Desde DC a PR: Updates on Cancer Care Issues in the USA

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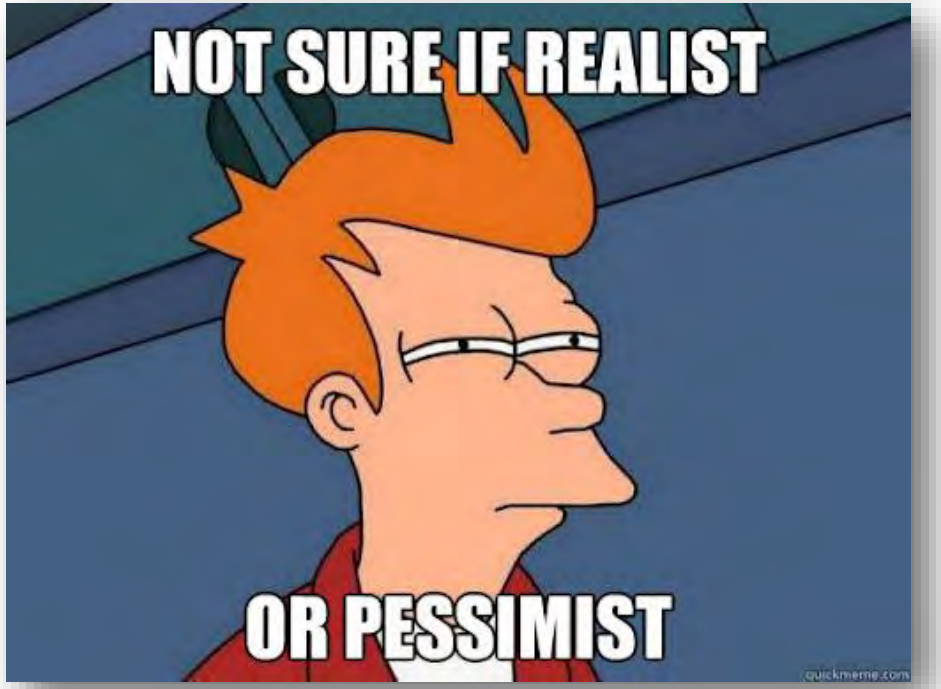
14th Annual Puerto Rico Oncology Symposium
February 8, 2025

Housekeeping Notes & Disclaimers

- I'm often called a pessimist - I prefer *realist* 🙃
- These slides/words represent my views and opinions
- Issues presented today impact ALL independent providers – not just oncologists
- Every day is a rollercoaster in Washington, so some of issues might already be outdated
- Q&A time at the end



About the Community Oncology Alliance (COA): Who We Are and What We Do

- A non-profit dedicated to advocating for independent, community oncology practices and patients.
  - The majority of Americans with cancer are treated in independent, community oncology practices.
- What COA does:
  - Public policy advocacy and engagement
  - Patient and professional empowerment
  - Practice community support and networking
  - Research and education
  - Payment and delivery system transformation
- Peer-to-peer support networks and initiatives:
  - Practice leadership teams and administrators (COA Administrators' Network, CAN)
  - Pharmacy teams (Community Oncology Pharmacy Association, COPA)
  - Patients, caregivers, survivors, and advocates (COA Patient Advocacy Network, CPAN)
  - Fellows initiative to reach future generations of physicians

2024 End-of-Year COA Survey: Practice Priorities and Concerns

1. **Staffing Challenges:** Post-COVID staffing shortages have driven up costs for less-qualified employees, increasing burnout and limiting patient care capacity.
2. **Pharmacy Benefit Managers (PBMs):** PBMs are seen as a major threat to community practices, affecting drug pricing, forcing biosimilar usage, reducing reimbursements, and impacting access to necessary medications.
3. **Reimbursement Declines:** Ongoing cuts to reimbursement rates, especially under Medicare, threaten the financial viability of practices and limit their ability to recruit new physicians.
4. **Drug and Biosimilar Management:** Complex payer requirements for preferred biosimilars, along with drug shortages, make managing inventory challenging and undermine value-based care.
5. **Hospital Consolidation and Competition:** Competing hospitals and academic centers increasingly dominate the market through 340B advantages, negatively impacting community practices and driving up overall health care costs.
6. **Prior Authorization and Formulary Issues**: Prior authorization delays, changing formularies, and insurer-mandated drug choices hinder timely and effective patient care, creating significant administrative burdens.
7. **Oral Pharmacy and Drug Shortages:** Increasing barriers in oral drug access, high out-of-pocket costs for patients, and frequent drug shortages complicate treatment delivery and impact practice solvency.
8. **Impact of Legislation (IRA and 340B):** The Inflation Reduction Act (IRA) and 340B program reforms are feared to have devastating financial impacts on private oncology practices, potentially leading to consolidation or closure.
9. **Revenue Cycle and Payer Limitations:** Practices rely on the fee schedule for survival, and frequent changes, especially without transparency, make managing revenue cycles difficult.
10. **Patient Financial Burden:** High drug costs, copay issues due to maximizers, and the potential end of copay assistance programs add to patients' financial stress, potentially impacting treatment adherence.
11. **Long-term Viability of Private Practices:** Members express concerns that current policies and payer practices are designed to eliminate independent oncology practices, potentially leading to a consolidation-driven market shift.

Beyond the IRA:
COA Overall Policy and Advocacy Priorities

1. Ensuring Sustainable Provider Payments and Reimbursement 
2. Prior Authorization and Utilization Management Reform 
3. Pharmacy Benefit Manager (PBM) Reform 
4. Addressing Anti-Competitive Hospital Policies 
5. Provider Wellness and Workforce Issues
6. Cancer Drug Shortages 
7. Supporting System Transformation and New Payment Models 
8. Improving Cancer Health Equity 

The Health Care World We Live In: Vertical Alignment and Integration

Parent/Owner	CVS Health Corporation	The Cigna Group	UnitedHealth Group Inc.	Humana Inc.	MedImpact Holdings Inc.	19 BlueCross BlueShield plans
Drug Private Labeler	Cordavis Limited	Quallent Pharmaceuticals	NUVAILA			
Health Care Provider	MinuteClinic, Signify Health	Evernorth Care Group	Optum Health	CenterWell		
Pharmacy Benefit Manager	CVS caremark 34%	Express Scripts 23%	Optum Rx 22%	Humana Pharmacy Solutions 7%	MedImpact 5%	Prime Therapeutics 3%
"PBM GPO"/ Rebate Aggregator	Zinc Health Services	Ascent Health Services	Emisar Pharma Services	Ascent (via contract)	Prescient Holdings Group LLC	Ascent (minority owner)
Pharmacy - Retail	CVS Pharmacy					
Pharmacy - Mail Order	CVS Caremark Mail Service Pharmacy	Express Scripts Pharmacy	Optum Rx Mail Service Pharmacy	CenterWell Pharmacy	Birdi, Inc.	Express Scripts Pharmacy (via contract)
Pharmacy - Specialty	CVS Specialty Pharmacy	Accredo	Optum Specialty Pharmacy	CenterWell Specialty Pharmacy	Specialty by Birdi	Accredo (via contract)
Health Insurer	Aetna	Cigna Healthcare	UnitedHealthcare	Humana		19 BlueCross BlueShield plans

Vertical alignment within wholesale distribution channels

	cencora	CardinalHealth	McKESSON
Manufacturer	BluePoint Laboratories	Major Rugby	NorthStar Rx
Wholesale distribution	AmerisourceBergen, Besse Medical Oncology Supply	CardinalHealth	McKESSON
Specialty pharmacy	—	—	Biologics By McKesson
Retail pharmacy	Good Neighbor Pharmacy	The Medicine Shoppe Pharmacy	Health Mart
PSAO	Elevate Provider Network, Accelerate Specialty Network	LeaderNET	Health Mart Atlas
GPO	cencora Specialty GPOs	Specialty GPOs	Onmark, Unity
Provider	OneOncology, RETINA	Navista, GI Alliance	The US Oncology Network

PSAO = pharmacy services administrative organizations; GPO = group purchasing organization
Source: *The 2024-25 Economic Report on Pharmaceutical Wholesalers and Specialty Distributors*. Exhibit does not illustrate every subsidiary business operated by each company.

DRUG CHANNELS INSTITUTE
An HMP Global Company

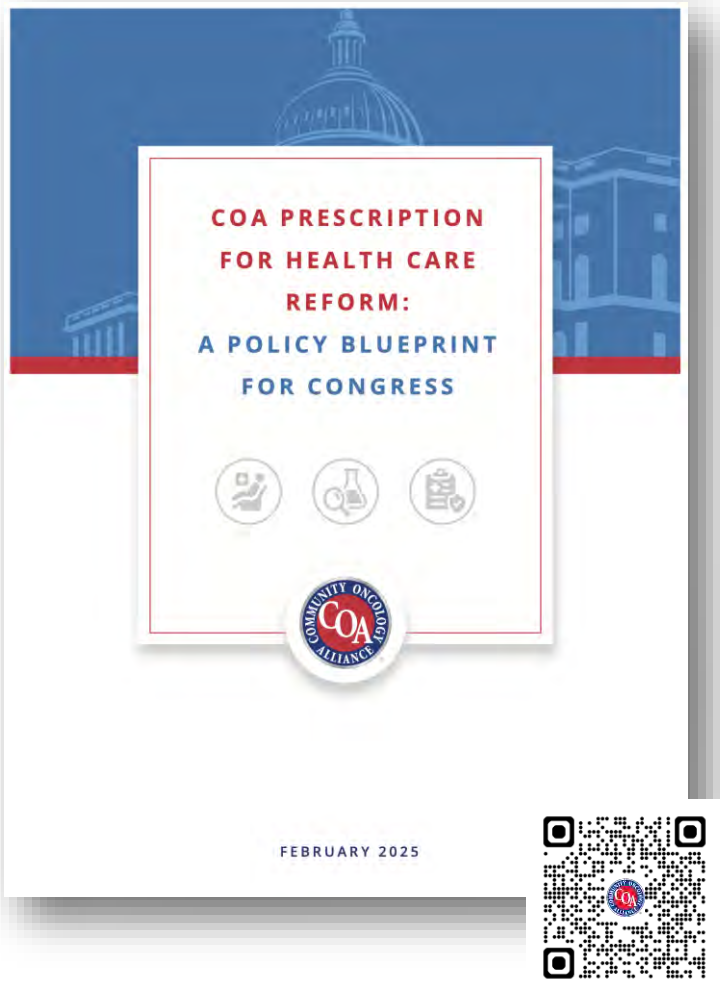
https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf
https://www.drugchannels.net/2025/02/vertical-integration-redux-how.html

COA Prescription for Health Care Reform

- A **policy blueprint** for Congress, applicable to *all* areas of medicine:
  - Diagnosis of major issues impacting the U.S. health care system
  - Prescription for what the 119th Congress needs to do to treat
  - Ongoing treatment for 120th Congress and beyond must do

- **Five-part plan** that covers:
  1. Hospitals and Health System Consolidation
  2. Insurance and PBMs Consolidation and Market Dominance
  3. Fixing Physician Reimbursement and Workforce Shortages
  4. Ensuring Access to Oncology Therapies (Drugs)
  5. Modernizing Structural CMS Medicare Policies

- Released this week in Washington with Congressional briefing, media roundtable, and stakeholder meeting



All Politicians Have Made Big Promises to Address/ Lower Health Care and Drug "Costs"

- Every elected official in the U.S. has promised to "lower health care costs"
- The term "health care costs" conflates and confuses several pocketbook issues:
  - Insurance prices, drug prices, hospital costs, Medicare/Medicaid/MA premiums
  - On purpose? Conveniently?
- "Big Pharma" has long been vague punching bag boogeyman for politicians
- But… IRA drug price "negotiations" has allowed politicians to focus attention on other areas
  - Especially pharmacy benefit managers (PBMs), hospitals, and insurers

