

Update on Cancer Care Issues in the U.S.A.

Ted Okon
Executive Director
February 4, 2023



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 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 Topics Related to Cancer Care



- Inflation Reduction Act
 - 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

Problems Related to Cancer Care



- Inflation Reduction Act
 - Will create a new reimbursement rate (MFP) for “negotiated” drugs in Medicare and that will lower ASP commercial rates
- “Non-Profit” Hospitals and 340B
 - Aggressive debt collections and other tactics adversely impacting patient care
 - 340B fueling hospitals’ “profits” and drug costs
 - 340B increasing drug launch prices
- Pharmacy Benefit Managers (PBMs)
 - Delaying and denying patients from getting their drugs
 - Fueling drug prices and costs

IRA Drug Pricing Provision



G:\M\17\YARMUT\YARMUT_021.XML

1940

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

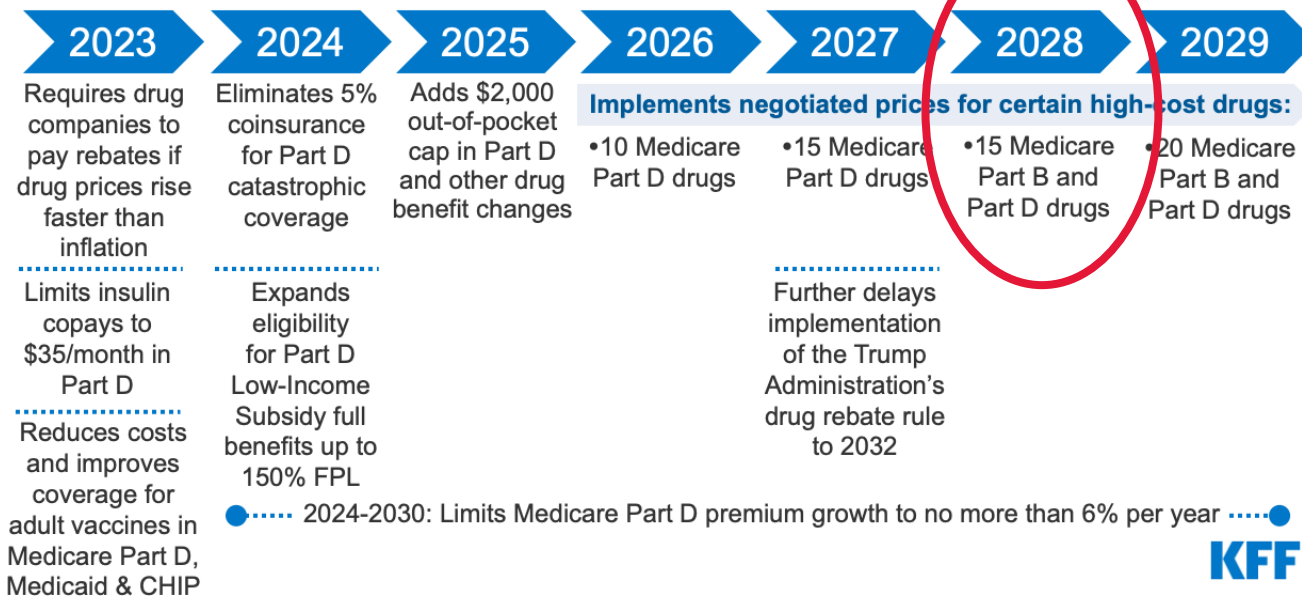
“SEC. 1191. ESTABLISHMENT OF PROGRAM.

“(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
November 3, 2021 (12:14 p.m.) (824350122)

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



[Who We Help](#)[Services](#)[Products](#)[Insights](#)[About Us](#)[Q](#)

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

Amanda Tripp
Associate Principal

Ekemini Isaiah
Consultant II

Blair Burnett
Consultant II

Reed Diskey
Senior Associate

Next Steps & How This Plays Out



- CMS ramping up hiring to staff the “negotiation” arm
 - \$3 billion allocated for 10 years
- Lots of time and lots of things will happen before 2028
 - CMS has no experience “negotiating” drug prices
 - Steep learning curve
 - The wheels of government turn slowly
 - With Republicans taking the House they will drag CMS up to the Hill every chance possible
 - This will end up in the courts when at least one company will not “negotiate”
 - Possibly end up in the Supreme Court over constitutional issues
 - The outcome of the 2024 election for President will absolutely impact this if a Republican is elected
- We have spent a lot of time with the White House and Congress trying to get providers out of the middle of “negotiations”
 - Now working with Senate and House Republicans to introduce a bill where pharma companies rebate Medicare directly without creating a new reimbursement rate
- ***Good news is biosimilars are reimbursed at ASP + 8%!***

