREL 25 MG/0.5 ML SYRINGE	\$ -	\$ -	\$ -	
11	58406002101	ENBREL 50 MG/ML SYRINGE	\$ -	\$ -	\$ -	
12	58406002104	ENBREL 50 MG/ML SYRINGE	\$ -	\$ -	\$ -	
13	58406003201	ENBREL 50 MG/ML SURECLICK	\$ -	\$ -	\$ -	
14	58406003204	ENBREL 50 MG/ML SURECLICK	\$ -	\$ -	\$ -	
15	58406004401	ENBREL 50 MG/ML MINI CARTRIDGE	\$ -	\$ -	\$ -	
16	58406004404	ENBREL 50 MG/ML MINI CARTRIDGE	\$ -	\$ -	\$ -	
17	58406005501	ENBREL 25 MG/0.5 ML VIAL	\$ -	\$ -	\$ -	
18	58406005504	ENBREL 25 MG/0.5 ML VIAL	\$ -	\$ -	\$ -	
19	58406042534	ENBREL 25 MG KIT	\$ -	\$ -	\$ -	
20	58406045504	ENBREL 25 MG/0.5 ML SYRINGE	\$ -	\$ -	\$ -	
21	00078065920	ENTRESTO 24 MG-26 MG TABLET	\$ -	\$ -	\$ -	
22	00078065967	ENTRESTO 24 MG-26 MG TABLET	\$ -	\$ -	\$ -	
23	00078069620	ENTRESTO 97 MG-103 MG TABLET	\$ -	\$ -	\$ -	
24	00078069667	ENTRESTO 97 MG-103 MG TABLET	\$ -	\$ -	\$ -	
25	00078077720	ENTRESTO 49 MG-51 MG TABLET	\$ -	\$ -	\$ -	

# OBJECTIVE

Other Topics of  
Interest

# 340B Rebate/Credit Models

Manufacturer	Status of Proposal	Litigation	Affected CEs	Affected Drugs	Vendor
Sanofi	Withdrawn Dec. 16 due to HRSA enforcement threat (PPA termination)	Sued HRSA Dec. 16	Hospitals (DSH, CAH, RRC, SCH) Health centers	25 drugs	Beacon
J&J	Withdrawn Sept. 30 due to HRSA enforcement threat (PPA termination)	Sued HRSA Nov. 12	Hospitals (DSH)	Two drugs	Beacon
Lilly	Never publicly announced	Sued HRSA Nov. 14	All CEs	All drugs	Kalderos
BMS	Never publicly announced	Sued HRSA Nov. 26	All CEs	One drug	Beacon
Novartis	Never publicly announced	Sued HRSA Jan. 15	Hospitals (DSH)	All drugs	Not stated in court filing

# 340B REBATE MODEL LITIGATION UPDATE

- April 29 - DC District Court hearing
  - Judge requested HHS to provide timeline for responding to manufacturer rebate proposals
- May 2 – HHS notice
  - Plan to release guidance on 340B rebates in context of impending IRA deadlines within 30 days
- May 15 – J&J federal judge allows two member hospitals to intervene as defendants

## NOTICE

Large-scale implementation of rebate models to effectuate the 340B ceiling price would be a significant change for the 340B Program and its stakeholders. Because the implications are not straightforward, the Department of Health and Human Services continues to carefully evaluate its options alongside ongoing efforts to address 340B program integrity matters and keeping in mind the approaching effective date of certain Inflation Reduction Act requirements. The Department expects to be in a position to provide guidance for stakeholders in thirty days.

Dated: May 2, 2025



# 340B REBATE/CREDIT MODEL – OPERATIONAL CONSIDERATIONS

## Legal

### Terms of Use

- Review the Beacon Terms of Use to ensure your site is comfortable signing them.
- Consider outside counsel review of terms

## Leadership

### Understand the Impact

- Weigh pros/cons of participating
- Plan for what services will need to be cut/scaled back/reallocated

## Pharmacy Leadership

### Budget and Operations

- Likely to increase drug spend with initial and potentially additional WAC exposure
- Will the financial changes be enough to impact formulary decisions

## Finance Team

### New process to handle ACH rebate payments

- Will need documentation to establish ACH payments from Beacon
- May need new GL accounts and processes to reconcile payments

## IT

### New extracts

- Will need to ensure data can be submitted to rebate processor (+/- the TPA)
- Note Sanofi requires hospitals to provide encounter data with pharmacy claims data



# TOPICS TO WATCH

- HRSA
  - Healthy America
  - CMS
    - 340B Program has been proposed to fall under CMS.
      - May impact reimbursement etc. (2018-2022)
      - Will this effect eligibility?
      - Will this effect compliance requirements and enforcements?
- 'Most Favored Nation' drug pricing
  - May 12<sup>th</sup>, 2025, announced that Trump signed an executive order aimed at lowering drug prices

# Questions?



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*THANK YOU*