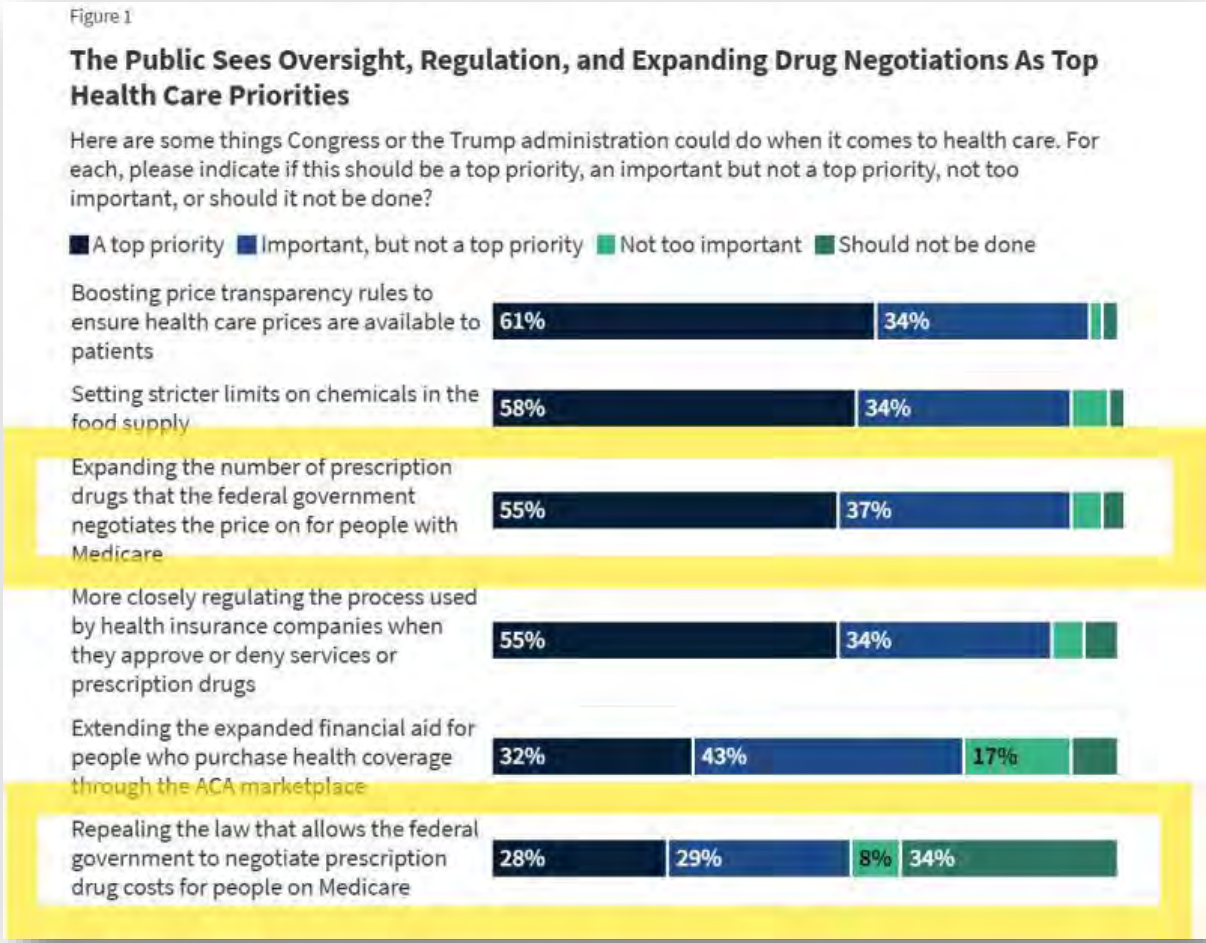


Figure 1

The Public Sees Oversight, Regulation, and Expanding Drug Negotiations As Top Health Care Priorities

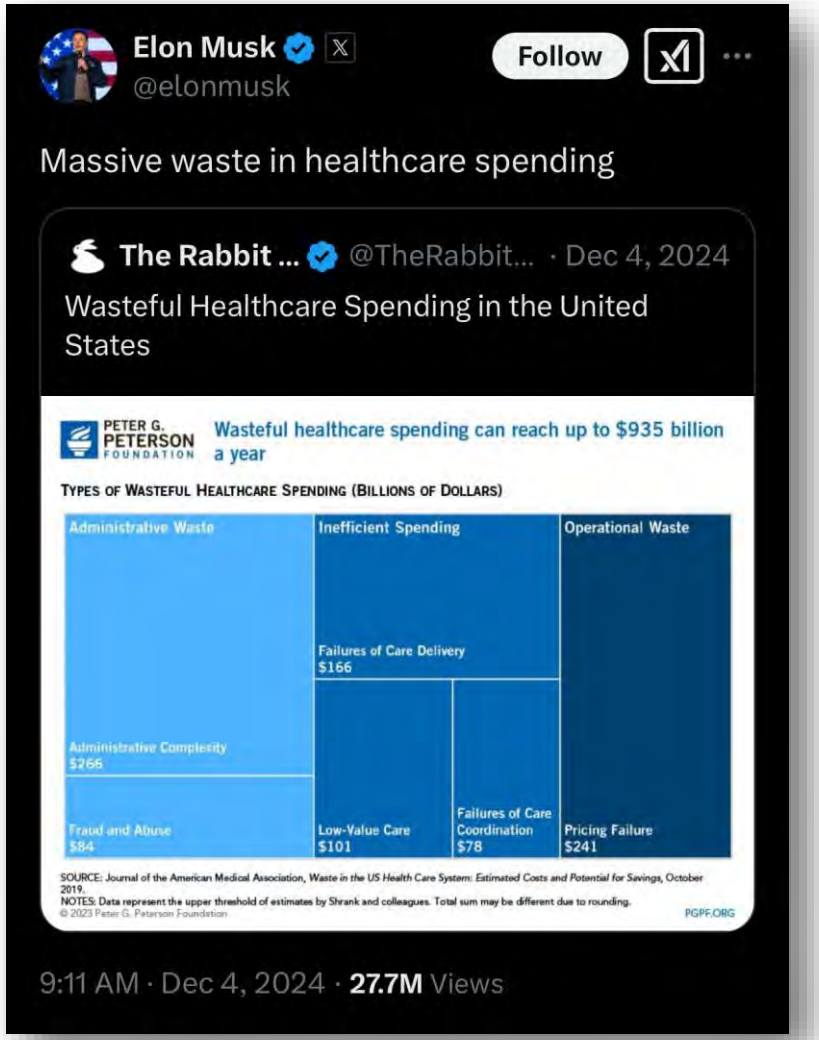
Here are some things Congress or the Trump administration could do when it comes to health care. For each, please indicate if this should be a top priority, an important but not a top priority, not too important, or should it not be done?

https://www.kff.org/quick-take/whats-next-for-medicare-negotiated-drug-prices-under-the-trump-administration/

Overall Political and Health Policy Outlook: Unified Republican Control Will Drive Health Policy Shift

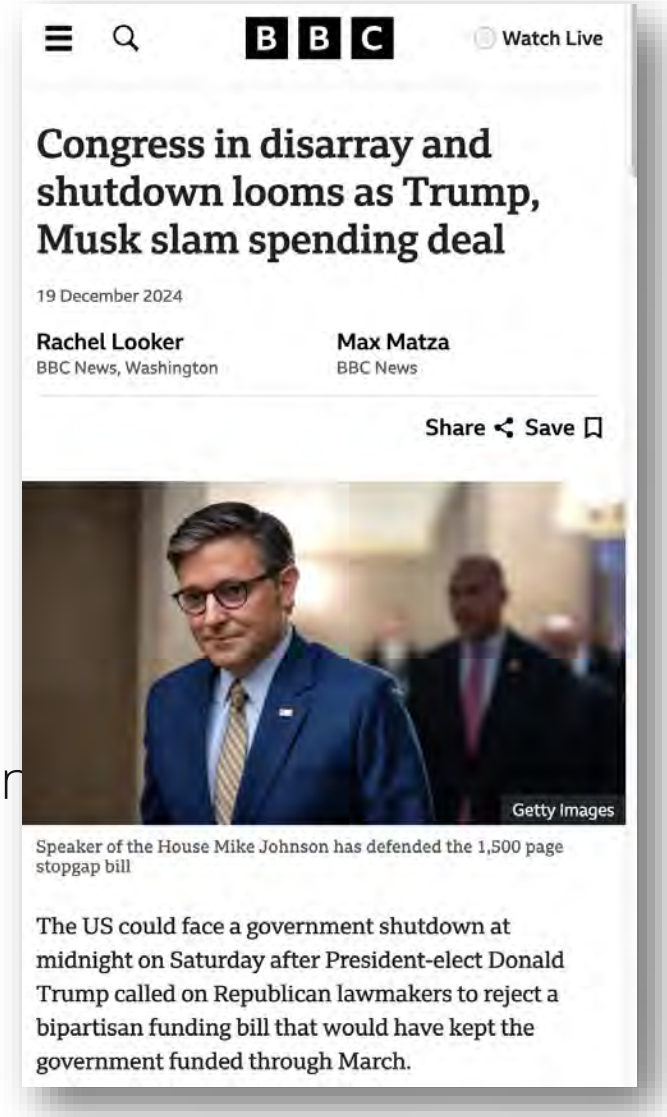
- Republicans Trifecta Controls Washington – White House, House of Reps., Senate
  - Republican leadership sets the stage for significant legislative action.
- Trump Administration Signals Shift in Health Care Priorities
  - Focus on regulatory reform, preventive health/chronic disease, and MA.
  - Cabinet nominations of RFK Jr., Dr. Oz, along with agency leadership will drive policy implementation
- Slim Republican Majority in Congress – Gridlock?
  - Narrow margins (House: 217-215, Senate: 53-47) will require bipartisan support for major reforms.
- Don't forget about Elon Musk/DOGE and outside pressures
  - Think tank leadership ideas – AFPI, Paragon, Heritage
- State-Level Policy Momentum Continues
  - No major shifts in state party control post-2024 elections.
  - Continued state-led efforts on drug pricing, PBM reform, and health care cost containment.

2025 Off to a Busy Start in DC, Health Care Included: Cabinet Nominations (RFK, Oz), DOGE "Investigations"…



2024 Was Filled With Great Potential, Finished With Some Disappointment

- What was POSSIBLE in Congressional at end of 2024?
  - Fix to CMS restrictions on drug delivery (Stark)
  - Major PBM reform
  - Site-neutral payment reform
  - Offsetting some of Physician Fee Schedule cut to provider payment/reimbursement
  - More…
- What HAPPENED with Congress at end of 2024?
  - Last minute political torpedo, near shutdown
  - Congress only passed bare-bones continuing resolution (CR) budget – keeps government funding and appropriations at curren levels until March 2025
  - Really, only success is Telehealth waiver extended, for now
- We came so close…



BBC

Watch Live

Congress in disarray and shutdown looms as Trump, Musk slam spending deal

19 December 2024

Rachel Looker
BBC News, Washington

Max Matza
BBC News

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Getty Images

Speaker of the House Mike Johnson has defended the 1,500 page stopgap bill

The US could face a government shutdown at midnight on Saturday after President-elect Donald Trump called on Republican lawmakers to reject a bipartisan funding bill that would have kept the government funded through March.

Short Term COA Policy Agenda: Q1 Advocacy Priorities

1. Ending CMS restriction on delivery/courier/family or caregiver pickup of medications (Stark law)

2. Averting full physician payment (Physician Fee Schedule) pay cut

3. Enacting PBM reforms

4. Socializing technical fix to the Inflation Reduction Act (IRA)

Short Term COA Policy Agenda: How We Might Make Progress on Priorities

- Many health priorities left undone at end of 2024 and must pass new budget by March 14.

- Two approaches to health care legislation being discussed in Congress:
  1. Standalone health care bill?
     - Congress wants to clear deck of outstanding health care legislation from December
     - To include doc fix partial offset and PBM reform
     - This is currently what rumors say will happen, but that can change

  2. Reconciliation package(s)
     - Reconciliation is expedited way for Congress to pass tax and spending legislation with simple majority votes. But must deal have budget/spending implications.
     - Focus right taxes, border security, defense, and energy.
     - Republicans discussing if there will be one or two reconciliation bills.
     - Current timing is ambitious: drafts by February , vote in March. Unlikely.

- Working to get Stark drug dispending bill momentum and regulatory fixes
  - Need to get re-introduce into House and Senate. Possibly next week.
  - Either get passed on own or hitch ride on health care package.
  - Also have some ideas for regulatory relief that CMS could offer.

CMS Reinterpretation of Drug Delivery: A Stark Law Violation?