Problems with Negotiating Drug Prices



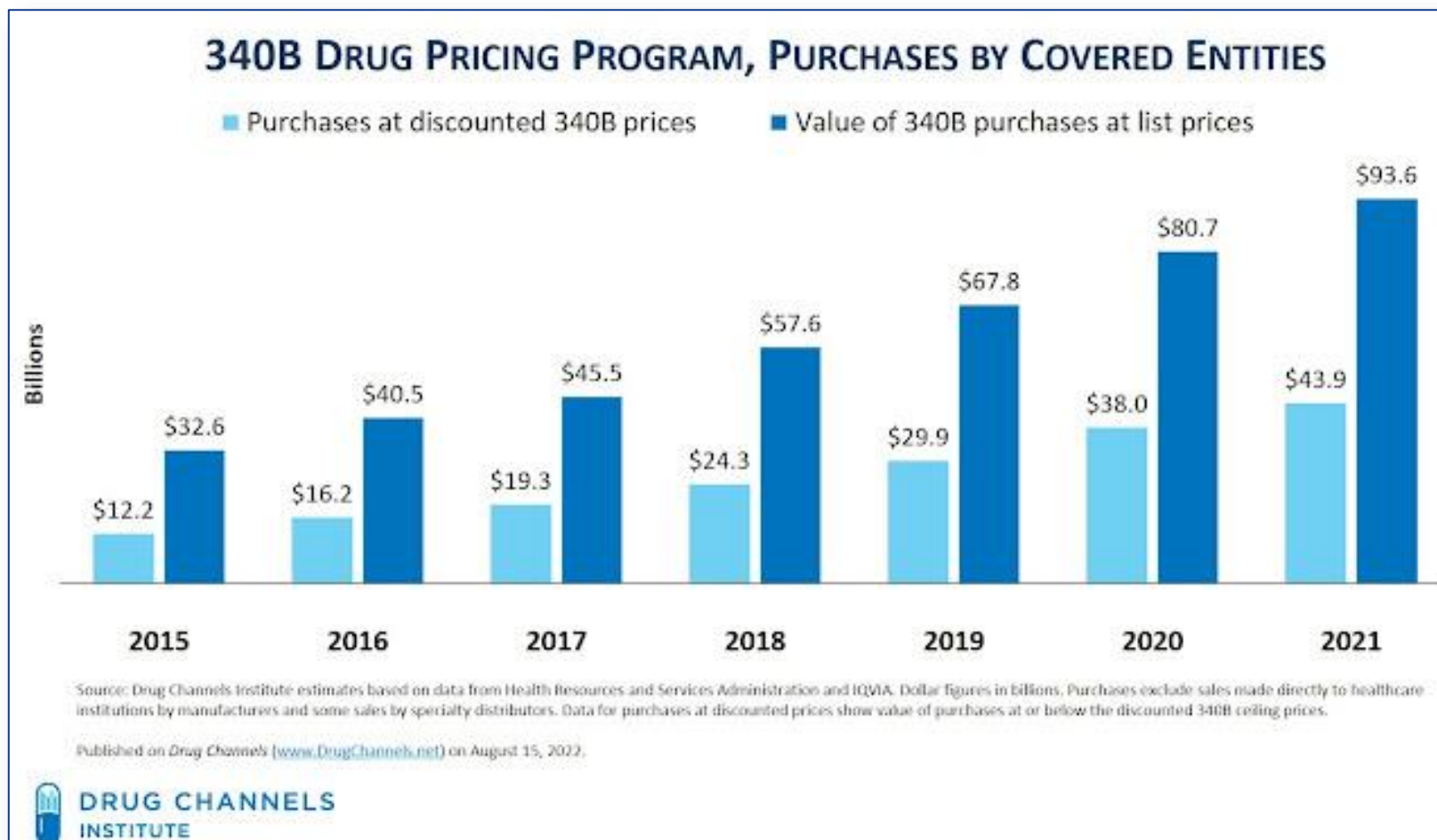
- This is targeted only at 60 million Medicare beneficiaries
 - Leaves 250 million Americans with commercial insurance or no insurance swinging in the wind
- Drug launch prices will likely be increased
 - Pharma will protect products that may end up facing “negotiations” and from inflation caps
- Won’t stop hospitals, especially large 340B hospitals, from marking up prices to patients with commercial insurance or no insurance
 - The more Medicare reduces reimbursement on “negotiated” drugs, the more hospitals will charge commercial payers and patients
- 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](#)*)
- 180 340B sites in Puerto Rico (32 are DSH hospitals)

