

# NCOA/SCOS 2023 Joint Conference

*Update from Capitol Hill: What to look for in 2023*

Ted Okon  
Executive Director  
February 17, 2023



# Disclosure of Conflicts of Interest



- Ted Okon, MBA, has no relevant financial relationships to disclose.

# Political Landscape & Implications



- Democrats control the White House and the Senate (barely)
  - Will have to work with (some) Republicans to get legislation passed
- Republicans control the House (barely)
  - Will have to work with (some) Democrats to get legislation passed
    - Will have a tough enough time just getting legislation passed in the House
- Drug “prices” still the biggest health care issue
  - CMS tooling up to implement Medicare “negotiating” drug prices
    - Republicans looking to stop this
  - More Democrats not just blaming pharma for drug costs but have turned to pharmacy benefit managers (PBMs) as a major problem
- But right now, Democrats & Republicans can’t agree on stopping the U.S. government from defaulting on its debt.

# Hottest Oncology Topics in D.C.



- Inflation Reduction Act & ASP
  - Gives Medicare the power to “negotiate” drug prices for Part D (orals) and Part B (injectables)
- “Non-Profit” Hospitals and 340B
  - Coming under closer scrutiny as more major media investigative reports are published
- Pharmacy Benefit Managers (PBMs)
  - Increasing state pressures to rein in PBM bad behaviors
  - Congress already introducing bills to shed light and stop PBMs

# IRA Drug Pricing Provision



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ness by reason of such requirements before final action on such application.

**SEC. 138521. TERMINATION OF EMPLOYER CREDIT FOR PAID FAMILY AND MEDICAL LEAVE.**

Section 45S(i) is amended by striking “December 31, 2025” and inserting “December 31, 2023”.

**Subtitle I—Drug Pricing**

**PART 1—LOWERING PRICES THROUGH DRUG PRICE NEGOTIATION**

**SEC. 139001. PROVIDING FOR LOWER PRICES FOR CERTAIN HIGH-PRICED SINGLE SOURCE DRUGS.**

(a) PROGRAM TO LOWER PRICES FOR CERTAIN HIGH-PRICED SINGLE SOURCE DRUGS.—Title XI of the Social Security Act is amended by adding after section 1184 (42 U.S.C. 1320e–3) the following new part:

**“PART E—PRICE NEGOTIATION PROGRAM TO LOWER PRICES FOR CERTAIN HIGH-PRICED SINGLE SOURCE DRUGS**

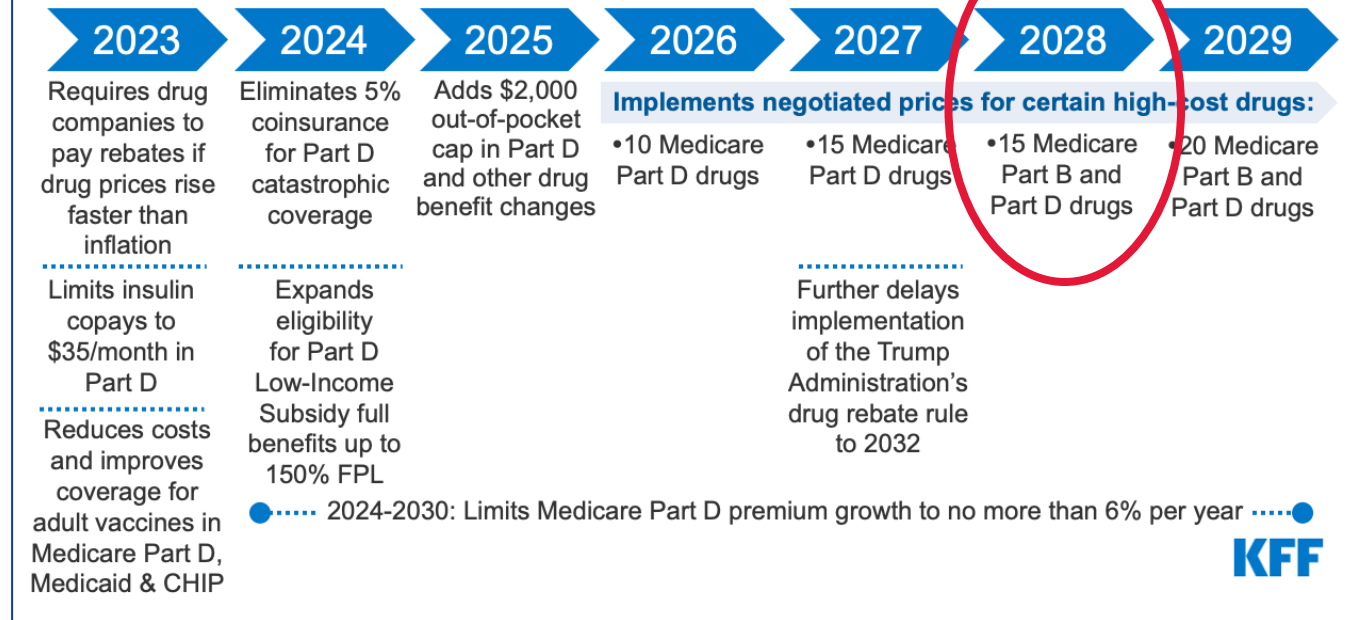
**“SEC. 1191. ESTABLISHMENT OF PROGRAM.**

