National Cancer Treatment Alliance™

Update/Perspective on PBMs & 340B

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June 7, 2023

Today's Presentation

- Provide an update on two issues impacting the quality and cost of cancer care for employers
  - Focusing on pharmacy benefit managers (PBMs) and legislative activity at the federal and state levels
  - Focusing on the federal government's 340B drug discount program
- Both PBMs and 340B are subject to greater media scrutiny and federal/state legislation.
- Both are very important for employers to understand because they can increase costs and negatively impact the experience of employees and covered lives dealing with cancer.

National Cancer Treatment Alliance (NCTA)

- NCTA is a national network of independent, community oncology practices partnering with self-funded employers to provide their employees with high-quality, most affordable, and most accessible cancer care, close to where they live and work.
- Through our network of practices and pharmacies, **NCTA boosts quality, improves the patient experience, and reduces cost.**
- Employers and their covered lives can also receive much-needed resources and education around key issues in cancer care.

Community Oncology Alliance (COA)

- COA is the recognized leader in Washington, D.C. focused on cancer care policy.
- COA is a non-profit 501.c.6. governed by a Board of Directors comprised of oncologists and practice administrators.
- NCTA is a B-Corp that is 100% owned by COA.

State of PBMs and Policy

Ted Okon
Executive Director
Community Oncology Alliance

Chairman & CEO
National Cancer Treatment Alliance

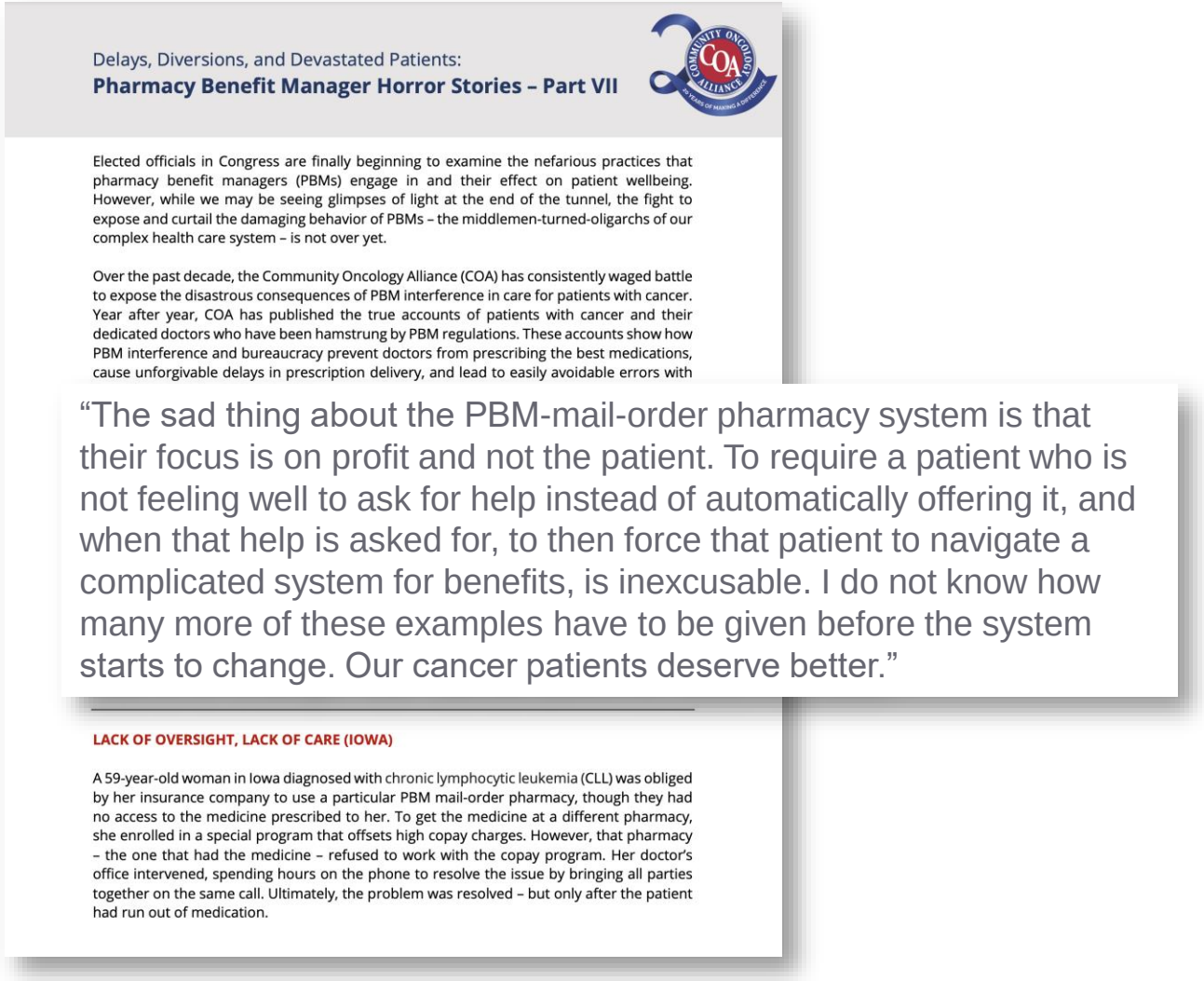
Sea Change on Capitol Hill on PBMs

- Pre-COVID, Democrats barely acknowledged PBMs as an issue
  - Everything was focused on the problems with drug pricing by the pharma companies
- Republicans acknowledged PBM issues but not a major focus
- Post-COVID, this has all changed
  - Democrat controlled Senate held first two hearings on PBMs
  - Republicans are much more focused on going after PBMs
- FTC working on a major PBM report
- Hearings and bi-partisan legislation signal best chance this year for PBM legislation
  - Helps that states have actually taken the lead on PBM legislation

Why Employers Should Care?

- Aside from the question of where rebate dollars go and how are they shared with employers, PBMs adversely impact the quality of cancer care and fuel drug prices
- Cancer patients face delays and denials in getting their medications
