# NJSOM Fall Meeting

2024 Capitol Hill Update and Election Impact on Health Care Policy

Ted Okon Executive Director October 24, 2024

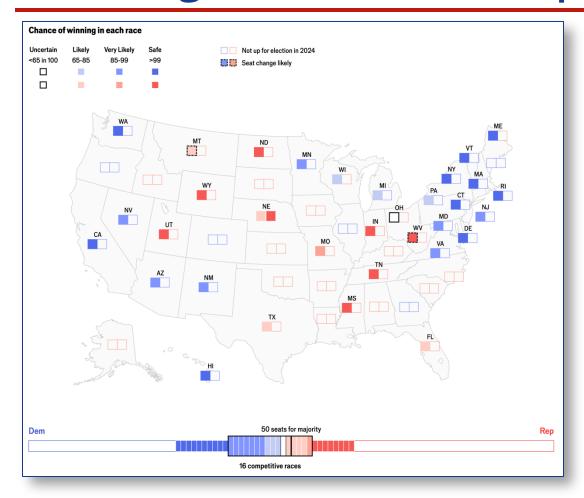


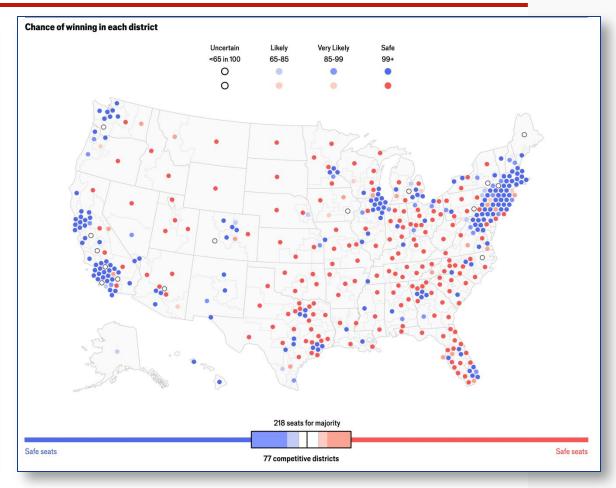
#### The Punchline of This Presentation

- Surprisingly little <u>specific</u> discussion on health care policy (not including abortion and related fertility issues) during the presidential campaign
  - Prior campaigns focused on ACA/Obamacare and prescription drugs
- However, the elections (White House and Congress) will determine what happens in health care
- There has been a rather seismic shift from the total focus on the pharmaceutical industry to pharmacy benefit managers (PBMs) and hospitals
- More bipartisan agreement on the need for PBM reform, and even the need to address 340B
- Fixing Medicare physician payments is another bipartisan issue
- Good news and bad news on the Inflation Reduction Act (IRA) and Medicare "negotiating" drug prices
- The only thing stopping Congress from doing anything is Congress itself!



## The Congressional Landscape





Senate: Advantage Republicans

Source: The Economist

House: Advantage Democrats





- Add a home health care benefit to Medicare
- Pay for it by "negotiating" more drugs and PBM reform

#### HARRIS:

- The value I bring to this is that access to health care should be a right and not just a privilege of those who can afford it. The plan has to be to strengthen the Affordable Care Act, not get rid of it."
- 'Medicare for all' bill] and over the last four years as vice president I have supported private health care options.

  But what we need to do is maintain and grow the Affordable Care Act."
- When Donald Trump was president, 60 times he tried to get rid of the Affordable Care Act; 60 times. I was a senator at the time. I will never forget the early morning hours when it was up for a vote in the United States Senate, and the late great John McCain... walked onto the Senate floor and said, 'No, you don't. No, you don't. No, you don't. No, you don't get rid of the Affordable Care Act.'"

#### TRUMP:

- fThe ACA is] still
  never going to be great. And it's too
  expensive for people...If we can come
  up with a plan that's going to cost our
  people, our population less money
  and be better health care than
  Obamacare, then I would absolutely
  do it. But until then, I'd run it as good
  as it can be run."
- I would only change it if we come up with something better and less expensive. And there are concepts and options we have to do that. And you'll be hearing about it in the not-too-distant future."
- Obamacare because Democrats wouldn't change it. They were unanimous. They wouldn't vote to change it. If they would have done that, we would have had a much better plan than Obamacare."