“(a) IN GENERAL.—The Secretary shall establish a Drug Price Negotiation Program (in this part referred to as the ‘program’). Under the program, with respect to each price applicability period, the Secretary shall—

“(1) publish a list of negotiation-eligible drugs and selected drugs in accordance with section 1192;

g:\WHLC\110321\110321\_122.xml (824350|22)  
November 3, 2021 (12:14 p.m.)

## Implementation Timeline of the Prescription Drug Provisions in the Inflation Reduction Act



Target Drugs: Cimzia, Eylea, Keytruda, Opdivo, Prolia/Xgeva, Soliris, Entyvio, Sandostatin Lar Depot, Simponi / Aria, and Tyvaso / Orenitram ER

# IRA Drug Pricing Provision Impact



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November 29, 2022 | Insights & Analysis | Drug Pricing

## IRA Medicare Part B Negotiation Shifts Financial Risk to Physicians

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### 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.

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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).

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# Problems with Negotiating Drug Prices



- This is targeted only at 60 million Medicare beneficiaries
  - Leaves 250 million Americans with commercial insurance or no insurance swinging in the wind
- Drug launch prices will likely be increased
  - Pharma will protect products that may end up facing “negotiations” and from inflation caps
- Won’t stop mark-ups on drugs outside of Medicare
  - The more Medicare reduces reimbursement on “negotiated” drugs, the more the mark-ups
- The courts may well kill this and weaken CMS

# Background on 340B



- **340B is a CRITICAL safety net program, especially for patients with cancer who are uninsured or underinsured**
- However, the program has expanded from a handful of safety net providers to 50+% of all U.S. hospitals (*Source: [Berkeley Research Group](#)*)
  - WAC list price value of 340B drug purchases reached \$93.6 billion in 2021 (*Source: [IQVIA](#)*)
    - 14% of the total U.S. pharmaceutical market
- 340B generated \$40 billion in profits for participants (*Source: [Masia/Columbia University & SSR Health](#)*)
- One estimate is that by 2026 340B will be the largest federal drug program, surpassing both Medicare and Medicaid drug programs (*Source: [Berkeley Research Group](#)*)



# Hospitals in the Media Like Never Before



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

The New York Times

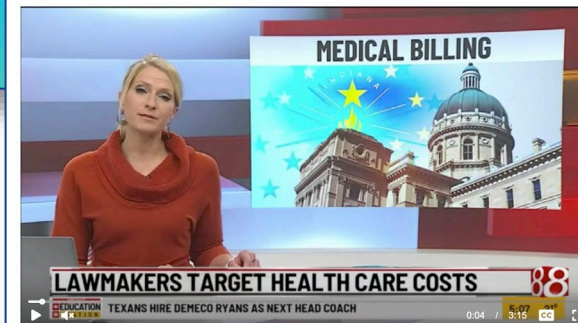
Jan. 25, 2023

## How Nonprofit Hospitals Put Profits Over Patients

A Times investigation

### Hospitals balk at Indiana lawmakers' plan to lower health care costs

g patients and



LAWMAKERS TARGET HEALTH CARE COSTS

110 shares

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by: Garrett Bergquist

Posted: Jan 31, 2023 / 06:38 PM EST / Updated: Jan 31, 2023 / 07:33 PM EST

INDIANAPOLIS (WISH) — Indiana lawmakers on Tuesday said hospitals already had their chance to lower costs, and it's now the state's turn.