- CMS "FAQ" prohibits practices from delivery of oral drugs to patients. Must be picked up in-person
  - Allowed during COVID, stopped with end of PHE
  - A Stark law violation against self-dealing (how???)
  - Friends, family, caregivers also not allowed to pick up
- Patients can get drugs through mail order from Part D plan sponsor (aka PBMs) - a nightmare for patients and practices
- COA lawsuit and FOIA requests with CMS ongoing
- Had legislative fix with 118th Congress – working to reintroduce in 119th
  - Seniors' Access to Critical Medications Act (H.R. 5526 & S. 3458)
  - Passed out of full Energy and Commerce with bipartisan, unanimous support (43-0 vote)
  - Fell apart with end-of-year Congressional budget fiasco

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HEALTH

Some Cancer Patients Must Travel Hundreds of Miles for Medication

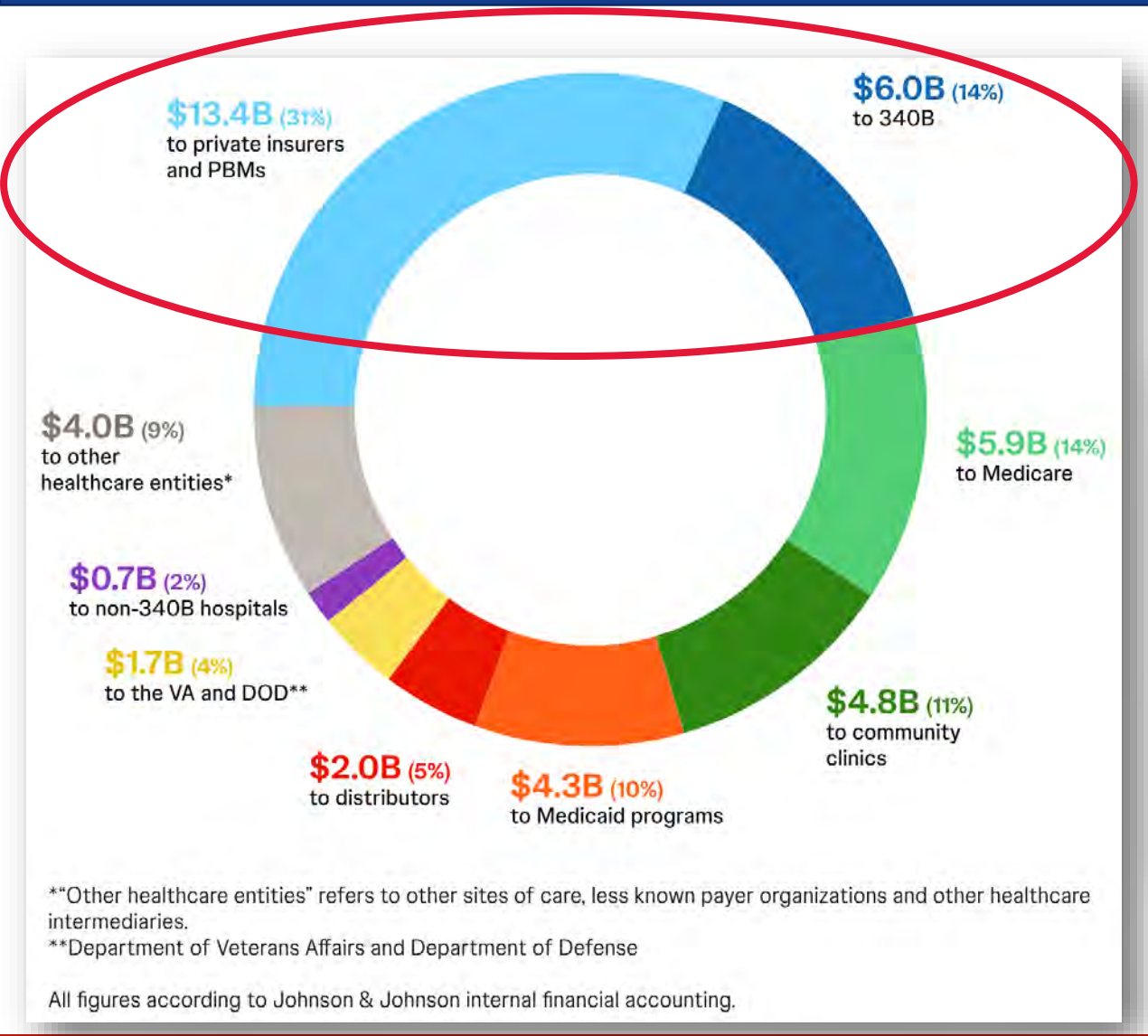
Health emergency's end means independent cancer doctors can't send prescriptions directly to their Medicare patients

By Stephanie Armour Follow

June 12, 2023 9:00 am ET

Gift unlocked article

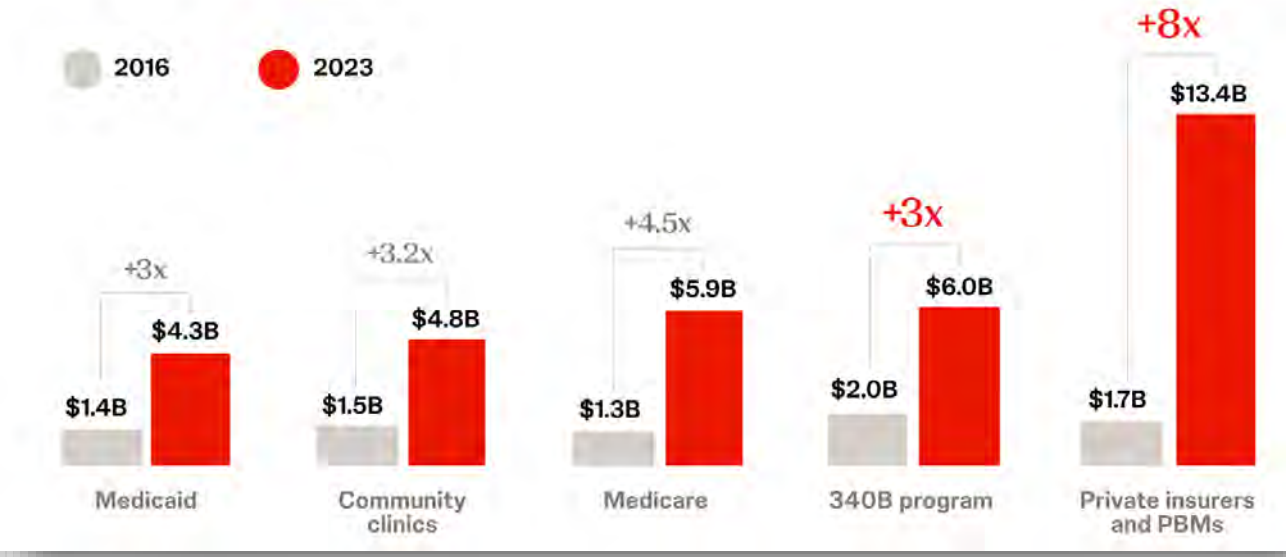
Growing Scale of Rebates & Discounts: J&J Transparency Report



*"Other healthcare entities" refers to other sites of care, less known payer organizations and other healthcare intermediaries.
**Department of Veterans Affairs and Department of Defense

All figures according to Johnson & Johnson internal financial accounting.

Our rebates, discounts and fees have risen significantly from 2016 to 2023[6]

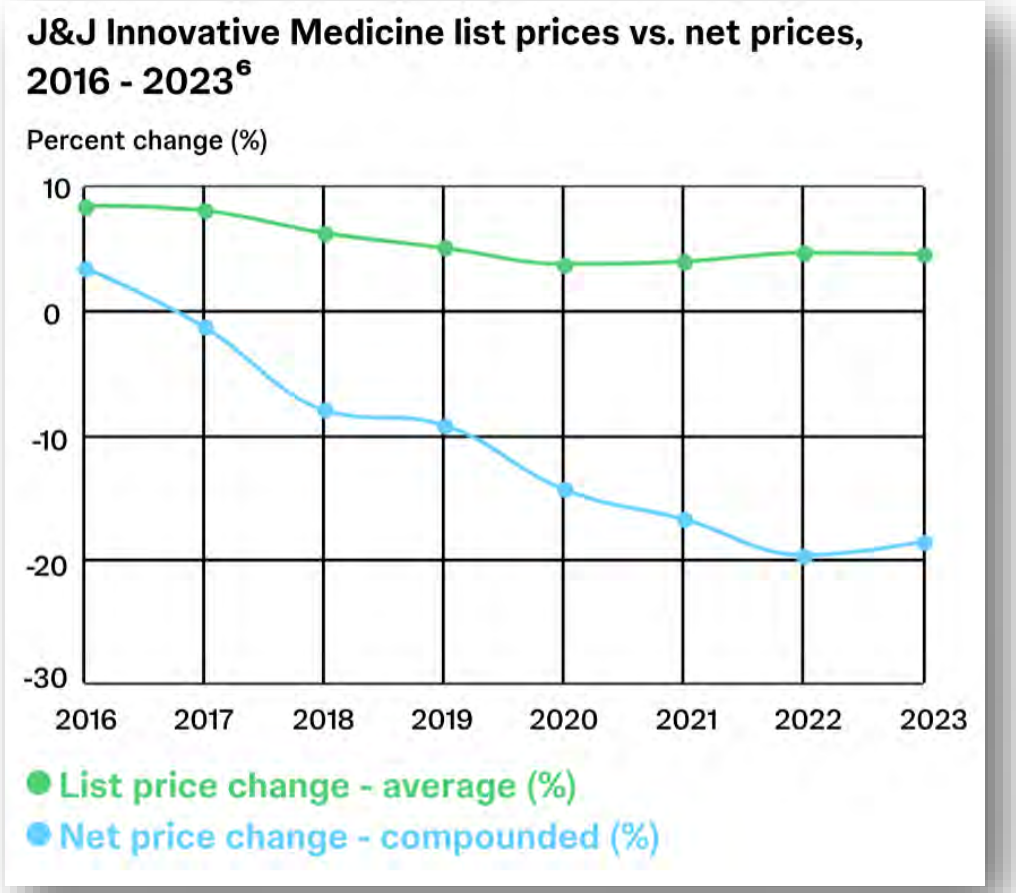


Rebates & Discounts Drive Up Drug Prices: Nothing in Life is Free

- Manufacturers account for PBM rebates and other discounts in setting drug list prices.

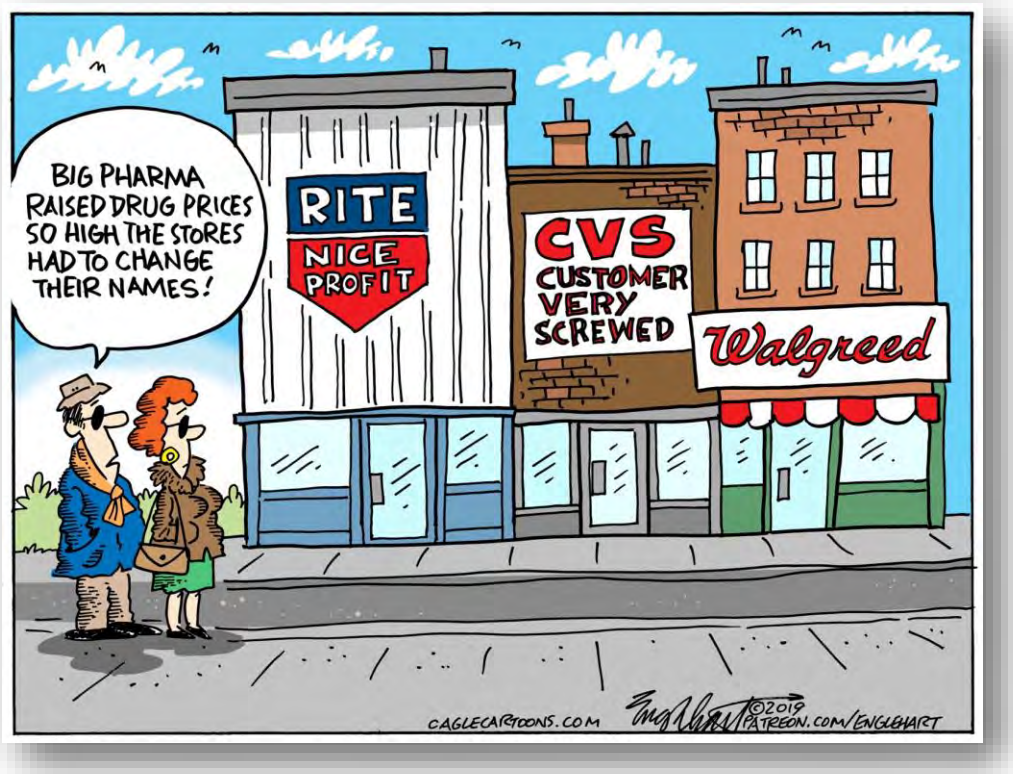
- Excessive scope and magnitude of PBM rebates and other discounts are fueling drug list prices that patients pay.
  - "List prices" are what employers and employees pay on!
  - Rebates are threatening the viability of the biosimilar market

- **There is no free lunch:** discounts and rebates are accounted for in drug prices.



PBMs, PBMs, PBMs: Major PBM Abuses, Consolidation Remain Unchanged

- Most people don't know about PBMs because they are middlemen, not always visible to patients.
  - Silently control what, when, and where patients access prescription drugs
- PBMs impact on patients
  - Delaying and denying cancer patients from getting their drugs
  - Forced use of mail order pharmacy
  - Using "fail first" step therapy, prior auth, and other utilization management to ensure most profitable (to the PBM) drugs used
- PBMs impact on practices
  - Underwater reimbursement in post-DIR Fee world
  - Excluding pharmacies from PBM networks
  - Moving medical benefit drugs to pharmacy benefit



Second Federal Trade Commission PBM Report

- FTC report key findings:
  1. Top three PBM's marked up drugs by as much as 1,000 percent
  2. Oncology drugs were largest revenue driver of spread pricing.
  3. PBM's reimburse their own higher rates than non-affiliated pharmacies

- FTC voted 5-0 to releases second report
  - COA organized FTC Commissioner Melissa Holyoak visit with practice last October to educate on business impact PBM's are having on practices

Will We See PBM Reform now? Probably, Maybe…?