- Has backed off "most favored nations" drug prices
- Has a "concept"

Source: BenefitsPRO



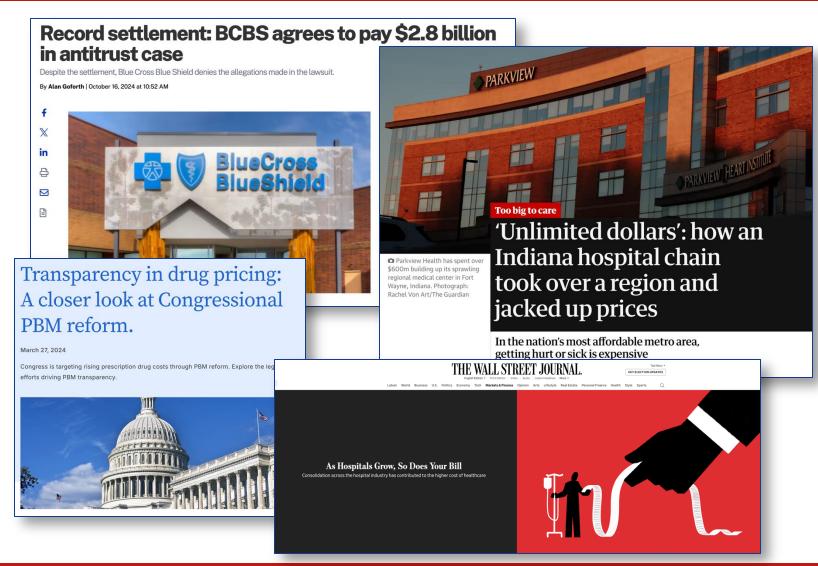
#### Some of the Top Issues Facing Oncology

- Restricting oncology practices from delivering drugs to patients
- PBM/insurer issues too long to list, but here are some of the most pronounced:
  - Spike in prior authorizations, especially in Medicare Advantage plans
  - Low-ball Part D reimbursements
  - Restricting biosimilar use
  - Mandatory mail order and white bagging
- Increasing cost of hospital care
  - Push for site-neutral payments
  - Address 340B abuses
- Medicare physician pay
- IRA and Medicare negotiating drug prices
- Drug shortages



## Two "Themes" Getting More Traction

- Consolidation
  - Insurers & PBMs
  - Hospital Systems
  - Others
- Transparency
  - Hospital pricing
  - PBM rebates
  - 340B discounts
  - Insurance contracts





#### The Stark Issue

- CMS using the Stark law to stop practices from delivering drugs (or even caregivers from picking up drugs for patients)
- COA working hard with Congress to get legislation advanced to stop CMS
  - H.R. 5526 passed by the full House!
  - Working to get the Senate companion bill (S. 3458) passed
- COA sued HHS/CMS
  - Judge sided with government's motion to not proceed
    - Clearly did not understand the issue



- FOIA request to uncover what prompted CMS to issue Stark FAQ
  - Totally ignored by CMS, so COA is suing CMS

118TH CONGRESS H.R. 5526

To amend title XVIII of the Social Security Act to clarify the application of the in-office ancillary services exception to the physician self-referral prohibition for drugs furnished under the Medicare program.

#### IN THE HOUSE OF REPRESENTATIVES

September 18, 2023

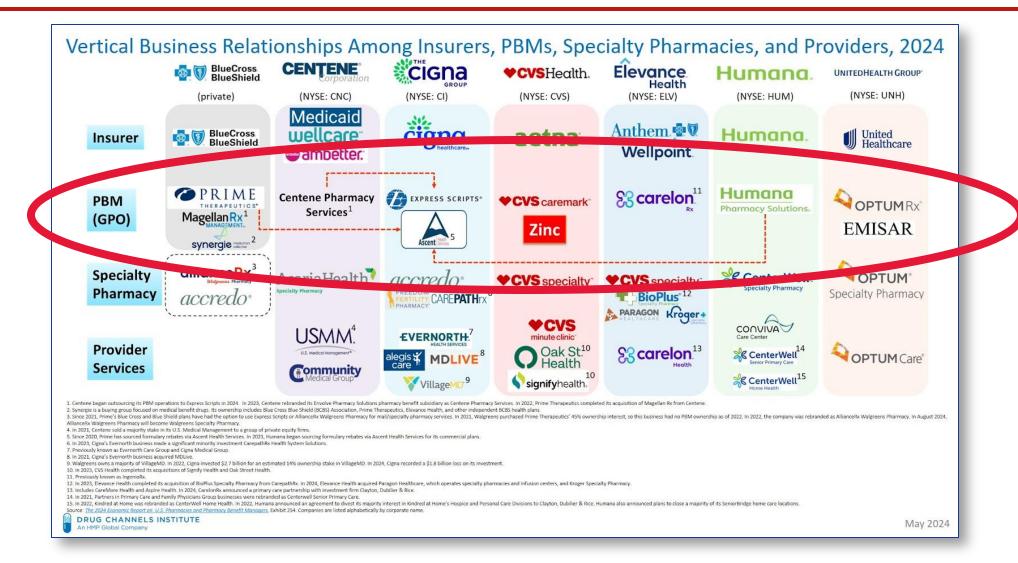
Mrs. Harsharder (for herself, Ms. Wasseman Schultz, Mr. Flarischmann, Mr. Dalvis of North Carolina, Mrs. Millzer-Merris, and Mr. Balderson) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

#### A BILL

- To amend title XVIII of the Social Security Act to clarify the application of the in-office ancillary services exception to the physician self-referral prohibition for drugs furnished under the Medicare program.
- Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE.
- 4 This Act may be cited as the "Seniors' Access to Crit-
- 5 ical Medications Act of 2023".