A Republican-backed bill on health care costs targets several hospital practices.

# 340B in Media Crosshairs

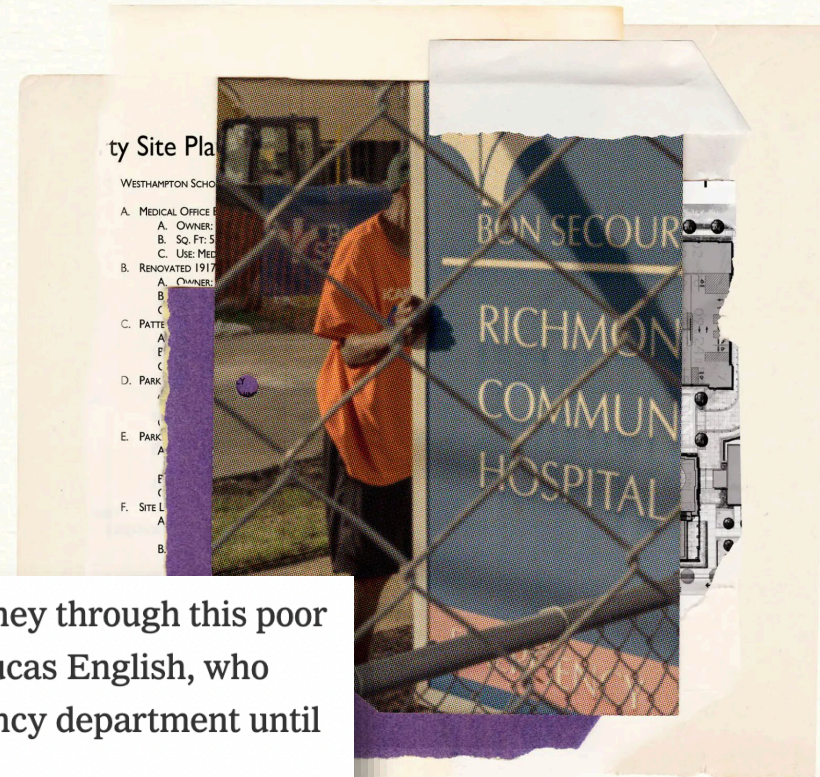


PROFITS OVER PATIENTS

## *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.”



# Creating a 340B Firestorm



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## How Bon Secours allegedly exploited a government drug program for profit

Eric Kolenich, Michael Martz Sep 27, 2022 3

### Richmond Mayor Stoney Asks U.S. Health Secretary to Investigate Loopholes in Low-Income Drug Pricing for Hospitals

September 28, 2022 Eric Burk

LOCAL NEWS

### Virginia senator calls NYT in troubling: 'Bon Secours need answer'

By: Melissa Hipolit  
Posted at 8:56 PM, Sep 26, 2022 and last updated 4:18 AM, Sep 28, 2022

RICHMOND, Va. — Senator Tim Kaine (D - Virginia) said the federal program at the center of a [New York Times investigation](#) featuring Richmond Community Hospital is "an absolutely critical program," and