- Pre-COVID and pre-IRA, PBMs were happy in shadows
  - Democrats – Barely acknowledged PBMs, focused on "big pharma"
  - Republicans - Acknowledged PBM issues but not a major focus
- Post-COVID and IRA: PBMs under bipartisan scrutiny
  - Multiple rebates on PBM abuses and behaviors
  - Two FTC staff reports
  - Trump mention of taking on the "middlemen"
- Bipartisan action on PBMs in Congress
  - At least 25 PBM-focused bills in 118th Congress
- Will we see PBM reform from Congress in 2025?
  - Failed to make into budget packages and lame duck
  - Bipartisan Congress serious about keeping momentum

Types of PBM Reforms Before Congress

1. Transparency
   - Reporting requirements on drug prices, rebates, formulary, benefit design.

2. Banning Spread Pricing
   - When PBMs reimburse pharmacies less than what they make from drug plans and keep the "spread" as profit.

3. Rebate Passthrough
   - Requiring PBMs to pass on 100% of rebates, fees, discounts to plan sponsors.

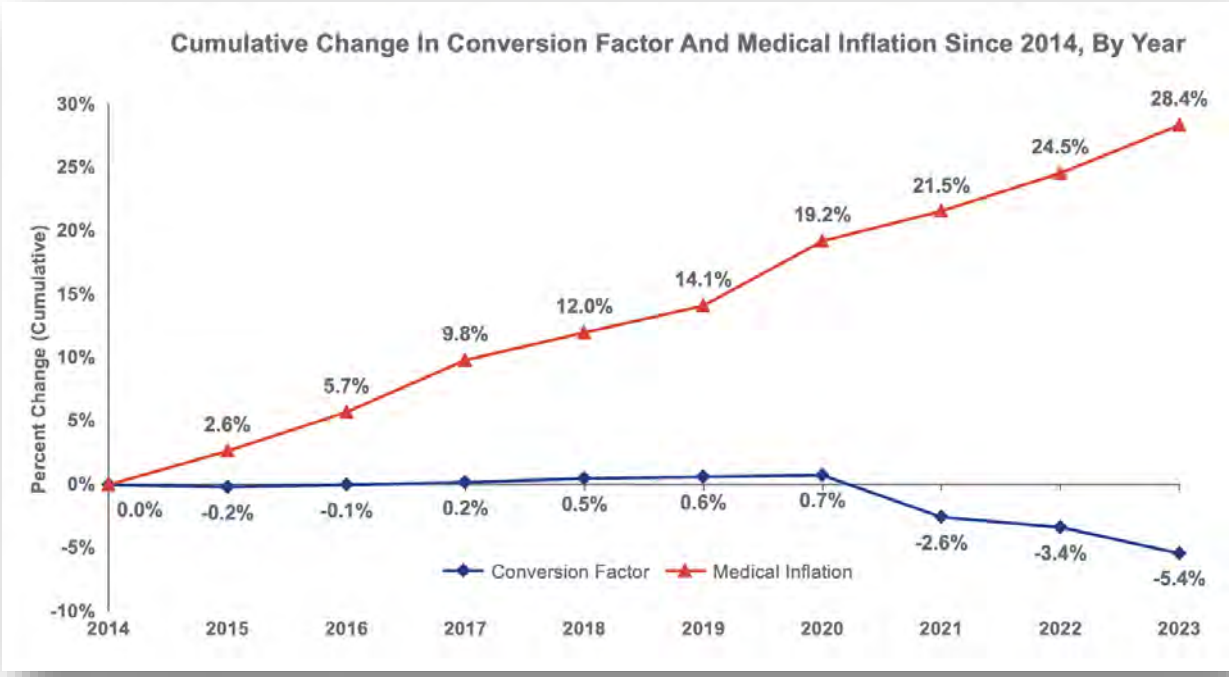
4. Reduce Patient Out-of-Pocket Costs
   - Tie cost-sharing to the negotiated net price, instead of the list price.

5. Delinking drug prices from PBM profits
   - Prohibiting PBMs from earning a profit based on drug list price. Instead, must be flat dollar service amount.

Medicare Payment and Reimbursement Continues to Decline

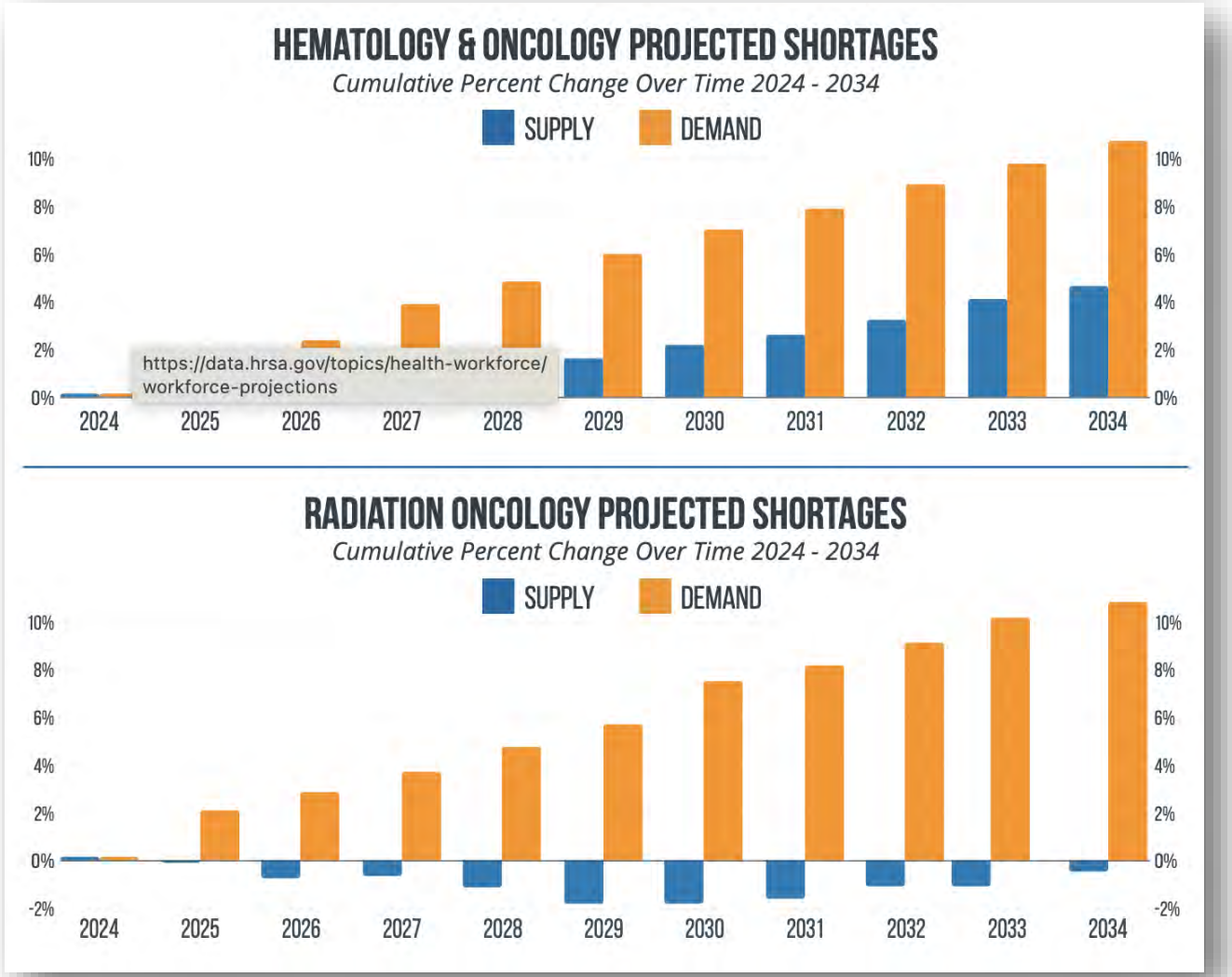
- Payment by Medicare for cancer care services at independent practices *decreased* last decade (2014-2023)
  - Medicare reimbursement (conversion factor) decreased 5.4%.
  - Compounded medical inflation increase was 28.4%.

- 2025 Physician Fee Schedule (PFS) another **3.98% overall payment cut for practices**
  - Evaluation/Management (E/M): 2.69% cut
  - Infusion: 7.14% cut
  - Imaging: 3.78% cut
  - Radiation: 2.22% cut



We Are Facing a Growing Oncology Workforce Shortage (Disaster!)

- The US is projected to see a shortage of more than 2,200 hematologists and oncologists in 2025
  - Demographic shifts of an aging population continue to fuel the need/demand for oncologists
- The oncology workforce is heavily concentrated in a few urban counties
  - The majority of rural counties in the US do not have an oncologist
- The need for oncology care is outpacing the capacity of current residency and fellowship programs



Physician Payment: Averting PFS Cut

- The Medicare Patient Access and Practice Stabilization Act of 2025
  - Rep. Dr. Greg Murphy (R-NC) introduced in January
  - 6.6% rate increase through 2026 and be retroactive to the beginning of this year, when a 2.9% cut took effect.

- Congress understands and wants to act, but permanent fix is expensive
  - Real fix: Pegging physician reimbursement to medical inflation
  - Very expensive fix to fully tie PFS to inflation
  - Tricky in era of tough Congressional budget hawks

- Prediction: Partial relief by Congress, and continued attention to Medicare physician payment.

Hospitals, "Non-Profit" Hospitals, 340B Program Under Increasing Scrutiny

HealthAffairs Topics Journals Forefront Podca

Nonprofit Hospitals: Profits And Cash Reserves Grow, Charity Care Does Not

Derek Jenkins and Vivian Ho

AFFILIATIONS

PUBLISHED: JUNE 2023 Free Access https://doi.org/10.1377/hlthaff.202

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Nonprofit hospitals received $37.4B in federal, local tax benefits in 2021, study finds

By Dave Muoio

Sep 26, 2024 11:00am

THE WALL STREET JOURNAL.

Big Nonprofit Hospitals Expand in Wealthier Areas, Shun Poorer Ones

Despite lucrative tax breaks for serving needy communities, many large systems focus growth on higher-income neighborhoods

KFF Health News

PERSPECTIVE

Why Many Nonprofit (Wink, Wink) Hospitals Are Rolling in Money

PROFITS OVER PATIENTS

How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits

Bon Secours Mercy Health, a major nonprofit health system, used the poverty of Richmond Community Hospital's patients to tap into a lucrative federal drug program.

"Bon Secours was basically laundering money through this poor hospital to its wealthy outposts," said Dr. Lucas English, who worked in Richmond Community's emergency department until 2018. "It was all about profits."

The New York Times

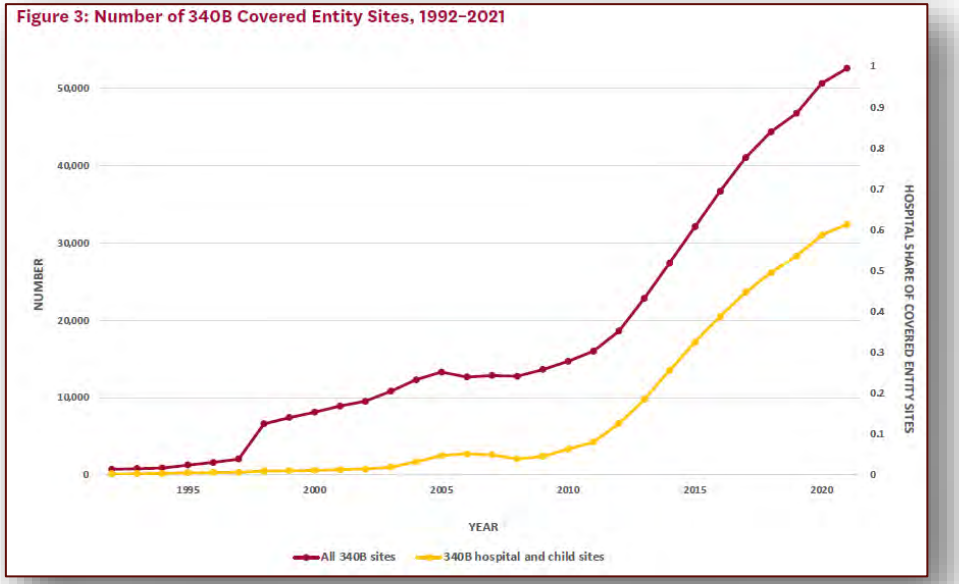
How a Company Makes Millions Off a Hospital Program Meant to Help the Poor

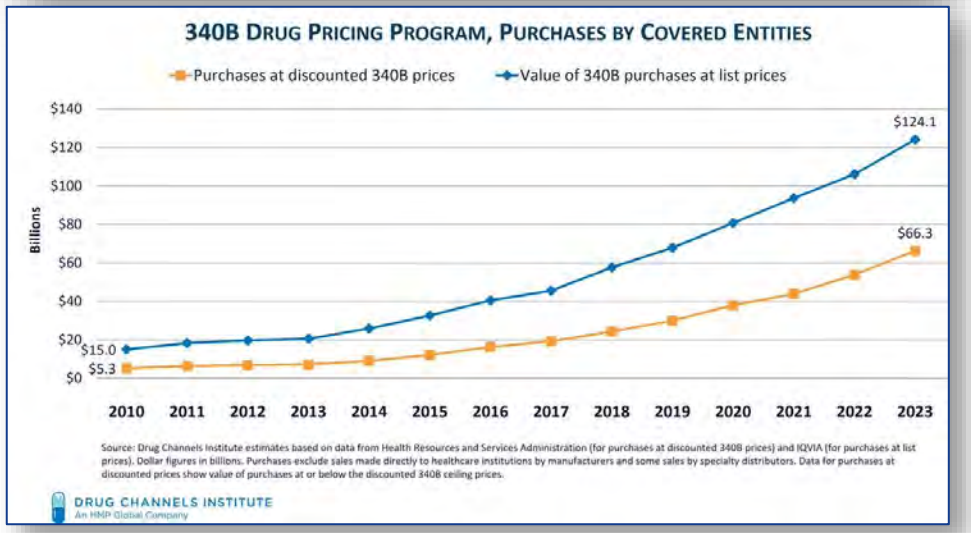
A private business has helped supercharge a controversial federal drug program. Patients and insurers have been left with big bills.