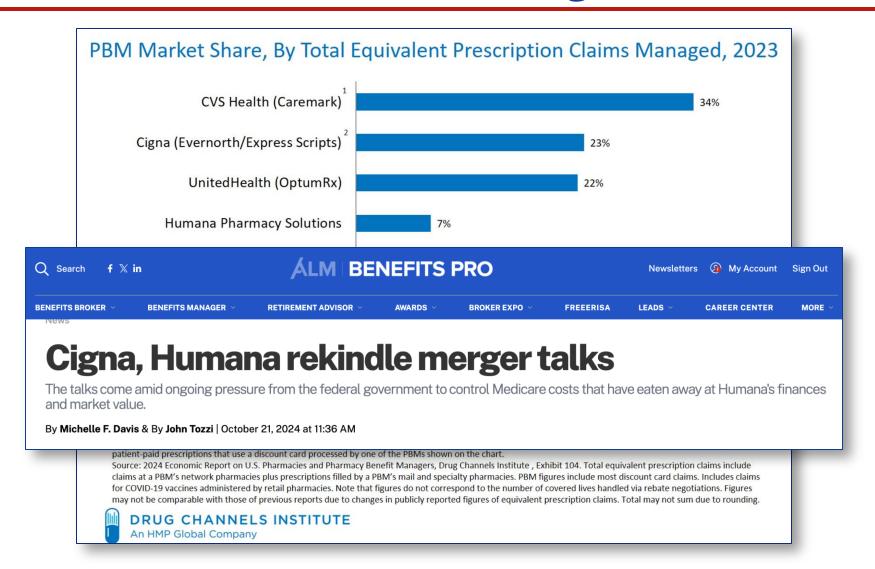


#### The Consolidation of Insurers & PBMs



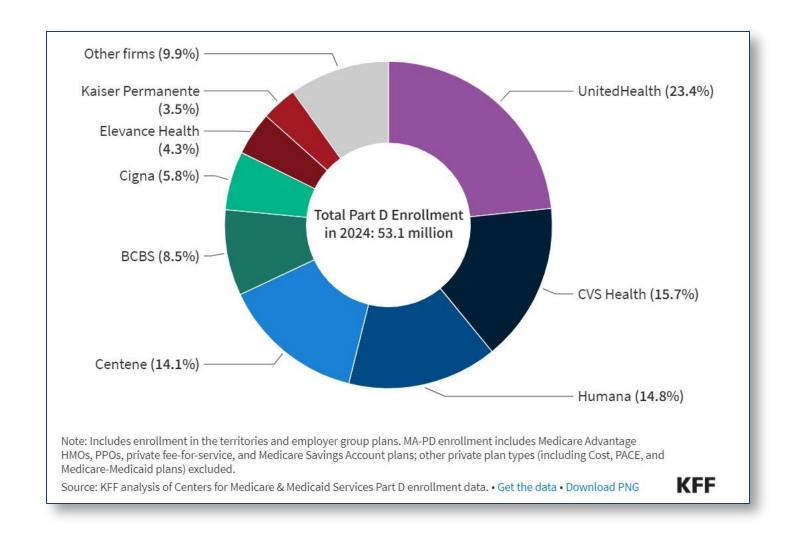


#### Top 6 PBMs Control 94% of Rx Drug Market





#### **Top 5 Insurers Control 77% of the MA Market**





#### PBMs Under Fire Like Never Before!

Cigna



#### **Pharmacy Benefit Managers:**

The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies

Interim Staff Report July 2024 U.S. Federal Trade Commission Office of Policy Planning



April 17, 2024 at 04:50 am EDT

By Kevin Smith

Pharmacy Benefit Managers (PBMs) are on the radar of both Republic Democrats in Congress, but have so far escaped any new litigation of that should have been included in last month's budget deal.



#### Bipartisan Group of Attorneys General Send Letter to Congress, Urging PBM Reform





#### Really Under Fire Like Never Before!!!





The Role of Pharmacy Benefit Managers in Prescription Drug Markets

Report Prepared by the House Committee on Oversight and Accountability Staff

# **Chairman Comer Calls on PBM Executives to Correct Hearing Testimony**

WASHINGTON—House Committee on Oversight and Accountability Chairman James Comer (R-Ky.) today is calling on the CEOs of three major Pharmacy Benefit Managers (PBMs)—CVS Caremark, Express Scripts, and Optum Rx—to correct the record for statements made during their appearance before the House Oversight Committee at a hearing titled, "The Role of Pharmacy Benefit Managers in Prescription Drug Markets Part III: Transparency and Accountability."