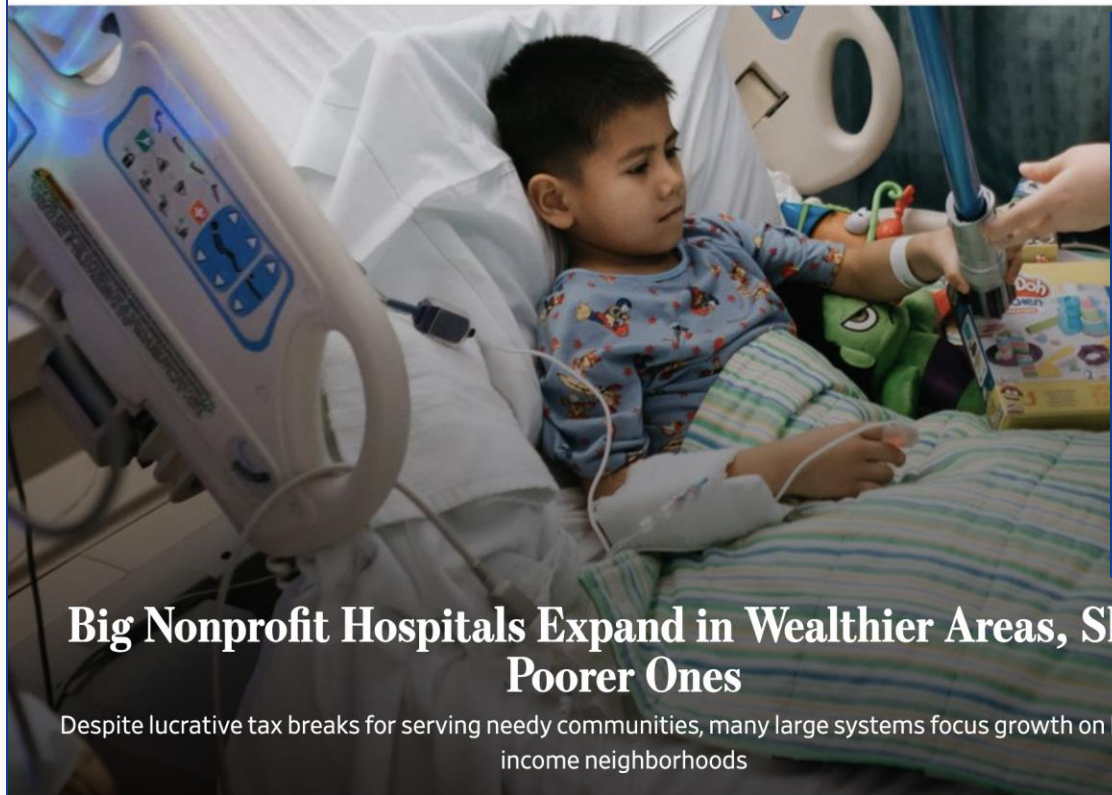
340B Growth Continues



Hospitals in the Media



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



110

Share

f Share

Tweet

Email