340B is a Good Program Gone Bad: Controversy and Growth

- 340B is an IMPORTANT PROGRAM that must be preserved, but it has been grossly abused by some large, mega hospitals and health systems.
  - Have used 340B program to generate huge profits from drug sales arbitrage
  - Buy cancer drugs at =50% discount, then sell to patients at 5-11x markups
  - Little transparency, oversight, or accountability to how savings are used
  - No requirement to use savings to lower costs or provide charity care

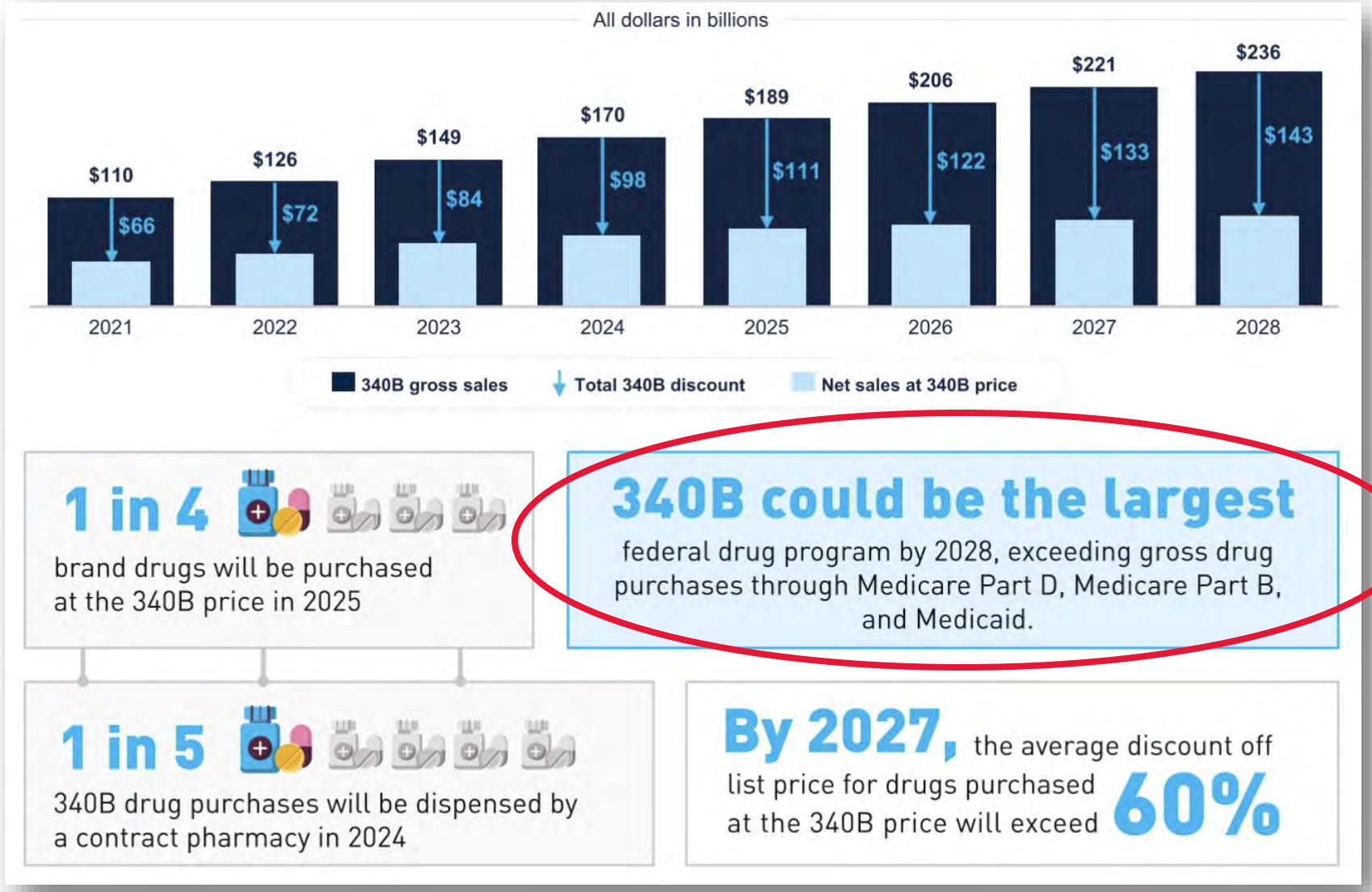
- Today 2/3 of U.S. hospitals participate in 340B
  - Expanded from small handful of safety net providers to 50,000+ sites in 2020.
  - Many of the major name brand institutions and mega dominant regional health systems





Source: USC Schaeffer Center for Health Policy & Economics (link)

The State of the 340B Program: Forecasts



Source: BRG (link)

Outrageous 340B Drug Markups in Hospitals: Average 5x Cost of Drug Acquisition

Exhibit 5.

Herceptin Markups Across Settings and Payers

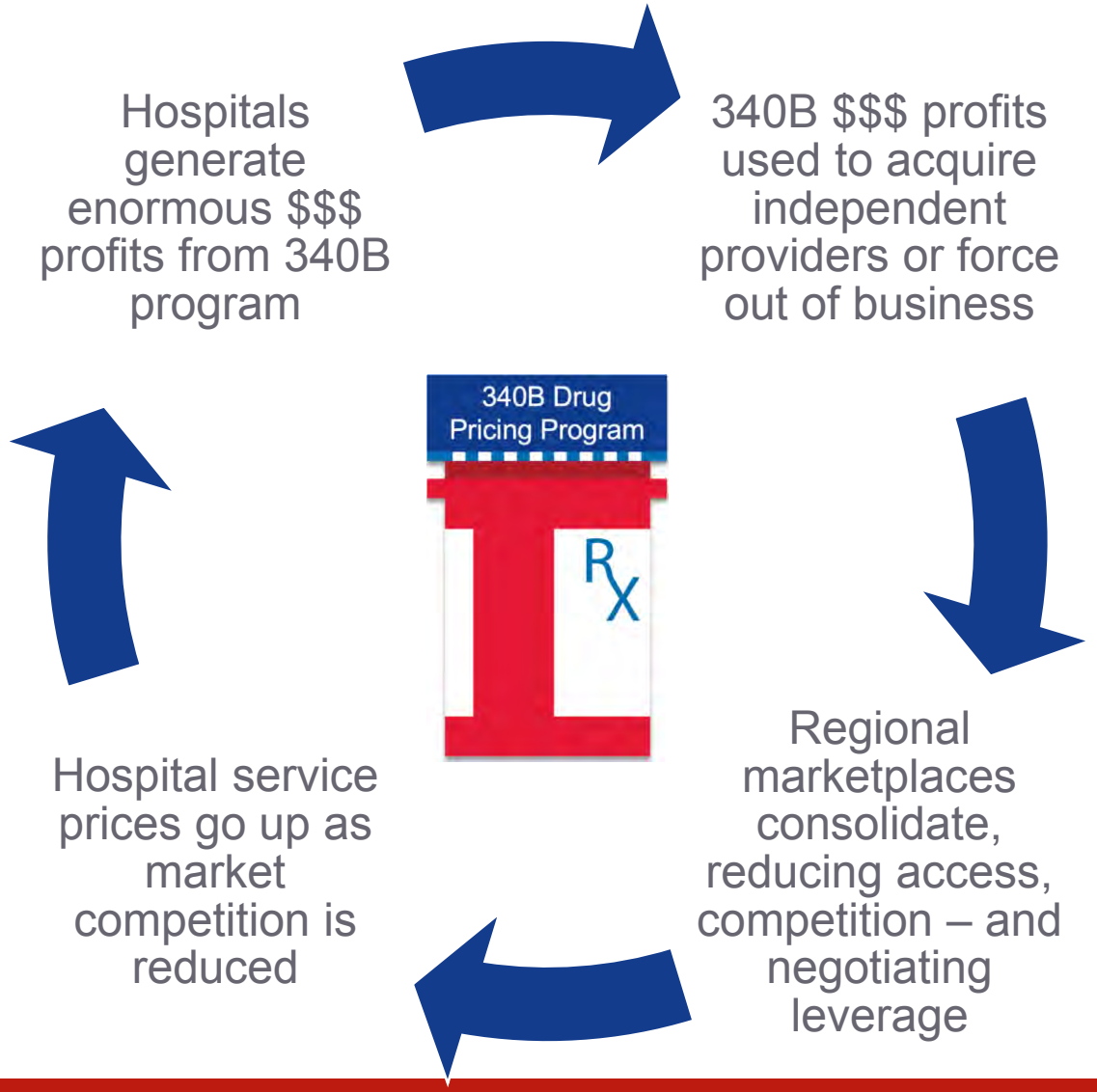
(one year of therapy)

Community Practice or non-340B Hospital Treating a Medicare Patient	
Purchased for	$66,107
Reimbursed at	$70,073
Margin	**$3,966**

340B Hospital Treating a Medicare Patient	
Purchased for	$43,168
Reimbursed at	$70,073
Margin	**$26,905**

340B Hospital Treating a Commercial Patient	
Purchased for	$43,168
Insurer Charged	$217,122
Margin	**$173,954**

340B Fuels a Vicious Cycle That Impacts Us All: Consolidation, Reduced Competition, Increased Costs

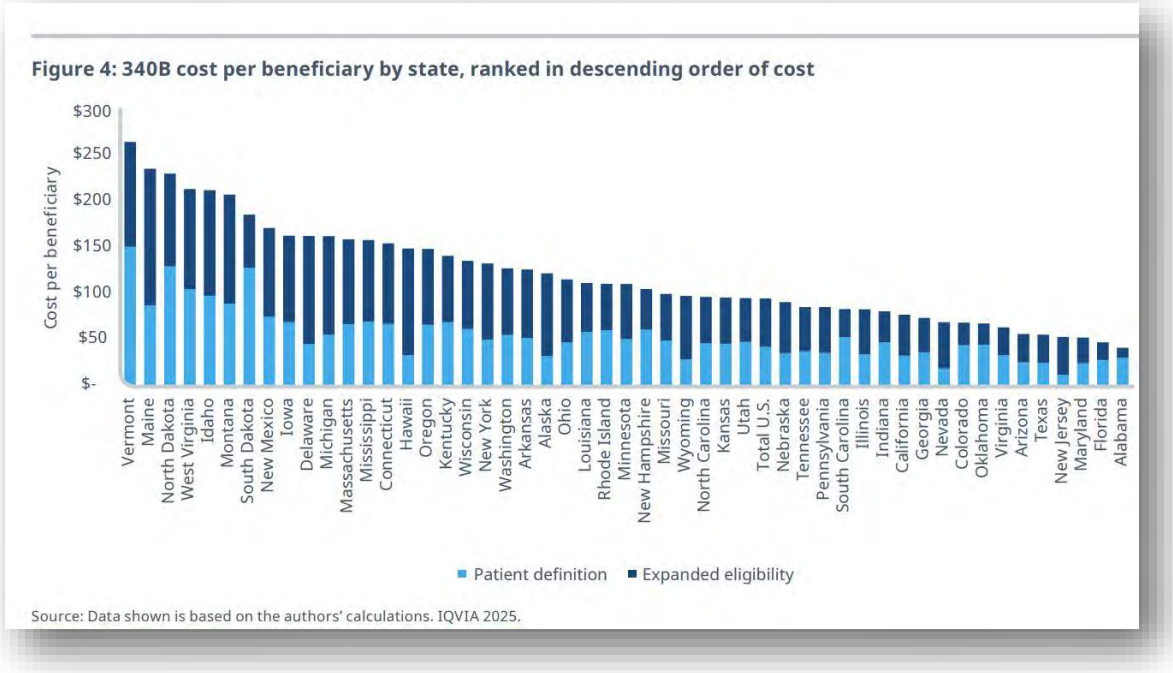


340B Raises Costs for Employers and State and Local Governments by Billions

- 340B not just a wealth transfer from pharma companies to hospitals. The average American (and their employer) is paying a hidden tax, too.