  - Especially true when PBMs mandate use of their mail order facilities
- Rebates and PBM administrative fees fuel artificially high list prices versus actual drug net prices
  - In particular, rebates are threatening the viability of the biosimilar market

PBM Patient Horror Stories



Delays, Diversions, and Devastated Patients:
Pharmacy Benefit Manager Horror Stories – Part VII

Elected officials in Congress are finally beginning to examine the nefarious practices that pharmacy benefit managers (PBMs) engage in and their effect on patient wellbeing. However, while we may be seeing glimpses of light at the end of the tunnel, the fight to expose and curtail the damaging behavior of PBMs – the middlemen-turned-oligarchs of our complex health care system – is not over yet.

Over the past decade, the Community Oncology Alliance (COA) has consistently waged battle to expose the disastrous consequences of PBM interference in care for patients with cancer. Year after year, COA has published the true accounts of patients with cancer and their dedicated doctors who have been hamstrung by PBM regulations. These accounts show how PBM interference and bureaucracy prevent doctors from prescribing the best medications, cause unforgivable delays in prescription delivery, and lead to easily avoidable errors with

"The sad thing about the PBM-mail-order pharmacy system is that their focus is on profit and not the patient. To require a patient who is not feeling well to ask for help instead of automatically offering it, and when that help is asked for, to then force that patient to navigate a complicated system for benefits, is inexcusable. I do not know how many more of these examples have to be given before the system starts to change. Our cancer patients deserve better."

LACK OF OVERSIGHT, LACK OF CARE (IOWA)

A 59-year-old woman in Iowa diagnosed with chronic lymphocytic leukemia (CLL) was obliged by her insurance company to use a particular PBM mail-order pharmacy, though they had no access to the medicine prescribed to her. To get the medicine at a different pharmacy, she enrolled in a special program that offsets high copay charges. However, that pharmacy – the one that had the medicine – refused to work with the copay program. Her doctor's office intervened, spending hours on the phone to resolve the issue by bringing all parties together on the same call. Ultimately, the problem was resolved – but only after the patient had run out of medication.