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

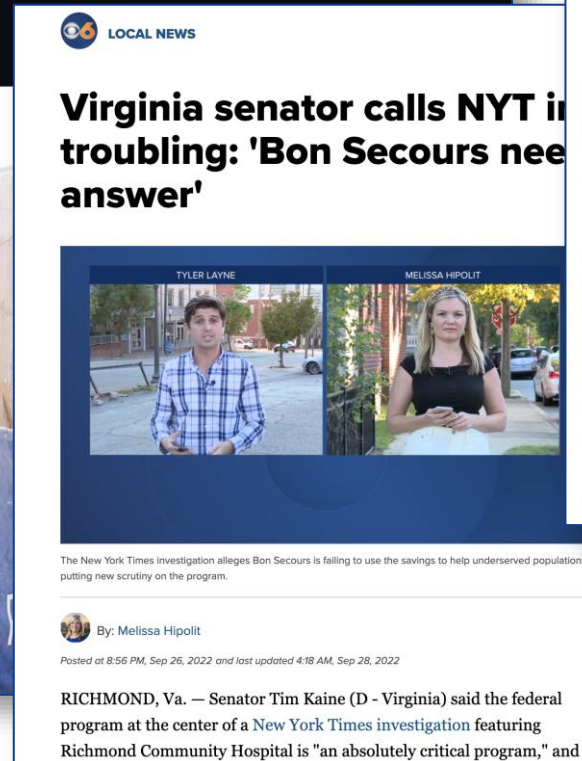
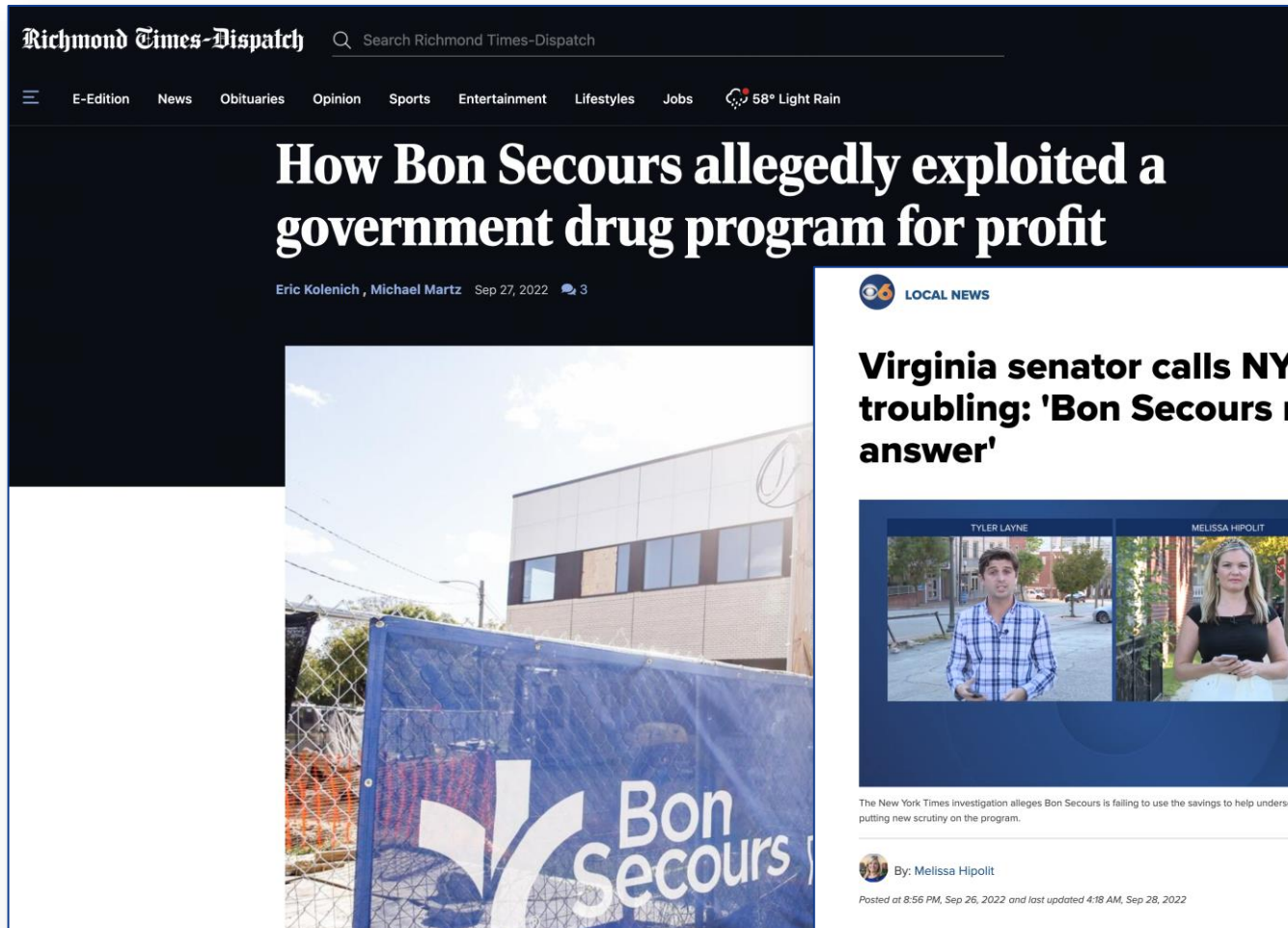
How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits

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



Download CBS 6 News App

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

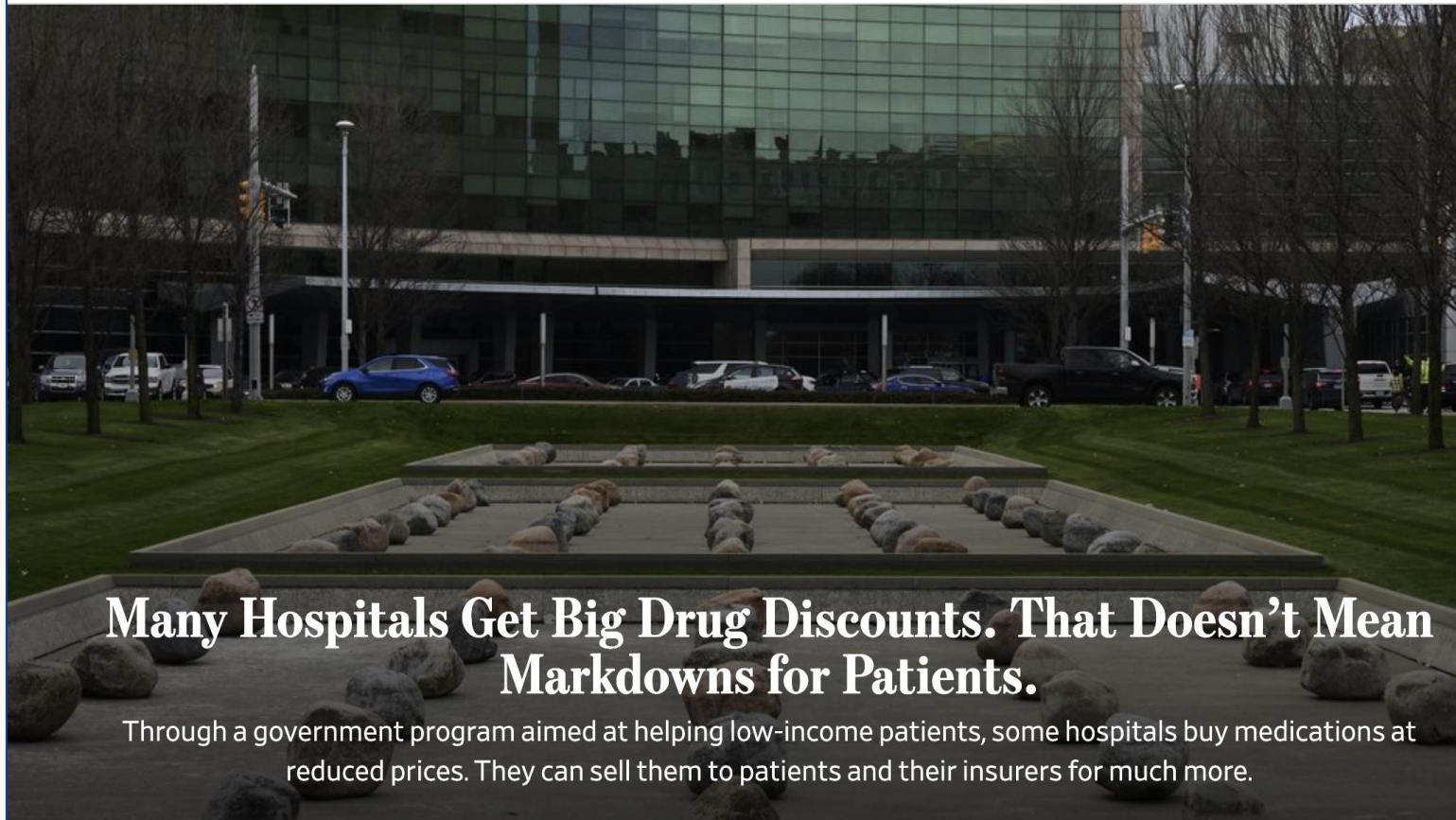
• CBS 6 News App for Android

• 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

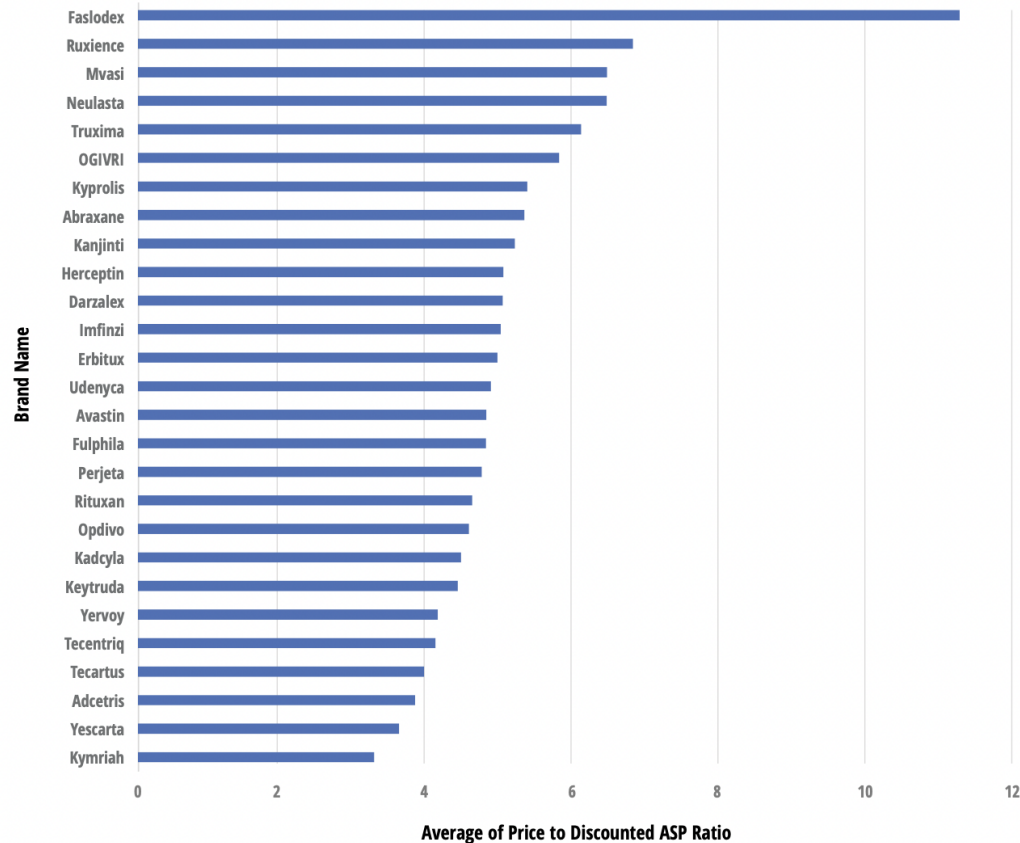
by Rev. Al Sharpton January 19, 2023



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.

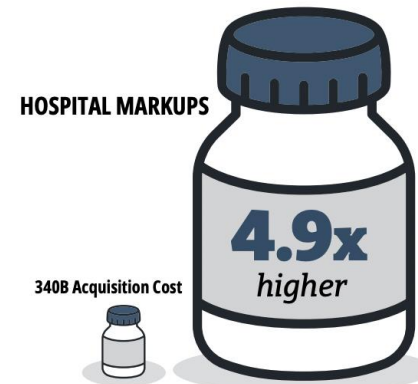


Exhibit 5.