- IQVIA study: 340B **increased costs for employer-sponsored plans from $13 to $152 per beneficiary** depending on the state
  - Aggregating to $6.6 billion over the entire United States for 2023.

- 340B found to **increase costs:**
  - **For employer-sponsored plans by $6.6B**
  - **For state and local governments by $1.0B**
  - Cost per covered beneficiary was about 10% larger due to higher government plan spending.



340B Reform Becoming More Likely at Both the Federal and State Levels

- Political outlook for 340B is changing, making reform possible
  - Bipartisan attention being paid to program
  - Some 340B grantees/community clinics distancing themselves from mega hospitals
  - Lots of money and savings to be found from regulating 340B
  - Remember: first Trump administration tried reducing 340B reimbursement – went to Supreme Court and lost on technicality. Could still come back!

- Possible 340B reforms:
  1. Improved transparency and reporting of 340B discounts.
  2. Accountability and true oversight of how money is being used by hospitals.
  3. Discounts follow the patient – directly benefit them.

- Increasing 340B regulation at state level – good and bad
  - Some bills do not fix 340B but reenforce problems – prevent PBM and insurer interference
  - Some state taking lead on holding "non-profit" and 340B hospitals accountable.

- Legal battles as manufacturers respond to program growth, abuse
  - Restricting sales to "unlimited" number of contract pharmacies
  - Emergence of "Rebate" model after purchase/dispensing vs discounts at purchase
  - Multiple lawsuits underway. Going to Supreme Court?

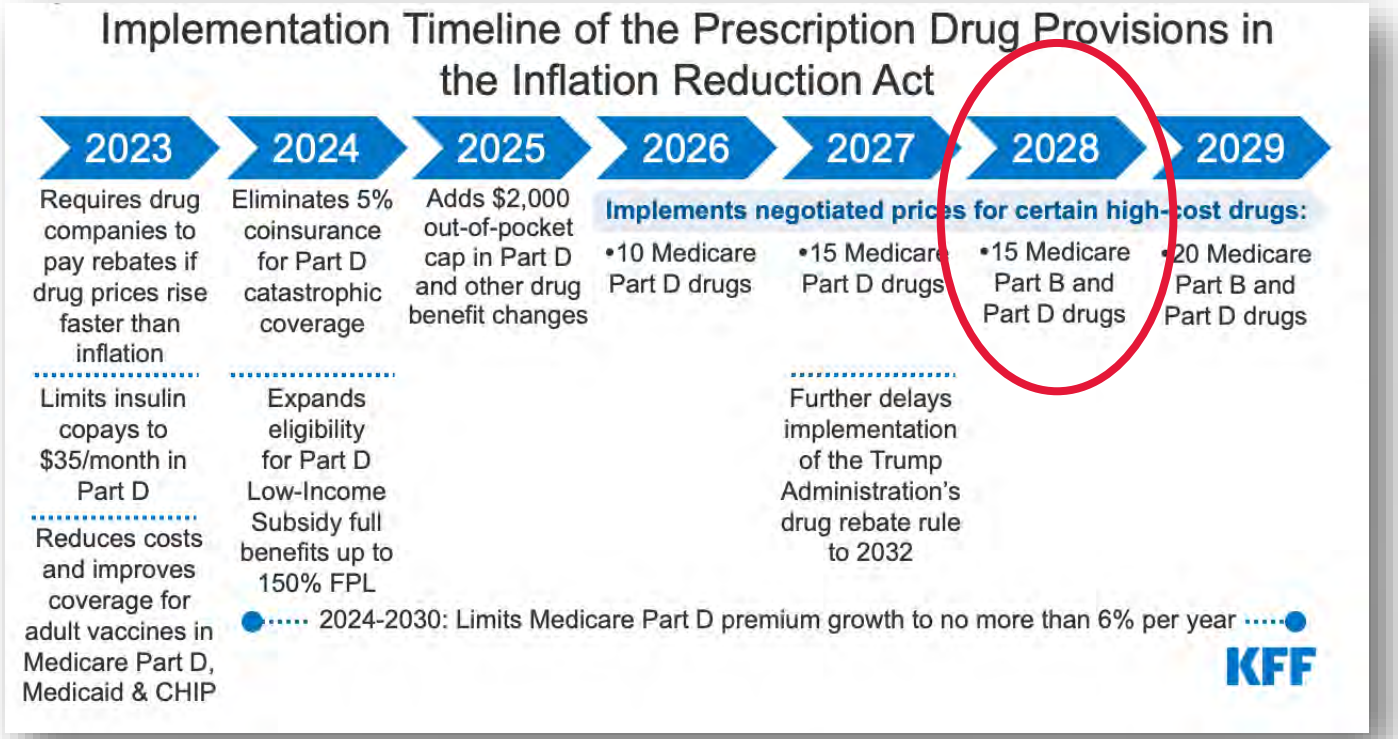
Key Takeaways on the IRA: A Big Impact, so Learn, Prepare, Advocate

- The IRA has several good provisions, particularly for patients.
  - Especially part D out-of-pocket cap and increased biosimilars reimbursement
- But IRA will have a huge impact on reimbursement AND operations.
  - Massive cuts to Part B reimbursement
  - Changes to operations, cash flow, contracting, treatment access and more
- There are technical fixes to the IRA being discussed, and they need your advocacy support to become a reality.
- Fixing the IRA is about the survival of independent community oncology.
  - You will feel this. Your patients will feel this. We have to respond.
  - The time to act is now!

IRA Impact in 2028: Massive Cut to Part B Reimbursement

Avalere estimates the first 10 Part B drugs likely to be negotiated include:

1. Orencia (Abatacept)
2. Opdivo (Nivolumab)
3. Keytruda (Pembrolizumab)
4. Botox (OnabotulinumtoxinA)
5. Nucala (Mepolizumab
6. Ocrevus (Ocrelizumab)
7. Tecentriq (Atezolizumab)
8. Cimzia (Certolizumab pegol)
9. Nplate (Romiplostim)
10. Entyvio (Vedolizumab)



https://www.kff.org/wp-content/uploads/2022/08/Inflation-Reduction-Act-Web-Event-Slides.pdf

IRA Impact in 2028: Massive Cut to Part B Reimbursement

- Medicare Part B drug payments will be based on new, lower, negotiated MFP (Maximum Fair Price), not ASP.
- Medical oncology/hematology would see 49.5% decrease in Part B add-on reimbursement.
- Threat to Independent Oncology:
  - Practices today rely heavily on Part B reimbursements to sustain operations—this disrupts financial stability.
  - Clinics may struggle to absorb losses, risking delays/disruptions in patient care, or worse.

Avalere

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November 29, 2022 | Insights & Analysis | Drug Pricing

IRA Medicare Part B Negotiation Shifts Financial Risk to Physicians

Summary

IRA would lead to a minimum 47% add-on payment reduction on average for Medicare providers who furnish the Part B drugs initially targeted for negotiation.

The Inflation Reduction Act (IRA) was signed in August 2022 and requires the Secretary of Health and Human Services (HHS) to negotiate and publish a "Maximum Fair Price" (MFP) for select single-source drugs that are covered under Medicare Part B (physician-administered products) and Part D (retail products). Varying with a product's number of years on market, the IRA established an automatic reimbursement reduction equal to an applicable percentage of a drug's average non-federal Average Manufacturer Price (non-FAMP).

Milena Sullivan
Managing Director

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Blair Burnett
Consultant II

Reed Diskey
Senior Associate

https://avalere.com/insights/ira-medicare-part-b-negotiation-shifts-financial-risk-to-physicians

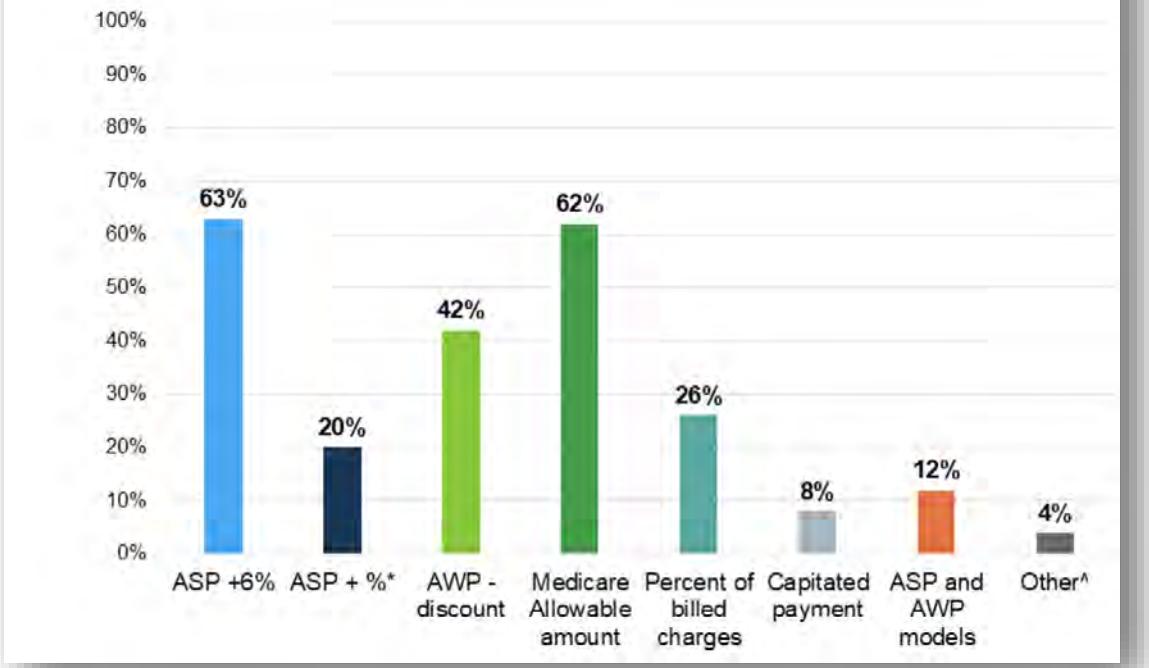
And More IRA Impact in 2028: Commercial Spillover and Private Payer Risks

- Medicare negotiations will ripple into commercial contracts
  - **Many commercial plans peg Part B reimbursement** to Medicare's ASP+6% or the Medicare Allowable rate—both will drop with IRA

- **63% of payers** use **ASP+6%**, and **62% use Medicare Allowable rates**—both will be affected by lower MFP prices.

- Oncology faces more than **$12 billion** in reimbursement cuts through 2032.
  - Oncologists may experience a **39% to 64%** decrease in Medicare FFS add-on payments.
  - Commercial and Medicare Advantage add-on payments could see a **13% to 21%** reduction.

Figure 1. Percent of Payer Respondents Using Certain Provider Reimbursement Methodologies

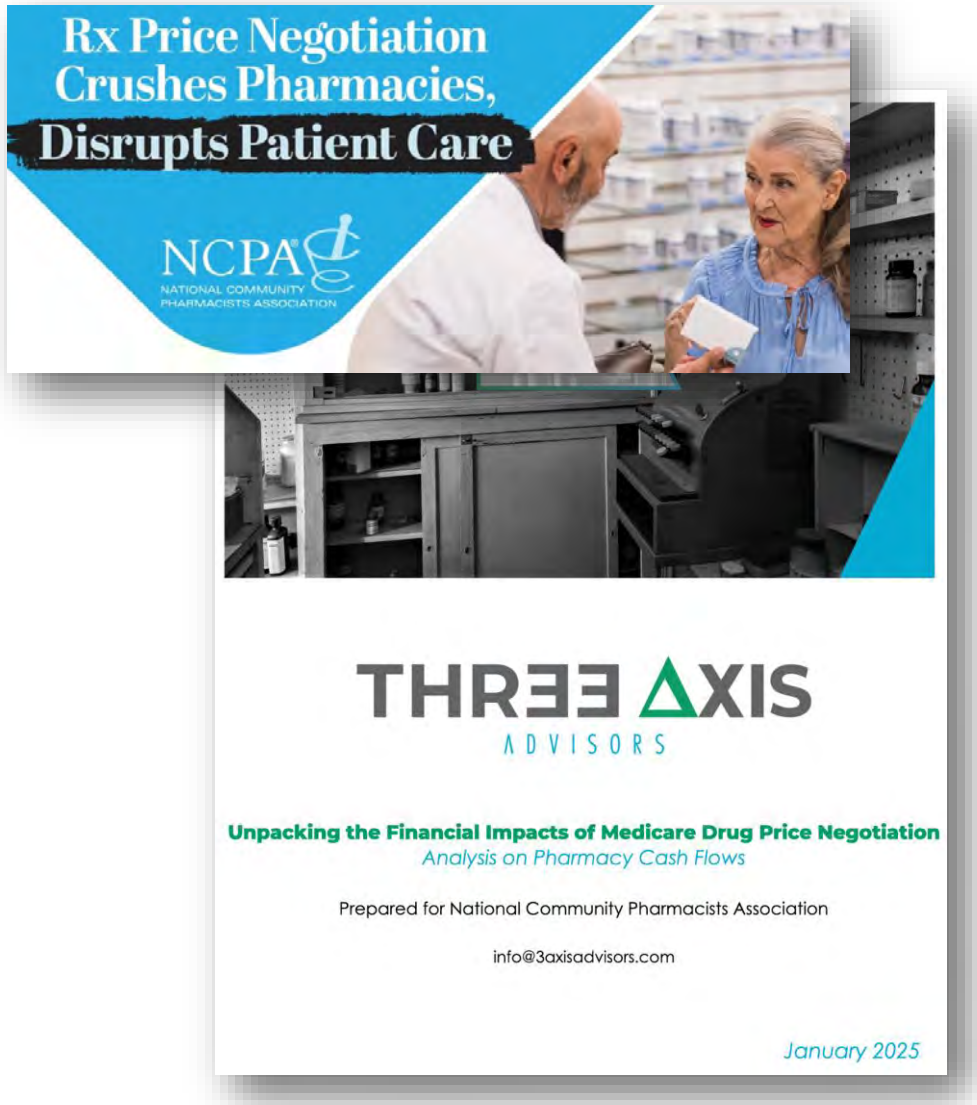


https://avalere.com/insights/estimating-the-spillover-impact-of-ira-part-b-negotiationhttps://avalere.com/insights/commercial-spillover-impact-of-part-b-negotiations-on-physicians