At the House Oversight Committee's hearing, the PBM chief executives made statements that contradict the **Committee's** and the **Federal Trade Commission's** findings about the PBMs' self-benefitting practices that jeopardize patient care, undermine local pharmacies, and raise prescription drug prices. The chief executives for CVS Caremark, Express Scripts, and Optum Rx claimed they do not steer patients to PBM-owned pharmacies. The executives also made claims contradicting the Committee's and FTC's findings regarding contract negotiations, contract opt outs, and payments to pharmacies.

In the letters to the chief executives, Chairman Comer writes: "The Committee highlights 18 U.S.C. § 1001, which states, 'in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly and willfully-...(2) makes any materially false, fictitious, or fraudulent statement or representation;...shall be fined under this title, imprisoned not more than 5 years.' The Committee also highlights 18 U.S.C. § 1621, which states, 'having taken an oath before a competent tribunal, officer, or person, in any case in which a law of the United States authorizes an oath to be administered, that he will testify, declare, depose or certify truly, or that any written testimony, declaration, deposition, or certificate by him subscribed, is true, willfully and contrary to such oath states or subscribes any material matter which he does not believe to be true...is guilty of perjury and shall...be fined under this title or imprisoned not more than five years, or both.' Please provide any necessary corrections to the record prior to September 11, 2024."



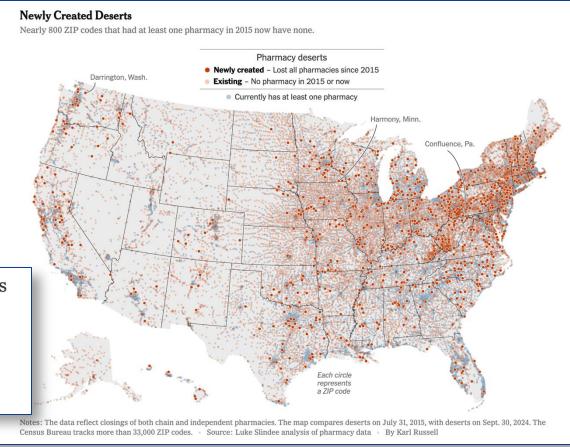
## Just This Past Weekend Major NYT Investigative Report

THE MIDDLEMEN

# The Powerful Companies Driving Local Drugstores Out of Business

The biggest pharmacy benefit managers are profiting by systematically underpaying independent drugstores, creating "pharmacy deserts" across the country.

This has been happening all over the country, a New York Times investigation found. P.B.M.s, which employers and government programs hire to oversee prescription drug benefits, have been systematically underpaying small pharmacies, helping to drive hundreds out of business.





#### Implications of Insurer/PBM/Etc. Consolidation

- Insurers increasingly dictating treatment decisions
  - Leverage based on market size
  - Owning physicians
- Utilization management being utilized more by insurers
  - Prior authorizations
    - Now using Al
  - Step therapy
- Increasingly dictating higher cost therapies that are the most profitable drugs to the insurer/PBM
- Fueling drug prices by demanding rebates
- Dictating where and how patients receive treatment
  - Mandatory mail order
  - White bagging



#### **Insurers Under the Same Fire**



#### 'Deny, deny!' That's how a staff doctor at Cigna was told how to review claims Inside UnitedHealth's strategy to pressure physicians: \$10,000 bonuses and a doctor leaderboard

The insurer meticulously tracked the output of its medical directors—and sent a message loud and clear: Cigna valued speed, says a former medical director who reviewed cases nurses flagged for denial or were unsure about.

By Patrick Rucker, The Capitol Forum, & By David Armstrong, ProPublica | May 06, 2024 at 11:00 AM



By <u>Tara Bannow</u> , <u>Bob Herman</u> , <u>Casey Ross</u> , and <u>Lizzy Lawrence</u> ✓ Oct. 16, 2024



#### Low-Ball PBM Reimbursement

- Eliminated retroactive DIR fees starting 1/1/24
  - But expected PBMs to jack down Part D reimbursement to make up for lost DIR fee revenue
- Preliminary look at PBM reimbursement, especially Express Scripts, shows this is what has happened
  - Net 2023 reimbursement (reimbursement plus DIR fees) AWP minus 20%
  - 2024 reimbursement AWP minus 25%
- Letters to ESI and CMS, copying Congress
- Met with CMS
- Engaged congressional committees
- COA considering suing CMS over Medicare Part D
- Held a webinar on how to engage practices