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

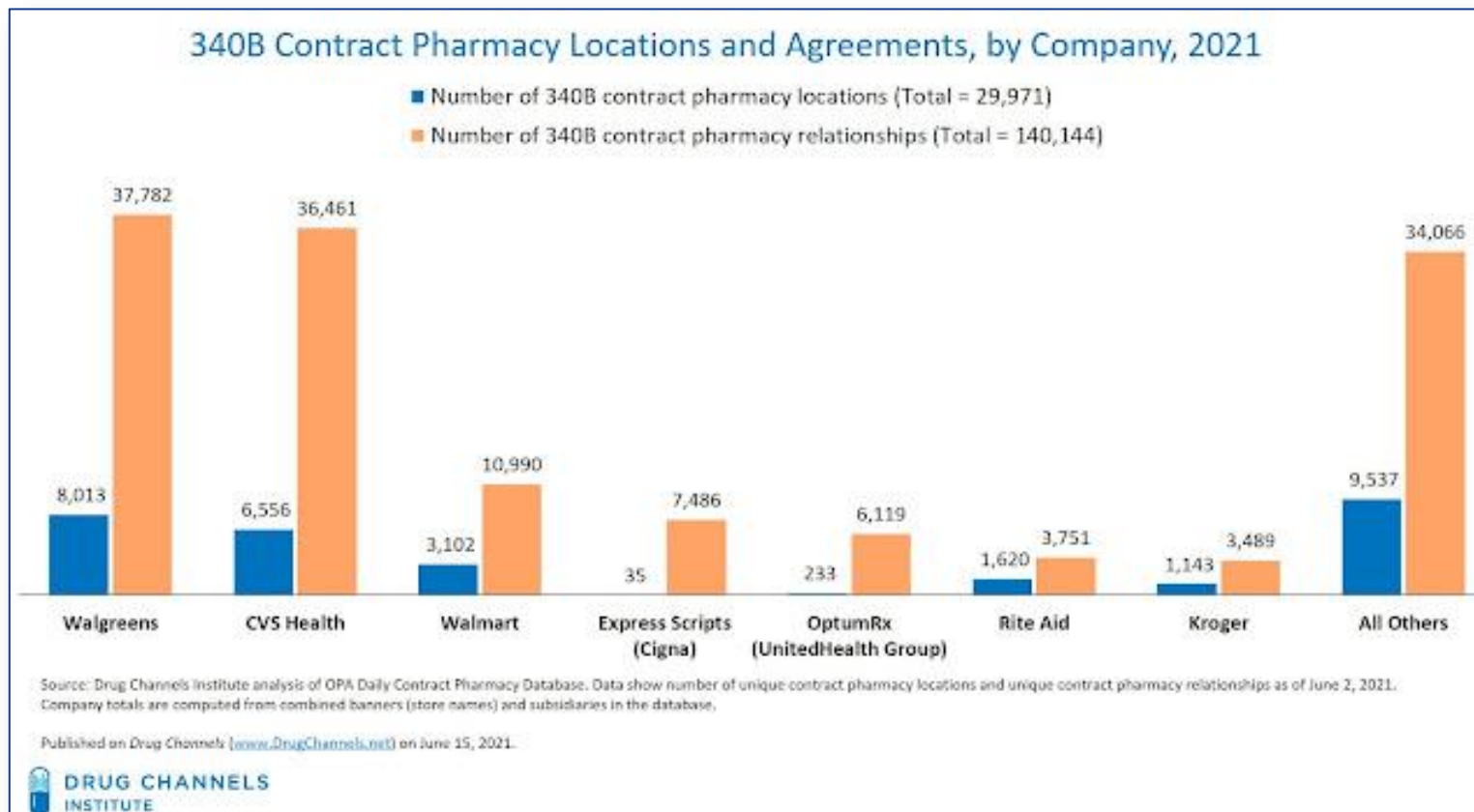
340B Hospital Treating a Medicare Patient

Purchased for \$43,168
 Reimbursed at \$70,073
Margin \$26,905

340B Hospital Treating a Commercial Patient

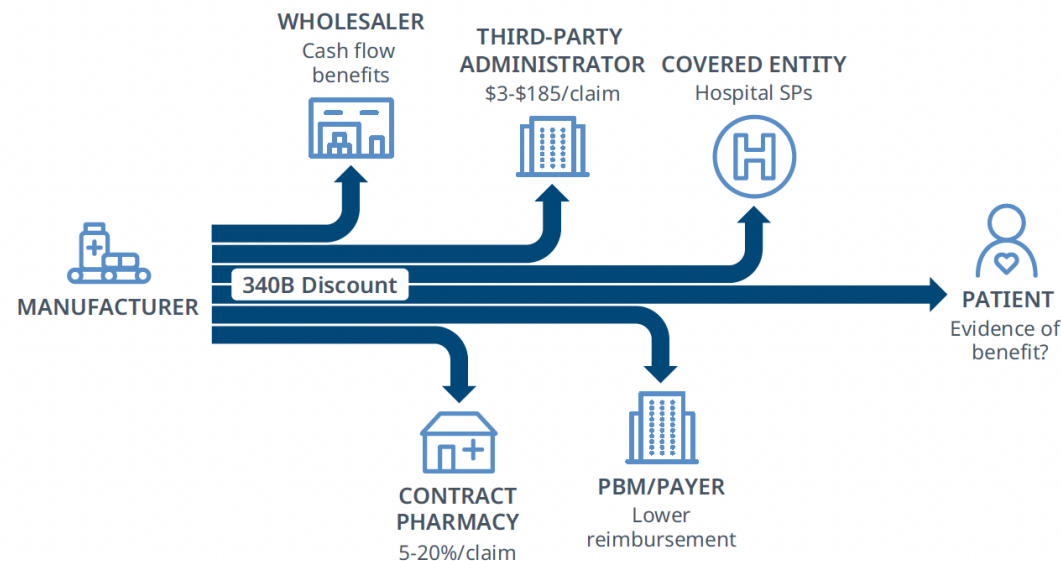
Purchased for \$43,168
 Insurer Charged \$217,122
Margin \$173,954

PBMs Major Players in 340B



Top 3 PBM non-retail pharmacies now account for 18% of 340B pharmacy relationships (Source: [Drug Channels](http://www.DrugChannels.net))

Patients Benefiting from 340B?



These findings demonstrate that 340B discount sharing at the point of sale at contract pharmacies is possible, but that most 340B-eligible patients at contract pharmacies are not directly benefiting from 340B discounts.