IRA Part D Implementation Starts 2026: Lost Pharmacy Revenue, Cash Flow Disruptions

- Part D IRA drug price negotiations expose pharmacies to significant financial risk.
  - Revenue losses & major cash flow disruptions—without safeguards.
  - Set to start in 2026.

- NCPA and 3 Axis Advisers analysis:
  - **Payment Delays:** At least **7-day delays** for negotiated drug payments, exceeding Medicare Part D's prompt pay rules.
  - **Cash Flow Shortfalls:** Pharmacies lose nearly **$11K per week** due to delayed reimbursements.
  - **Annual Revenue Hit:** Average loss of **$43K/year**, equal to a pharmacy tech's salary.



https://ncpa.org/newsroom/news-releases/2025/01/30/new-analysis-finds-medicare-drug-price-negotiation-program

IRA Impact on Cancer Drug Ecosystem

- "Pill penalty" and shift from **oral small molecules to biologics** due to IRA's longer negotiation delay for biologics (Lilly, Pfizer cutting small molecule programs).
- **Post-approval R&D cuts**, especially in oncology, reducing research on new tumor types/stages and increasing off-label prescribing risks.
- **Orphan drug development reduced**, as IRA's exemption applies only to single-indication orphan drugs (e.g., Alnylam halted follow-on indication).
- **Pediatric research deprioritized** due to slow enrollment and long timelines beyond IRA's price negotiation window.
- **Drugs with high Medicare/Medicaid patient mix avoided** to reduce exposure to inflation penalties and negotiation.
- **Generic & biosimilar margins squeezed** as Medicare negotiation cuts prices right before loss of exclusivity (LOE).
- **Rare disease & small population indications delayed** to avoid starting the negotiation clock before pursuing larger patient markets.

Additional Issues With IRA Drug Negotiations

- Negotiations won't really make an impact on for 2-3 years!
  - A lot can and will change between now and then…
- Only directly impacts 60 million Medicare beneficiaries, not rest of insured
  - **Only 0.03-0.1% of Medicare FFS beneficiaries will experience lower OOP** costs for the first 10 Part B drugs expected to be negotiated (Not a typo!!!)
- Drug launch prices will likely increase to account for negotiations
  - Manufacturers will protect products that may end up facing "negotiations" and from inflation caps
- Does not stop hospitals – especially large 340B hospitals – from marking up prices to patients with commercial insurance or no insurance
  - The more Medicare reduces reimbursement the more hospitals will try make up for difference
  - COA study of oncology drugs found median 340B hospital markup was 4.9x acquisition cost

Not Just the IRA:
Don't Forget During Trump 1 We Had IPI, MFN…

- International Pricing Index (IPI): Proposed aligning Part B drug prices with international rates, shifting provider payments to a flat fee.
- Most Favored Nation (MFN): Would have mandated nationwide price alignment for Part B drugs to global benchmarks.
- Drug Importation: Authorized in 2022 but faced implementation challenges.
- Drug Pricing Blueprint: Proposed multiple reforms to increase competition and reduce costs:
  - Moving some Part B drugs to Part D
  - Greater flexibility in Part D formularies
  - Reforming manufacturer rebates
  - Price transparency in direct-to-consumer ads
  - Boosting biosimilar adoption

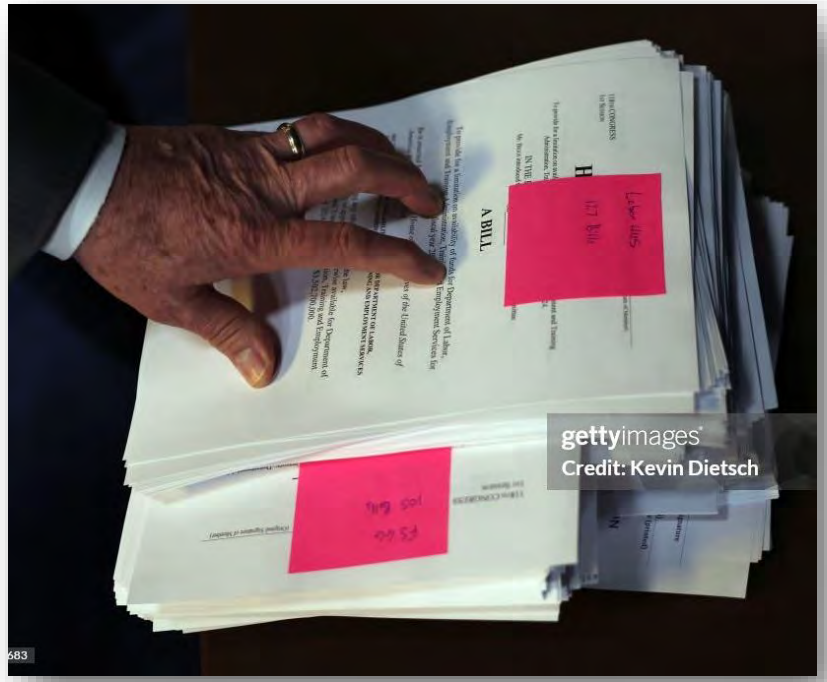
https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf

Fixing the IRA:
Remove Providers From Middle of Negotiations

- Technical fix: Remove physicians from the middle of drug price negotiations
  - Manufacturers rebate the difference between ASP+6% and MFP+6% directly to Medicare.
  - Keeps providers whole and ASP unchanged while still allowing Medicare to capture the savings from the negotiated MFP.

- The "Protecting Patient Access to Cancer and Complex Therapies Act"
  - In 118th Congress S. 2764, H.R. 5391, aka the Burgess/Barrasso bill
  - Will need to be reintroduced and championed in 119th

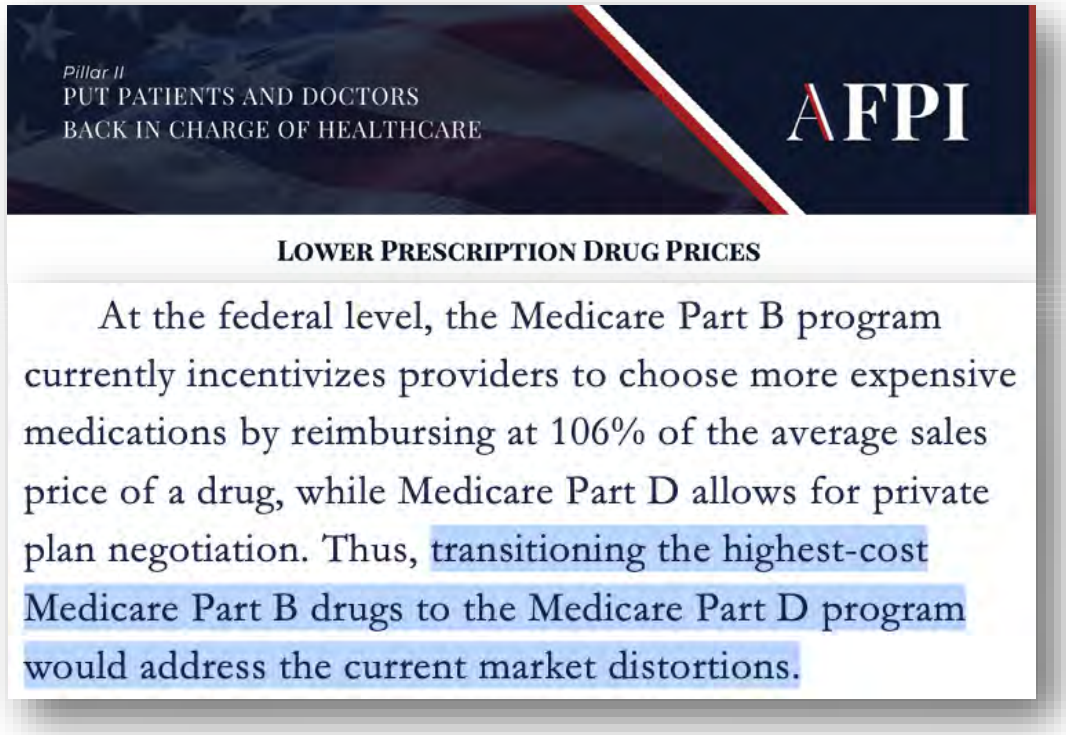
- Was very difficult to discuss last year when IRA drug price negotiations were main stump speech for elections, but now change is possible!
  - Very common for complex legislation like the IRA to be amended to fix issues not considered during drafting.



https://www.gettyimages.in/detail/news-photo/rep-andy-biggs-places-his-hand-on-a-stack-of-spending-news-photo/1477545683

Sidenote:
Think and Plan For the Future of Part B

- The ASP+6% system might not be here forever.
  - There are some in Washington who have been gunning for it for decades.
- Think beyond the drug margin and how you diversify or protect your revenue
  - Contracting strategy, value-based contracts, navigation codes, multispecialty integration
- Survival and success will come from adapting to changes.



Keep an Eye on CMMI & Federal Reform Models

- Yes, we have the Enhancing Oncology Model (EOM), but…
- CMMI is a "toolbox" for reform that Administrations can turn to for pet projects/issues
  - Past mandatory CMMI demonstration projects (see previous Part B demos) proposed
  - If a model such as EOM is demonstrated to "save money" it can become law. What are parameters or guardrails?
- Keep a close eye on CMMI

AJMC News Media Conferences Journals Compendia Events CME/CE

COA Continues Effort to Stop Most Favored Nation Model

Dec 21, 2020
Rose McNulty

Article

Doctors' Groups Spar Over Proposed Medicare Part B Drug Model

By Kerry Young, CQ Roll Call

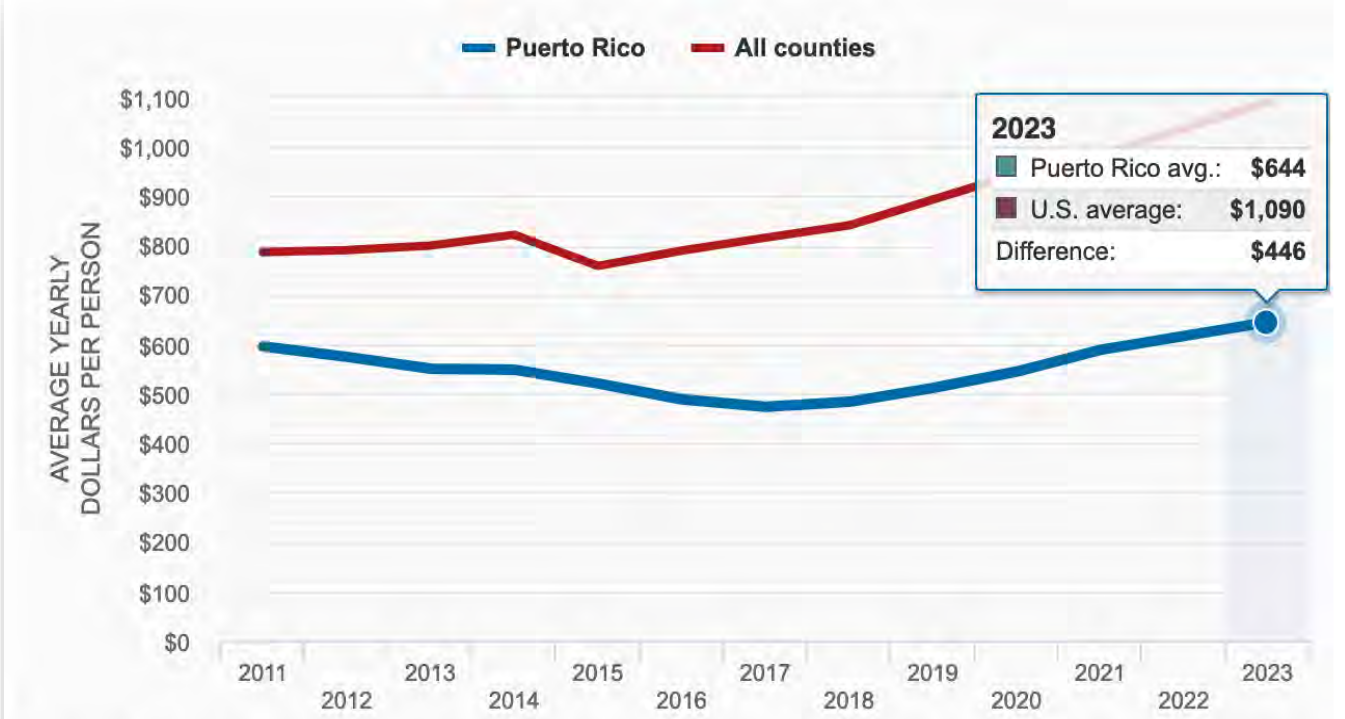
May 5, 2016 -- A group with roots in an effort by medical students to help elect Barack Obama president in 2008 is backing the president in one of his last major fights over health policy. The nonprofit Doctors for America is running a grassroots campaign in support of a proposal to alter how Medicare pays for drugs administered in doctors' offices, putting it at odds with much larger medical associations.