#### Download CBS 6 News App

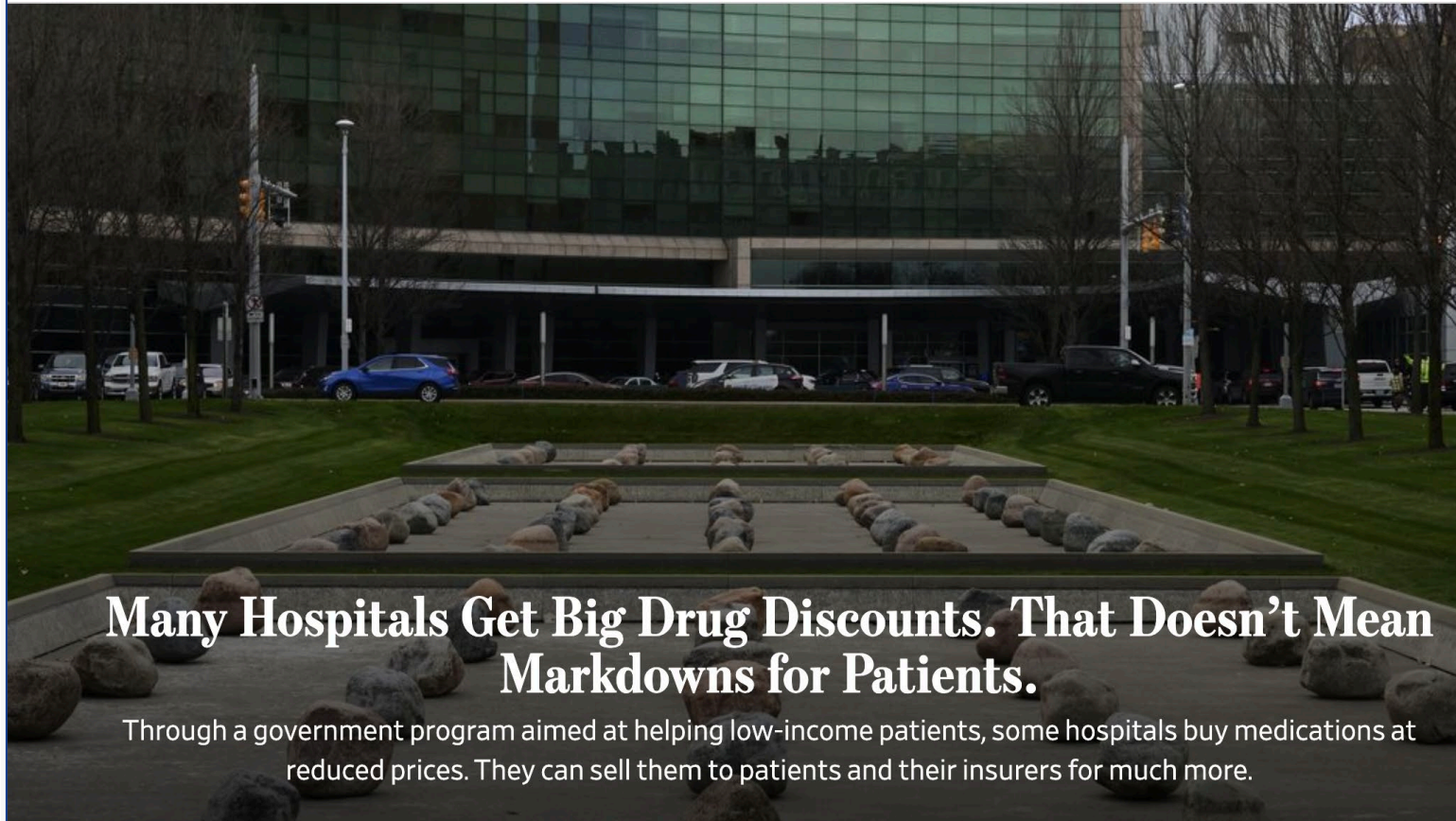
The app features breaking news alerts, live video, weather radar, traffic incidents, closings and delays and more.

- CBS 6 News App for Android
- CBS 6 News App for iPhone

# More 340B Media



## THE WALL STREET JOURNAL.

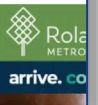


### Many Hospitals Get Big Drug Discounts. That Doesn't Mean Markdowns for Patients.

Through a government program aimed at helping low-income patients, some hospitals buy medications at reduced prices. They can sell them to patients and their insurers for much more.