- COA has published 7 volume of PBM patient horror stories
  - Latest version out tomorrow and another one out next week
- Detail very specific cases of where patient care is impeded and harmed at the hands of PBMs

Congressional Hearings on PBMs

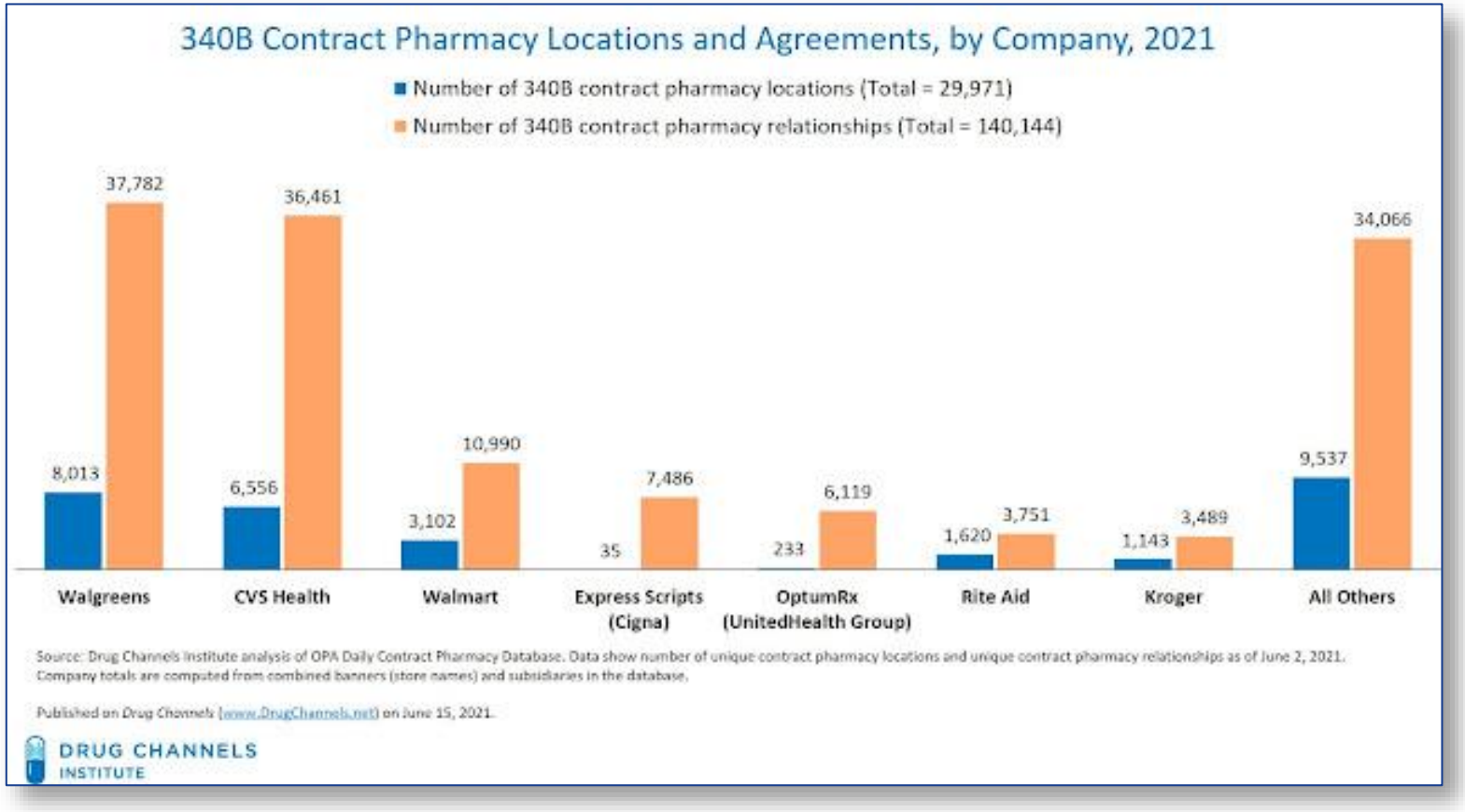
PBM Bills Already Introduced

- Prescription Pricing for the People Act (Senate)
- Pharmacy Benefit Manager Transparency Act (Senate)
- Drug Price Transparency in Medicaid Act (Senate)
- Pharmacy Benefits Manager Accountability Act (House)
- Pharmacy Benefit Manager Reform Act (Senate)
- Promoting Access to Treatments and Increasing Extremely Needed Transparency (PATIENT) Act (House)
- Senate Finance Committee working on major PBM legislation
- More bills to come in the House