Rapid Growth of Medicare Advantage Changing the Payer Environment

- Rapid growth of Medicare Advantage enrollment in past decade
  - 54% of Medicare beneficiaries enrolled in MA plans
  - 94% in Puerto Rico!
- Puerto Rico and MA
  - Benchmark payments 38% lower in Puerto Rico than in the mainland U.S. (2022 numbers)

BENCHMARK RATE DISPARITIES

Average county Medicare Advantage benchmark rates, as measured in yearly dollars per person

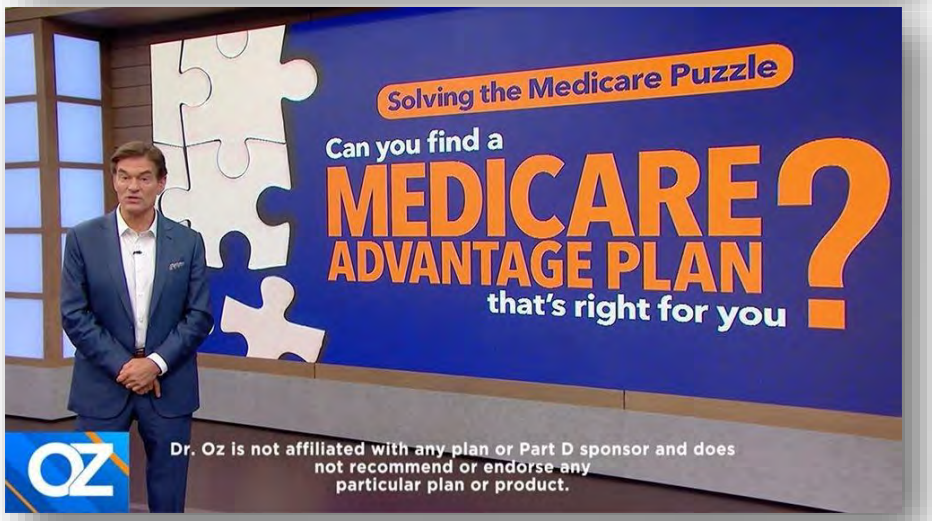


Source: Medicaid and Medicare Advantage Products Association of Puerto Rico analysis of Medicare Advantage Parts A&B 0% star bonus rates

Modern Healthcare

Insurer Challenges: Medicare DIS-Advantage

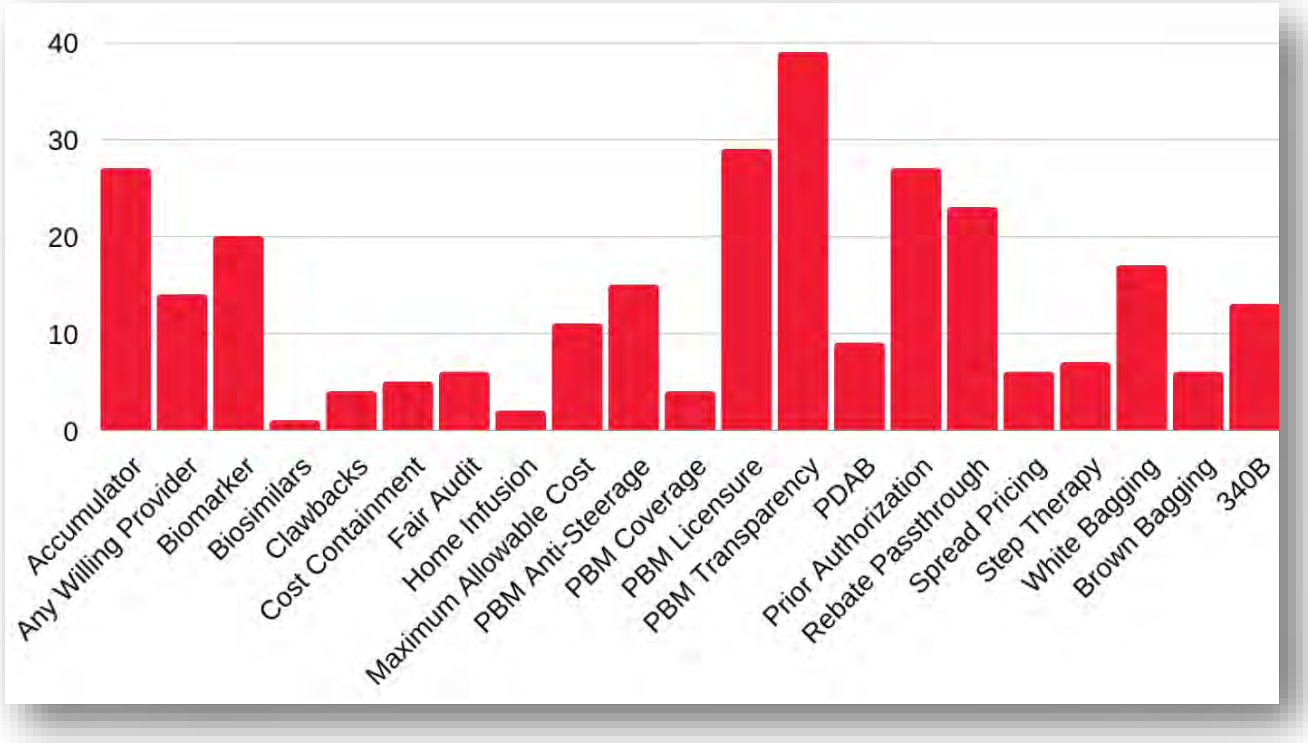
- *Many COA members call MA Medicare DIS-Advantage*
- MA presents challenges for oncology patients and practices
  - Restrictive networks and formularies
  - Burdensome prior authorization and utilization management
- There is increasing scrutiny of MA in Washington, but little movement to truly overhaul it
  - Increased spending vs. traditional Medicare
  - Upcoding investigations/lawsuit
- Republicans like MA and Trump pick to head CMS, Dr. Oz, is fan of MA and signaled support for MA expansion



Don't Forget Your States: States Are Taking Lead on Major Issues

- States are increasingly where the action is since Washington seems to be broken
  - 20% State law passage rate vs 3-4% Federal

- Top trends in state legislation:
  - Prescription Drug Affordability Boards (PDABs) (9 states so far)
  - 340B Contract Pharmacy Mandates (8 states so far)
  - PBM reform, limited by ERISA. Mainly transparency, licensure, and anti-steering.
  - Patient assistance program abuses, co-pay adjustment programs (accumulator/maximizer). (22 states accumulator limits)
  - Step therapy legislation (38 states have passed some form)



What Can *You* Do? Advocate and Engage

- Participate, participate, participate
  - Your voice is your superpower
  - If you aren't at the table, you are on the menu

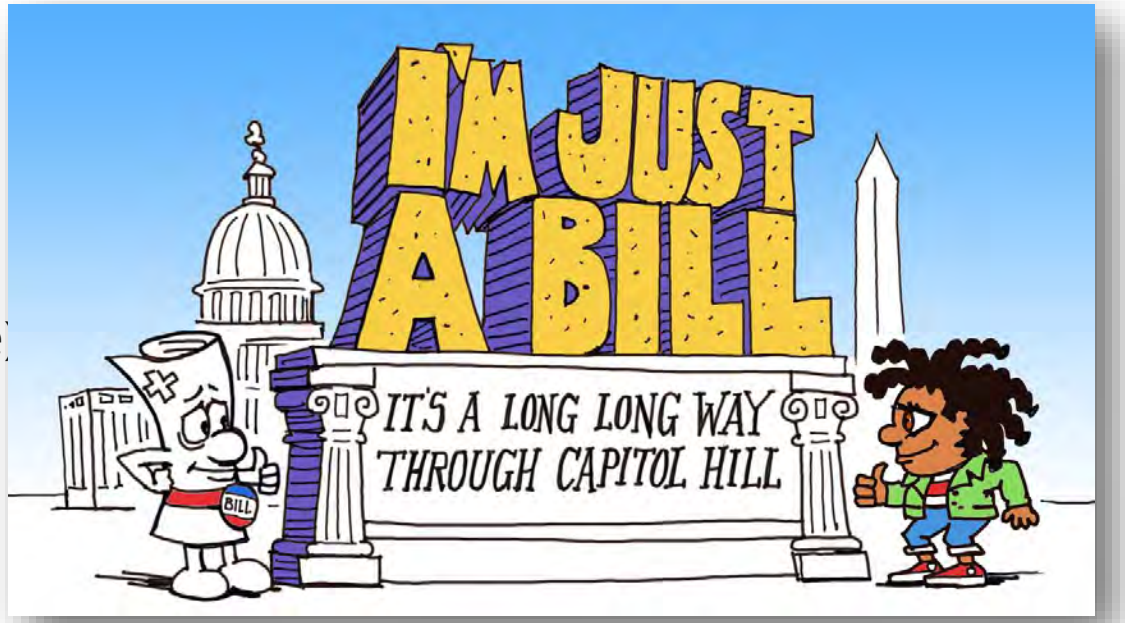
- What can you do NOW:
  1. Contact your elected officials
  2. Submit comments on proposals
  3. DC Hill Day's and visits
  4. Engage with your state/territory lawmakers

- Stay up-to-date and in touch with COA
  - Latest papers, comment letters, action alerts
  - Subscribe to our emails and newsletter

- Remember: The Fight is Never Over!
  - We are playing the long game
  - "Advocacy is Gentle Pressure, Applied Relentlessly"

Many Opportunity to Make a Difference: How a Bill Becomes a Law, in 20+ Simple Steps…

1. Idea for Bill
2. Research and Write the Bill
3. Identify Bill Sponsor(s)
4. Introduce Bill (House or Senate)
5. Referred to Committee of Jurisdiction
6. Referred to Subcommittee of Jurisdiction
7. Subcommittee Review and Vote
8. Referred Back to Full Committee
9. Full Committee "Mark Up"
10. Bill Sent to the "Floor" (Full Chamber of House or Senate)
11. Floor Vote by Full Chamber
12. Referred to Other Chamber (House or Senate)
13. Referred to Committee of Jurisdiction
14. Referred to Subcommittee of Jurisdiction
15. Subcommittee Review and Vote
16. Referred Back to Full Committee
17. Full Committee "Mark Up"
18. Bill Sent to the "Floor" (Full Chamber of House or Senate)
19. Reconciliation (If necessary)
20. Bill Sent to President
21. Becomes Law (or Congress Overrides Veto)



https://www.politico.com/news/2021/09/30/how-a-bill-gets-passed-into-law-gridlock-congress-514532

Bottom Line on All Issues: Prepare, Engage, Advocate

You didn't ask for this fight, but you must engage.

- Policy → Payment → Practice

Practice Operations:

- This isn't an "if" problem, it's a "when" problem.
- Start planning for IRA changes today – be proactive.
- COA is here to help guide practices through this.

Advocacy:

- You don't have to be a policy expert, but you need to be aware.
- Federal AND state advocacy matter.
- Your voice can change the future of oncology.

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Five tracks addressing the needs of clinicians, administrators, advocates, and more

Networking with independent community oncology leaders from across the country

Only conference created by community oncology, for community oncology

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April 29-30

COMMUNITY ONCOLOGY ALLIANCE

Gracias, Stay in Touch, Get Involved!

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