42 C.F.R. 8 423.505(b)(18); CMS Medicare Prescription Drug Benefit Manual, Chapter 5, Section 50.3

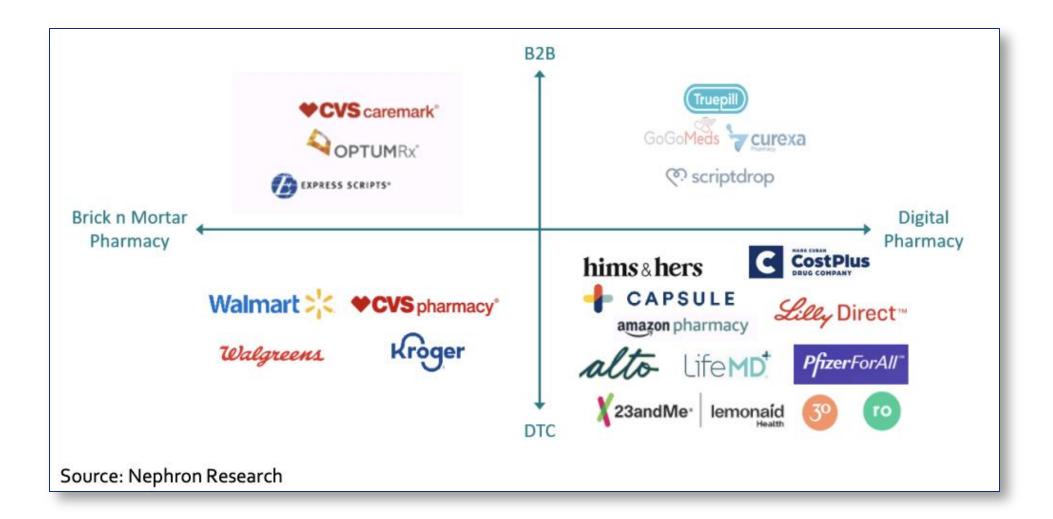


#### PBM Legislation in the Congress

- Amazing shift from bashing pharma to bashing the PBMs
- Over 25 bills dealing with curbing PBMs
  - Major bipartisan bills from Senate Finance and House Energy & Commerce Committees
- Also, the FTC is suing the big 3 PBMs over insulin pricing schemes
- Major push to get PBM legislation included in a lame duck (post-election) legislative package, if there is one
  - Depends on the outcome of the elections for President and Congress
    - If and what size the package will be
- Lot of motivation and support on both sides of the aisle in both houses of Congress to pass meaningful PBM legislation
- Wait and see



# **Changing Market Dynamics**



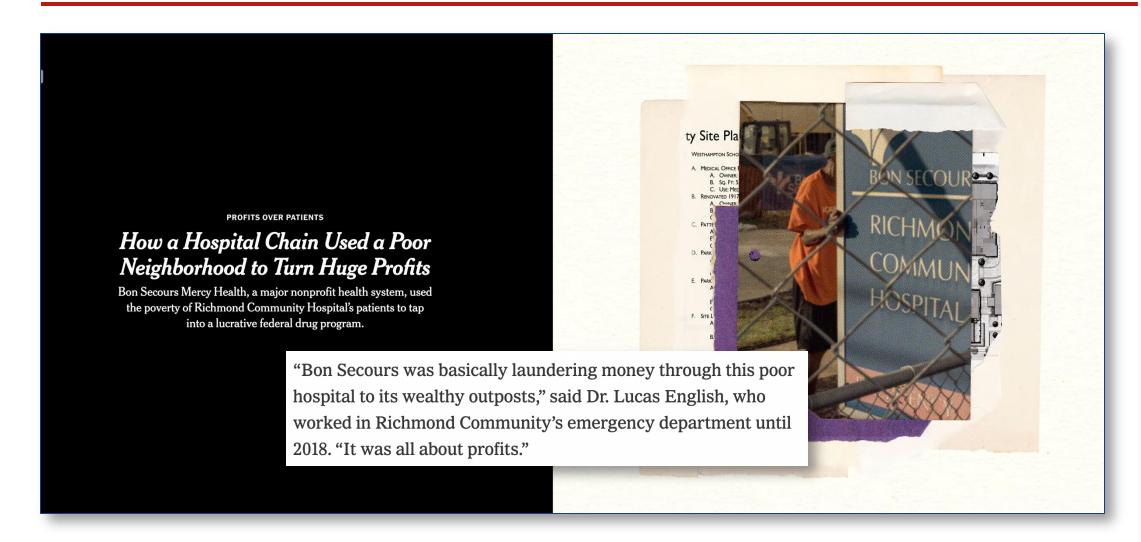


#### Focus on Hospitals Like Never Before





#### NYT Report Lit Up 340B in the Spotlight





#### The 340B Stories Get More Bizarre

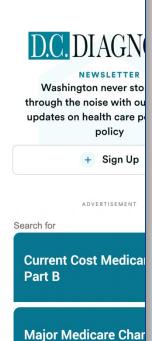
STAT+ POLITICS

#### How a drug discount program intended to benefit the poor got entangled in a California rent-control fight

California developers are taking aim at Michael Weinstein's AIDS Healthcare Foundation