### Rev. Al Sharpton calls for stronger Congressional oversight over hospital pharmaceutical program

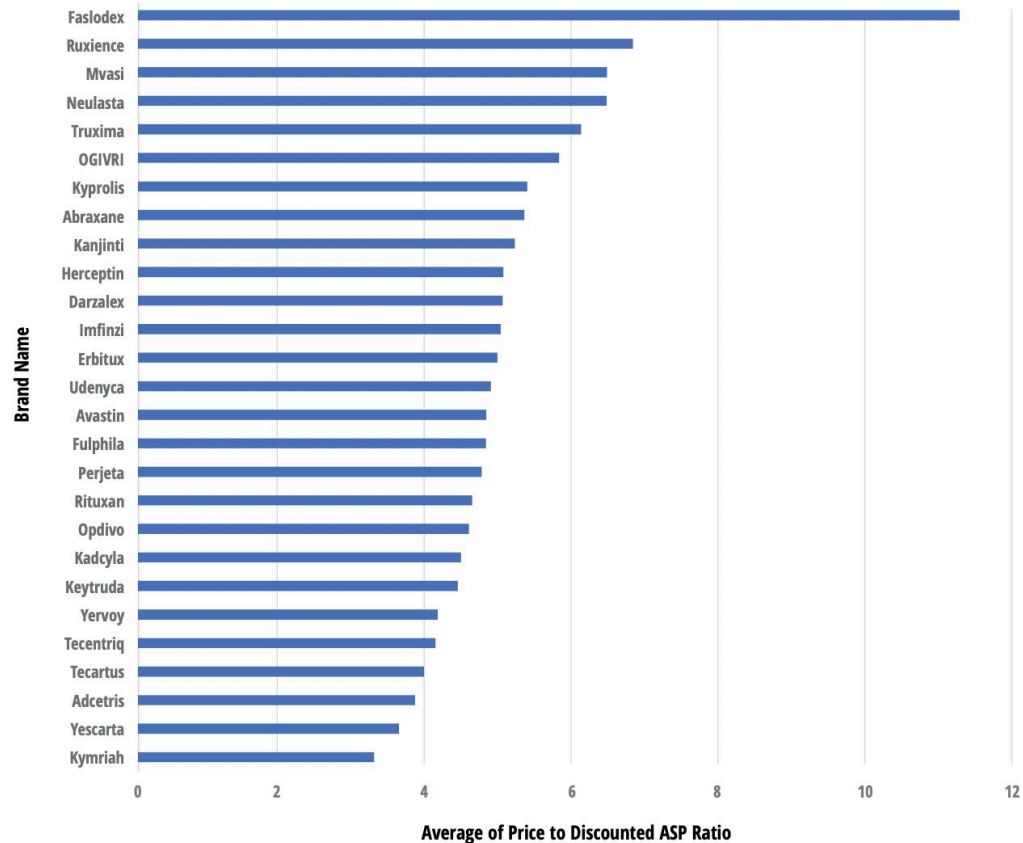
by Rev. Al Sharpton January 19, 2023



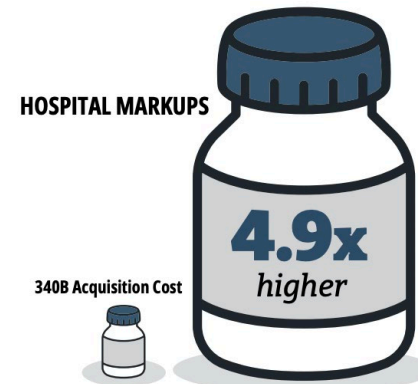
# 340B Hospitals Marking Up Drugs



**Exhibit 3. Average 340B Hospital Markup vs. 340B Hospital Discounted Acquisition Cost**



340B hospitals' own self-reported pricing data reveals that they price the top oncology drugs at **4.9 times their 340B acquisition costs**, assuming a 34.7 percent discount, which is a conservative estimate.