What's Next and Prognosis

- FTC working on a major report on PBMs
- PCMA (PBM lobby) launched a seven-figure advertising campaign
- Top PBMs reacting by launching major "feel good" campaigns aimed at pharmacies
  - While at the same time launching new DIR programs aimed to recoup lost revenue
- Likely Congress pulls together PBM legislation in an end-of-year package
- Pressure building on PBMs!

PBMs Major Players in 340B



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

The 340B Drug Pricing Program: Why Employers Should Care

Nicolas Ferreyros
Managing Director
Community Oncology Alliance

Background: 340B Drug Discount Program

340B is a CRITICAL safety net for patients who are uninsured or underinsured, particularly those with cancer.

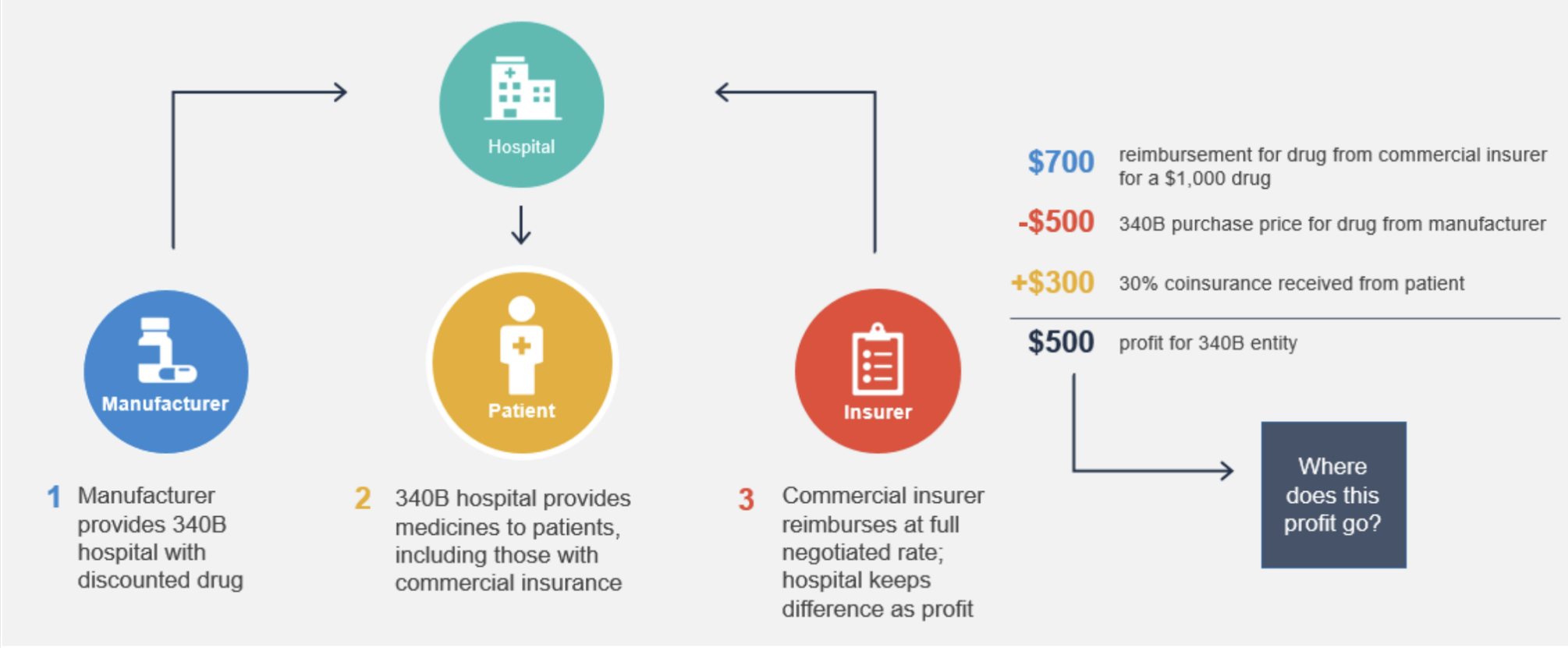
- The federal 340B drug discount program provides non-profit hospitals and grantees (community clinics, etc.) with drug discounts in excess of 50%.
- Grantees and *some hospitals* are using 340B as intended, and it must be preserved and protected for them.
  - Helping communities and patients in need
- Problem is most hospitals, especially large health systems, are pocketing the drug discounts and even providing less charity care.
- 340B has grown so much it is unsustainable, and we are all paying the price.