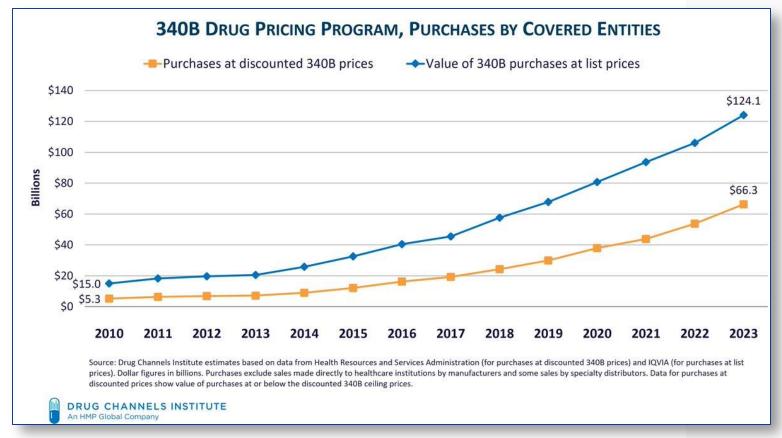
For 2025



#### 340B Growth Unchecked

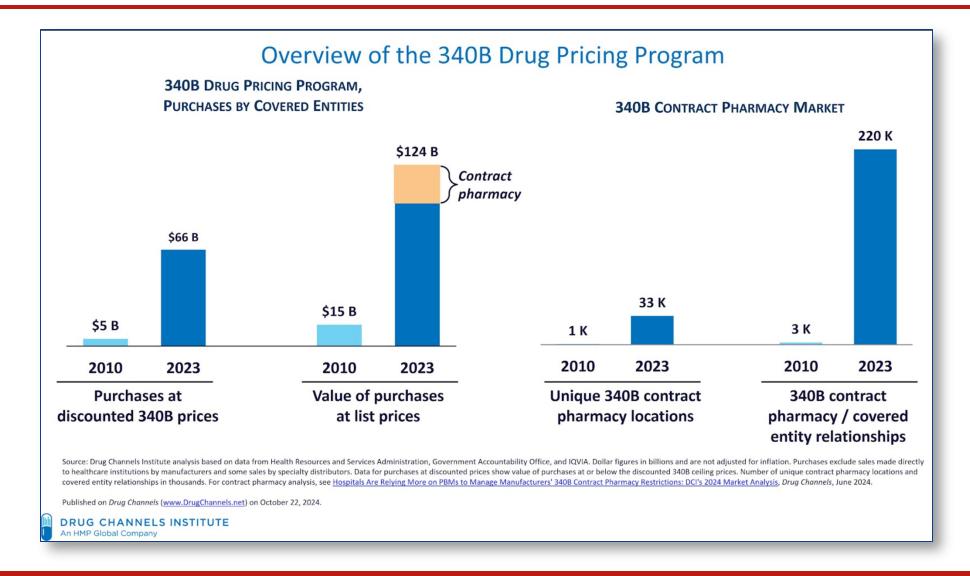
- DSH hospitals accounted for 78% of 340B sales
- 10 drugs accounted for approximately one-third of 340B sales
  - Oncology drugs 20%

Brand Name	Primary Indications	2023 Total 340B Sales
Keytruda	Oncology	\$6,905,377,755
Biktarvy	HIV	\$3,577,083,273
Opdivo	Oncology	\$1,953,824,181
Darzalex Faspro	Oncology	\$1,891,559,523
Ocrevus	Oncology	\$1,850,213,455
Trikafta	Cystic Fibrosis	\$1,817,226,143
Humira (CF) Pen	Immunology	\$998,809,804
Descovy	HIV	\$969,510,516
Entyvio	Immunology	\$949,744,300
Durvalumab	Oncology	\$889,594,527





#### 340B Growth & Contract Pharmacies





#### Where Does the 340B Issue Go?

- Senate bipartisan working group sent out an RFI for information on 340B and reactions to draft legislation
- May see a 340B bill after the elections
  - But don't think it will go anywhere
- Lots of money in regulating 340B
  - A Trump HHS/CMS will likely lower 340B reimbursement
  - A Harris HHS/CMS may see Congress use 340B as a large pay-for
- Expect pharma to keep pushing on contract pharmacy restrictions and rebates (versus discounts)
- Does 340B end up being bipartisan like PBMs



April 1, 2024

Submitted via email to: Bipartisan340BRFI@email.senate.gov

The Honorable John Thune
The Honorable Debbie Stabenow
The Honorable Shelley Moore Capito
The Honorable Tammy Baldwin
The Honorable Jerry Moran
The Honorable Ben Cardin
United States Senate
Washington, D.C. 20515

Re: Bipartisan 340B Request for Information ("RFI")

Dear Senators:

On behalf of the Board of Directors of the Community Oncology Alliance ("COA"), we are submitting this response to your bipartisan working group RFI seeking input on the 340B Drug Pricing Program ("340B") and specifically on the SUSTAIN 340B Act discussion draft.