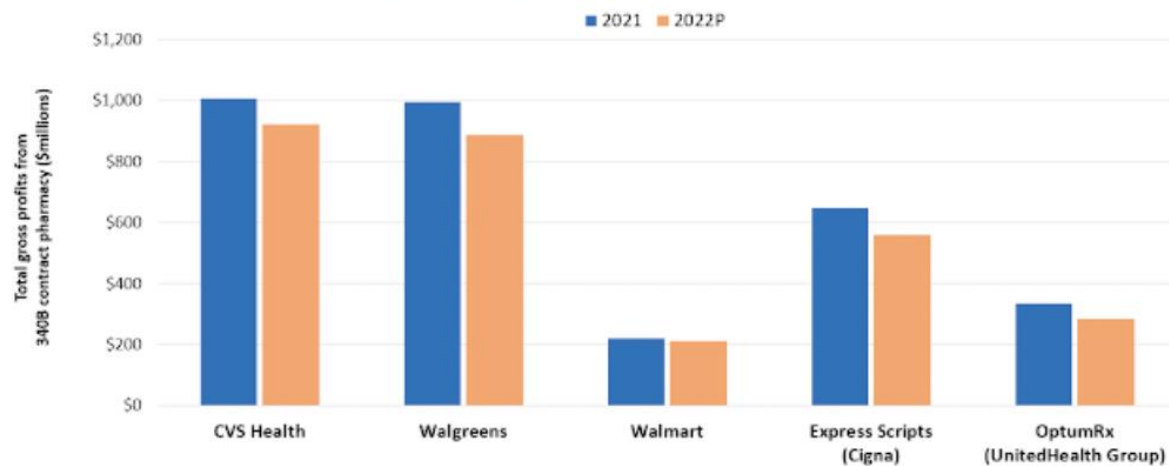


PBM Profiting from 340B



340B Pharmacy Profits

TOTAL ESTIMATED GROSS PROFITS FROM 340B CONTRACT PHARMACY, BY COMPANY



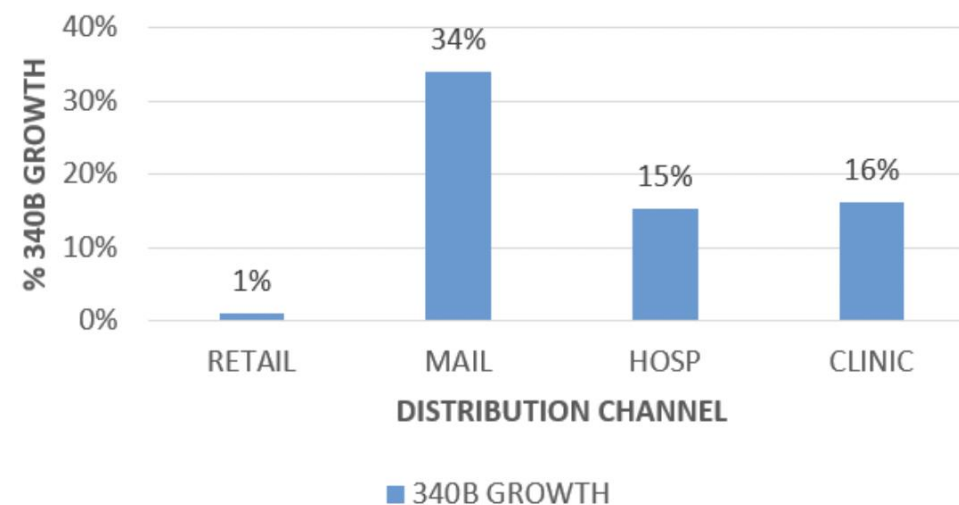
Source: Drug Channels Institute analysis of Nephron Research data. Figures reflect potential profit pool for each company. However, companies may not have retained all of the profits implied by the figures above.

See: (1) "The 2022 Economic Impact on U.S. Pharmacies and Pharmacy Benefit Managers," Section 11.5.5, and (2) CVS, Walgreens, Walmart, and Supermarkets Keep Profits in 2022 Part D Preferred Networks—With a Little Help from 340B, Drug Channels, November 2021.

DRUG CHANNELS
INSTITUTE

© 2022 Pembroke Consulting, Inc. d/b/a Drug Channels Institute. All Rights Reserved.

18



Major PBM Problems



- Delaying and denying cancer patients from getting their drugs
 - Trolling for patients and demanding they get their drugs by mail
- 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

Major COA Initiatives



- Inflation Reduction Act
 - Wrote legislation to remove practices from the middle of drug price “negotiations”
- “Non-Profit” Hospitals and 340B
 - Wrote legislation to force hospitals to be transparent and accountable on how 340B profits are utilized to serve patients and the community
- Pharmacy Benefit Managers (PBMs)
 - Wrote legislation to require cancer patients get their medication within 72 hours after the prescription
 - Working with Congress on other legislation and hearings
 - Working with state legislators to pass anti-PBM legislation