**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**

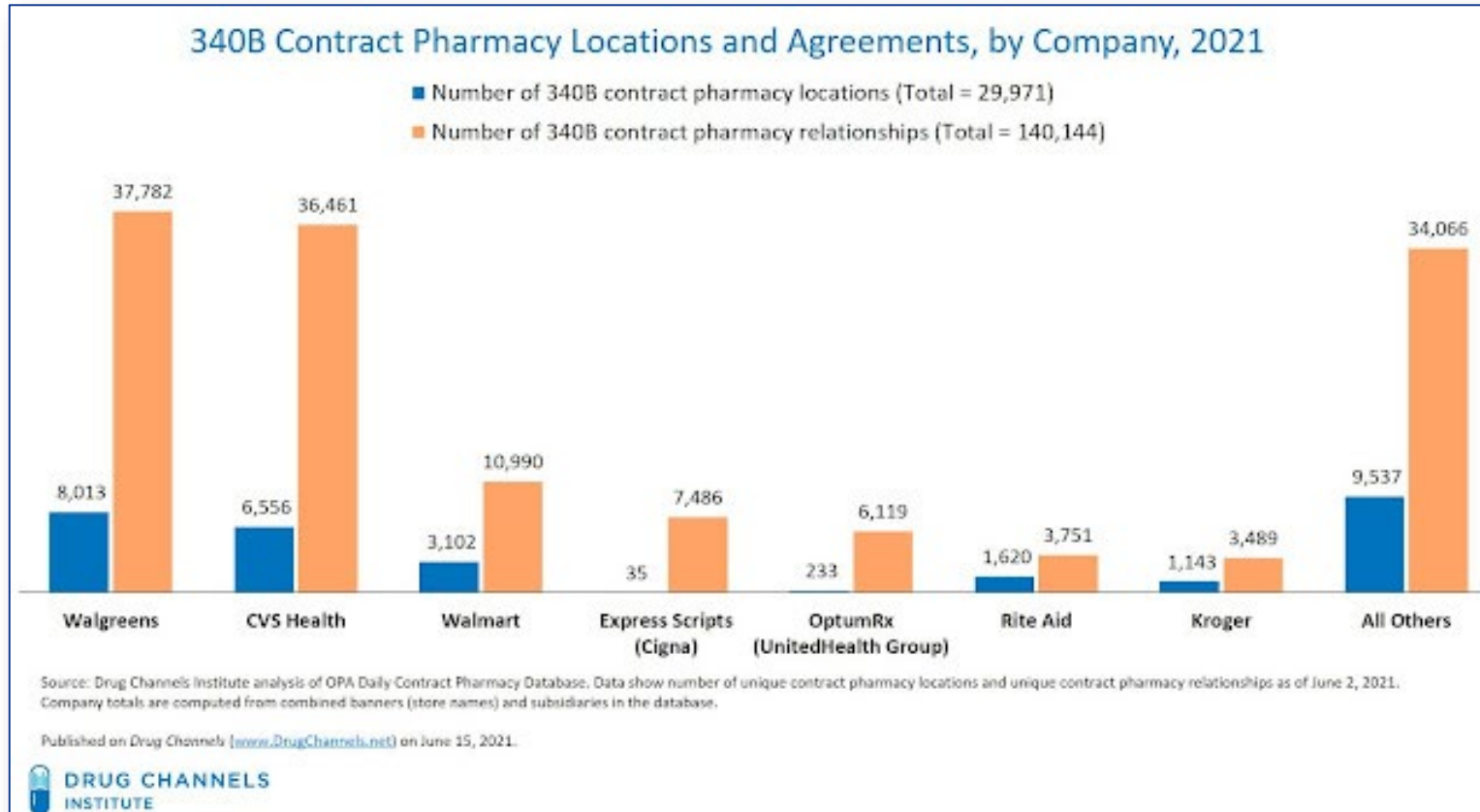
### 340B Hospital Treating a Medicare Patient

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**

# PBMs Major Players in 340B



Top 3 PBM non-retail pharmacies now account for 18% of 340B pharmacy relationships (Source: [Drug Channels](#))

# Court Stopped Multiple Pharmacies



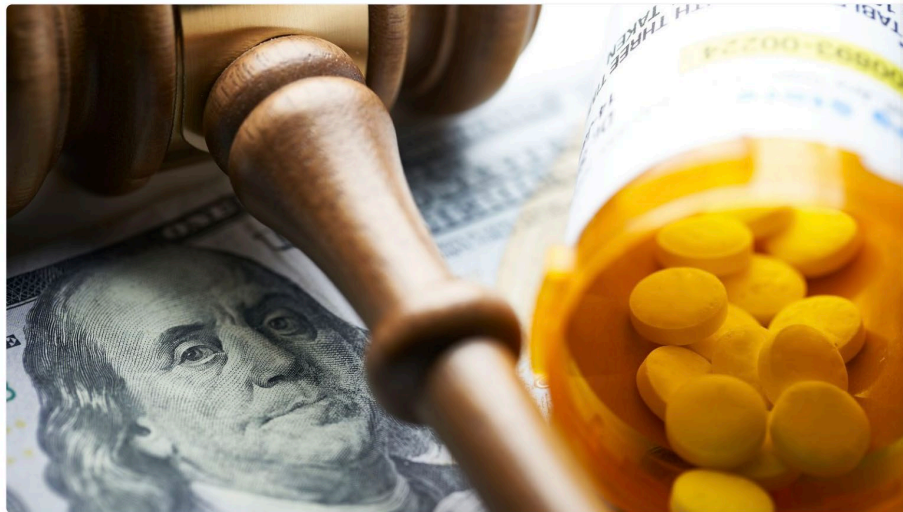
DIVE BRIEF

## Court rules for drugmakers over HHS in 340B fight over contract pharmacies

Published Jan. 31, 2023



**Rebecca Pifer**  
Senior Reporter



Bill Oxford via Getty Images

February 1, 2023

## Court Rules in Favor of Manufacturers in 340B Contract Pharmacy Case



### Health & Life Sciences News

Earlier today, the US Court of Appeals for the Third Circuit issued a much-anticipated decision in one of the 340B contract pharmacy cases. The decision is a win for drug manufacturers who have sought to restrict access to 340B prices on drugs dispensed through contract pharmacy arrangements.