As you know, COA is an organization dedicated to advocating for the complex care and access needs of patients with cancer and the community oncology practices that serve them. COA is the only non-profit organization in the United States dedicated solely to independent community oncology practices, which serve the majority of Americans receiving treatment for cancer. Since its grassroots founding more than 20 years ago, COA's mission has been to ensure that patients with cancer receive quality, affordable, and accessible care in their own communities where they live and work, regardless of their racial, ethnic, demographic, or socioeconomic status.

COA is committed to ensuring all patients with cancer have access to the highest quality and affordable care in their local communities in a treatment setting of their choosing. We want to make it abundantly clear that COA supports the original intent of the 340B program to assist providers in "stretching scarce federal resources" to help patients in need, especially those needing assistance in affording critical medications, such as cancer drugs. However, the 340B program has grown exponentially, creating perverse financial incentives for hospitals that significantly deviate from the program's original mission. Even worse, there are far too numerous examples of where patients do not get discounts on their medications, face extreme and inflated bills for treatment, and are then hounded by aggressive debt collection tactics by 340B hospitals.

Before we discuss our answers to the specific questions posed in the RFI, COA would like to articulate our key concerns with the program that require legislative action:

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Miriam Atkins, MD, FACP
Georgia
Vice President
Debra Patt MD, Ph.D, MB

Secretary
S. McDonald Wade III, MC
Virginia

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Stephen Schleicher, MD, MBA Tennessee Emily Touloukian, DO South Carolina Jeff Vacirca, MD, FACP New York Erin Wylam, MBA Oregon