More States Passing Anti-PBM Bills



46 States in Session

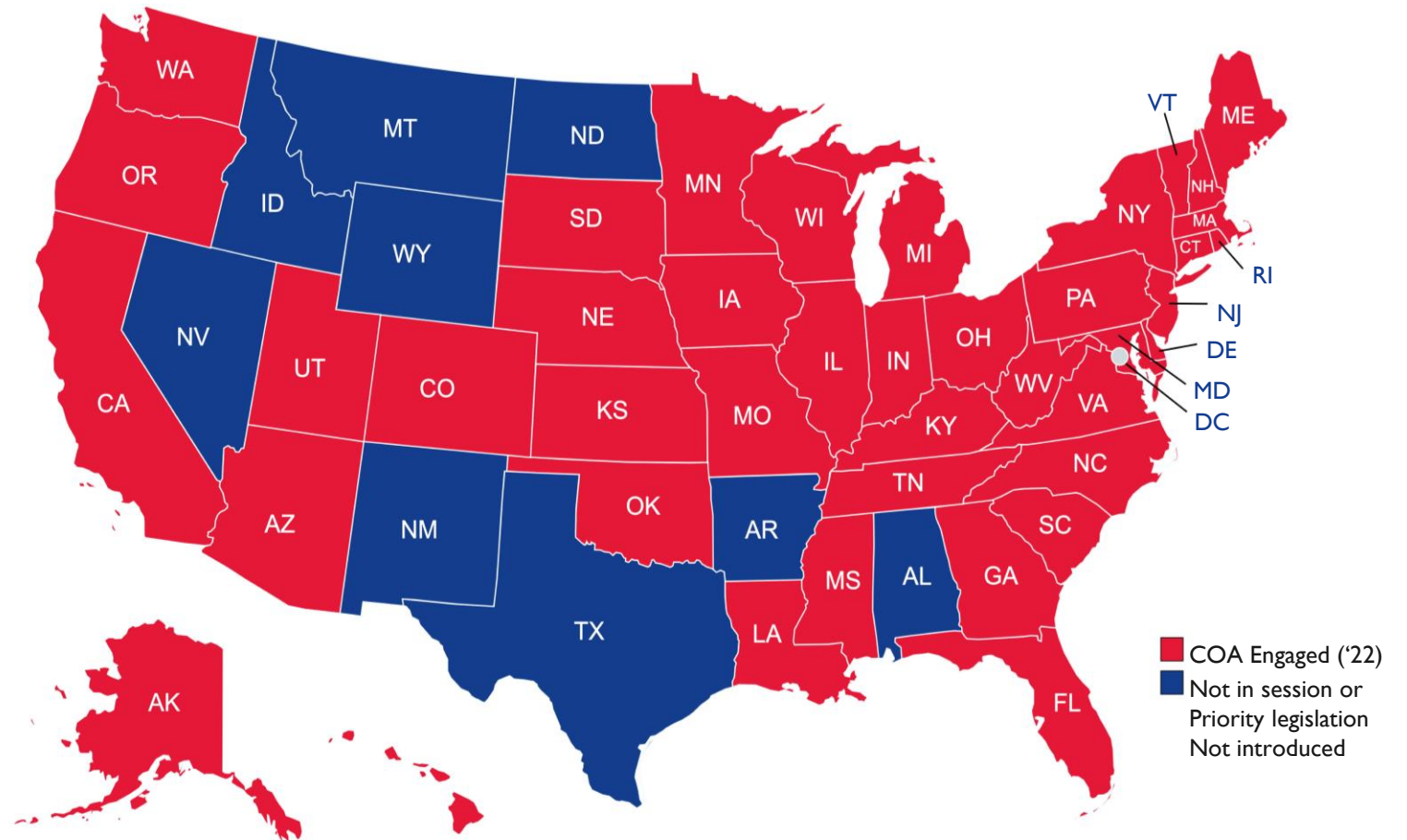
In 2022, 41 states introduced bills of relevance to oncology and pharmacy benefit managers.

350+ Industry Bills

300+ bills were introduced with the intention of reforming pharmacy benefit manager practices, while an additional 50+ concerned additional topics of relevance to oncology.

61 Bills Passed

17% of all bills filed were passed in 2022. Total passed is reflective of consolidation, not rate of success.



Congress Introduced Two 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.**

Other Important Issues



- Fixing Medicare payment for physician services
- Biden administration Medicare demonstration models to “fix” drug pricing
- Medicare Enhancing Oncology Model launching in July 2023
 - Successor to the Oncology Care Model, now completed

Proposed Changes to Medicare Advantage



2024 Medicare Advantage and Part D Advance Notice Fact Sheet

Feb 01, 2023 | Medicare Part C, Medicare Part D

Share



Today, the Centers for Medicare & Medicaid Services (CMS) released the Calendar Year (CY) 2024 Advance Notice of Methodological Changes for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (the Advance Notice). CMS will accept comments on the CY 2024 Advance Notice through Friday, March 3, 2023. CMS will carefully consider timely comments received before public final Rate Announcement by April 3, 2023.

Puerto Rico

The proportion of Medicare beneficiaries who receive benefits through MA (as opposed to Medicare FFS) is far greater in Puerto Rico than in any other state or territory. The policies proposed and under consideration for 2024 would continue to provide stability for the MA program in Puerto Rico and for Puerto Ricans enrolled in MA plans. These policies include basing the MA county rates in Puerto Rico on the relatively higher costs of beneficiaries in FFS who have both Medicare Parts A and B and applying an adjustment to reflect the propensity of beneficiaries with zero claims.

Thanks!



Ted Okon

Email: token@COAcancer.org

Web: www.CommunityOncology.org

Twitter: @TedOkonCOA