The Court found that the 340B statute does not require delivery of 340B drugs to an unlimited number of contract pharmacies because (1) the text of the statute is silent about delivery, (2) structural clues confirm that the statute does not require unlimited delivery, and (3) neither drafting history nor legislative purpose compels a different result.

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McDermott Will & Emery



Emily Jane Cook



PUBLISHED IN:

Administrative Dispute Resolution Act of 1996



Appeals



Department of Health and Human Services (HHS)



# Congressional Focus on PBMs



## U.S. SENATE COMMITTEE ON COMMERCE, SCIENCE, & TRANSPORTATION

### HEARINGS

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## Bringing Transparency and Accountability to Pharmacy Benefit Managers

**February 16, 2023**  
10:00 AM

U.S. Senator Maria Cantwell (D-Wash.), Chair of the Senate Committee on Commerce, Science and Transportation, will convene a full committee hearing titled "Bringing Transparency and Accountability to Pharmacy Benefit Managers" on Thursday, February 16, 2023, at 10 a.m. ET. Americans are paying increasingly more for their necessary prescription medications and there is little transparency into how drug prices are determined. Pharmacy benefit managers (PBMs) have a large role in how Americans access their medications and how much they pay, but PBMs operate out of the view of regulators and consumers. This hearing will address how the "Pharmacy Benefit Manager Transparency Act" will bring transparency into PBM business practices and prohibit unfair or deceptive PBM conduct that drives up costs for consumers. The bipartisan S. 127, Pharmacy Benefit Manager Transparency Act of 2023, was introduced by Chair Cantwell and Sen. Chuck Grassley (R-Iowa), on January 27, 2023.

#### Witnesses:

- Ryan Oftebro, PharmD, FACA; CEO of Seattle-based independent pharmacy Kelley-Ross Pharmacy Group
- Debra Patt, M.D., Ph.D., MBA; Oncologist, Texas Oncology
- Erin Trish, PhD; Co-Director and Associate Professor of Pharmaceutical and Health Economics, Schaeffer Center, University of Southern California
- Casey B. Mulligan, PhD; Professor in Economics, University of Chicago

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#### POLICY

## Drug company middlemen likely to be a focus in 118th Congress

Both parties say they want to look into the middlemen who negotiate with drug companies on behalf of health plans



U.S. Rep. Earl L. "Buddy" Carter says he and other lawmakers, including Democrats, will soon launch a bipartisan "Patient Access Caucus" to impact access to health care. PBMs will be a focus, he says. (Bill Clark/CQ Roll Call)



# Congress Already Introducing PBM Bills



01.26.2023

## Grassley, Cantwell Continue Campaign To Hold PBMs Accountable

Senators reintroduce pair of bills to improve transparency and curb deceptive practices by prescription drug middlemen

**WASHINGTON** – Sen. Chuck Grassley (R-Iowa), a senior member of the Senate Judiciary and Finance committees, and Maria Cantwell (D-Wash), chair of the Senate Commerce, Science and Transportation Committee, are continuing to press for transparency and fairness in the prescription drug supply chain. They partnered on several efforts to hold pharmacy benefit managers accountable for opaque and often deceptive practices that contribute to high drug prices for consumers. Now they're reintroducing a pair of bills to continue their work.

“Senator Cantwell reintroducing bipartisan legislation to shine the light of transparency on the murky underworld of PBMs is more critical than ever. The top PBMs use their inordinate market leverage to delay and even deny patients their cancer medications, lowball payments to pharmacists resulting in pharmacy closures, and fuel drug costs higher for all Americans. The Senator’s leadership is so critical in stopping the destructive influence of PBMs,” **said Ted Okon, Executive Director of Community Oncology Alliance.**

# Major PBM Problems



- Delaying and denying cancer patients from getting their drugs
  - Trolling for patients and demanding they get their drugs by mail
- Prior authorization hurdles from them and their corporate insurers
- Using “fail first” step therapy and other utilization management to ensure most profitable (to the PBM) drugs used
- Collecting unreasonable fees (DIR fees) from pharmacy providers
- Excluding oncology practice pharmacy providers from PBM networks

# Thanks!



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