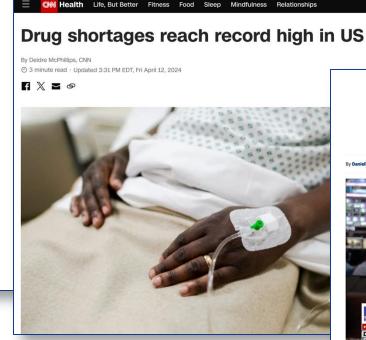
#### **Drug Shortages Well Documented**

#### Drug Shortages in the U.S. Reach All-Time High, Including Medications for Chemotherapy, ADHD and Severe Allergies

Pharmacists warn that there are 323 drugs in active shortage, a record high

By Vanessa Etienne | Published on April 15, 2024 02:54PM EDT



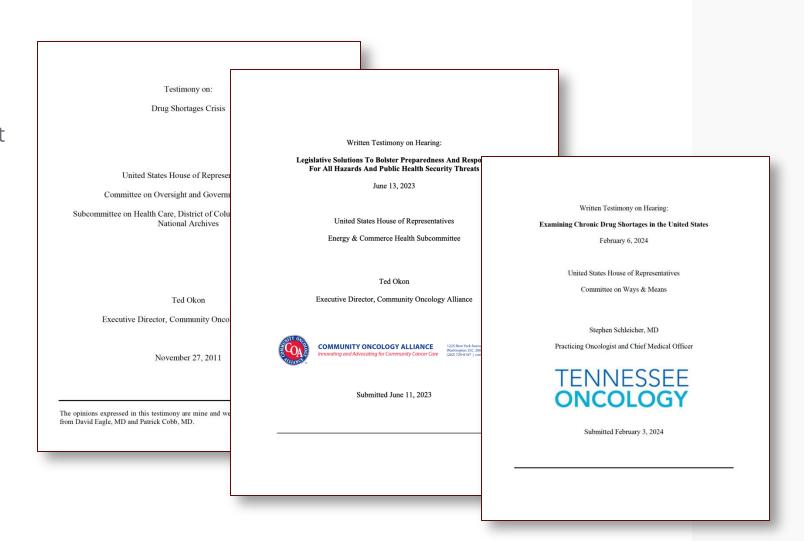






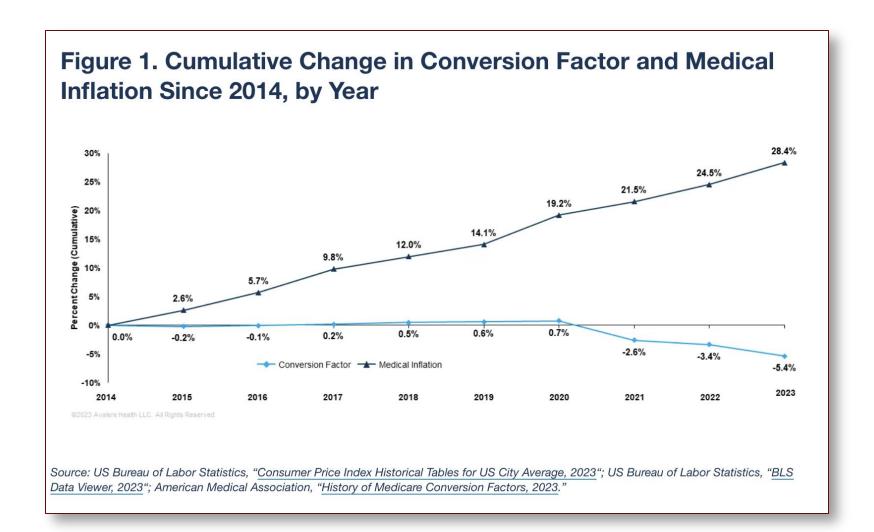
#### **Drug Shortages: Solutions**

- Problem won't be fundamentally fixed until underlying financial problem is addressed
  - Discounts and rebates mak low-cost generic drugs financially not viable
  - ASP reimbursement doesn't work
- Basic problem Congress has is acknowledging that fixing the problem of drug shortages means paying more for generics
  - Fundamentally that simple!





#### **Stopping Physician Pay Cuts**





## Problems with IRA Drug Price "Negotiations"

- Unclear how Part D IRA "negotiated" prices will play out in rebates to pharmacy providers
  - Concerns that pharmacy providers will have to float the discounts until rebated
- Part B maximum fair price (MFP) will artificially lower average sales price (ASP) and cause reimbursement headaches
- Will likely curb investments in additional cancer drug indications, especially pediatric indications
- Unclear if less research in small molecules



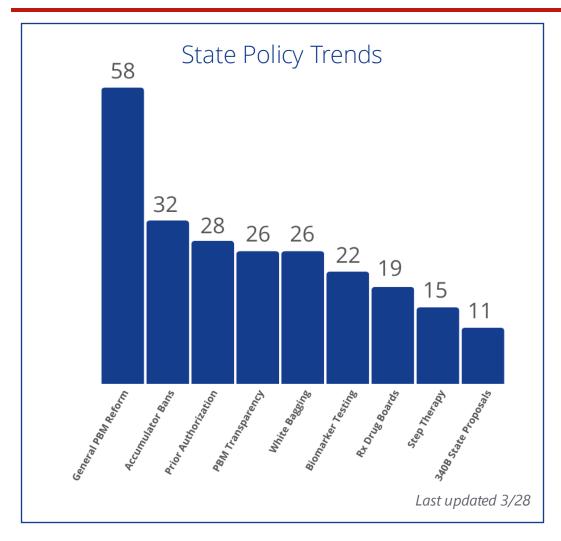


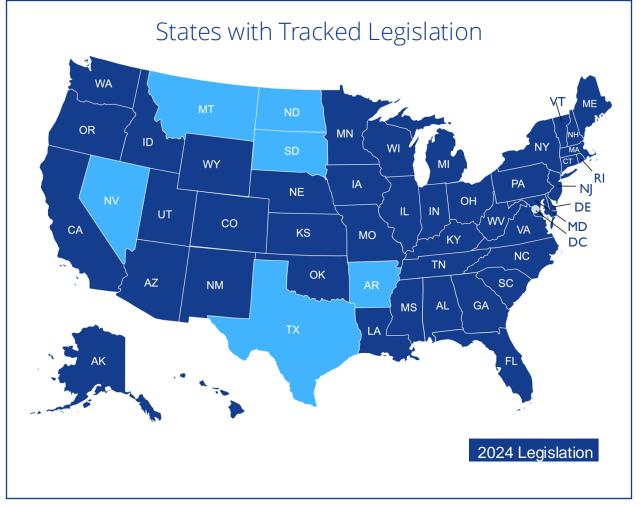
#### **Snapshot of COA Legislative Priorities & Action**

- Pushing for Stark drug delivery bill H.R. 5526 to be passed in year-end legislation
- Fighting for Medicare payment increases for physicians
- Push for PBM legislation to advance in year-end legislation
  - Includes transparent, "reasonable and relevant" reimbursement, and much more
- Possibly taking legal action against CMS for not "policing" Medicare Part D
- Working on solutions to IRA drug price negotiations
- Making sure practices understand the IRA cap on out-of-pocket patient expenses and how they can be "smoothed" out during the year
- Continue to ramp up state legislative activities

# COA State Policy Team Monitoring 222 Policy Proposals Introduced Across 44 State Legislatures in 2024









#### Questions?



#### **Ted Okon**

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