Why Should Employers Care About 340B?

- Large 340B hospitals and health systems are receiving HUGE discounts on cancer drugs (and other expensive specialty medicines) yet marking them up excessively
  - Employers are paying grossly inflated prices for drugs
  - Employees with out-of-pocket cost sharing are being over charged as well
- 340B is fueling drug prices as drug manufacturers account for a growing scope and magnitude of discounts
- 340B provides a powerful economic incentive for hospitals to consolidate markets and acquire independent oncology practices
  - Hospitals drive up cancer care costs as they are the most expensive site of care

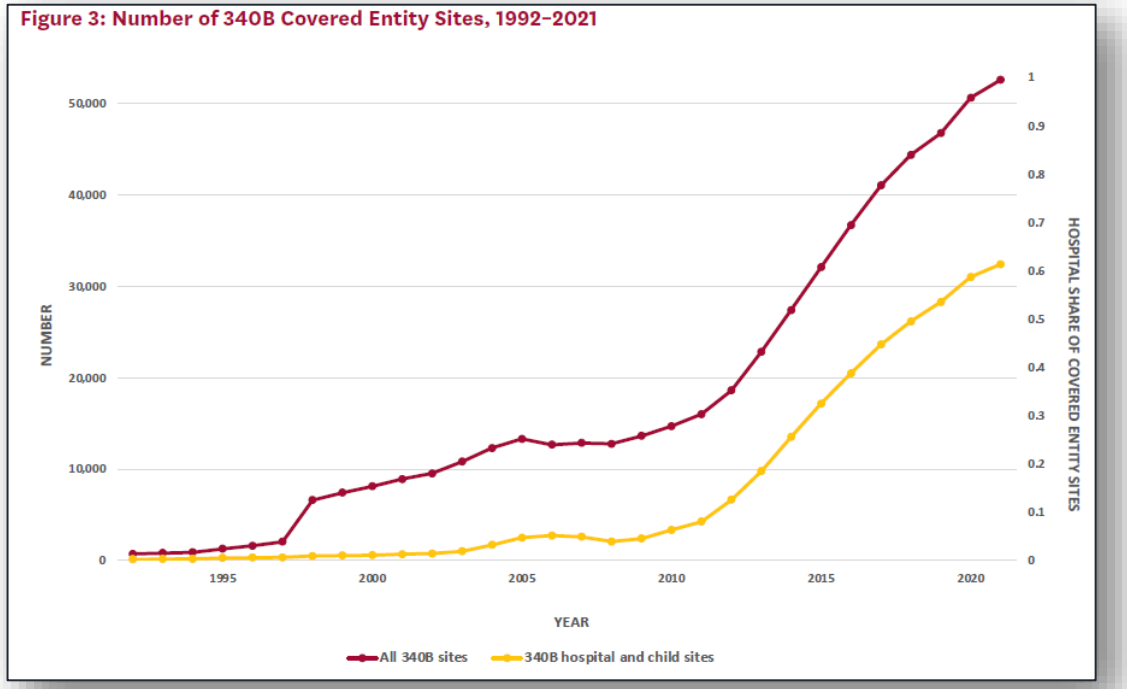
How 340B Works

Simplified Example of How 340B Discounts Work

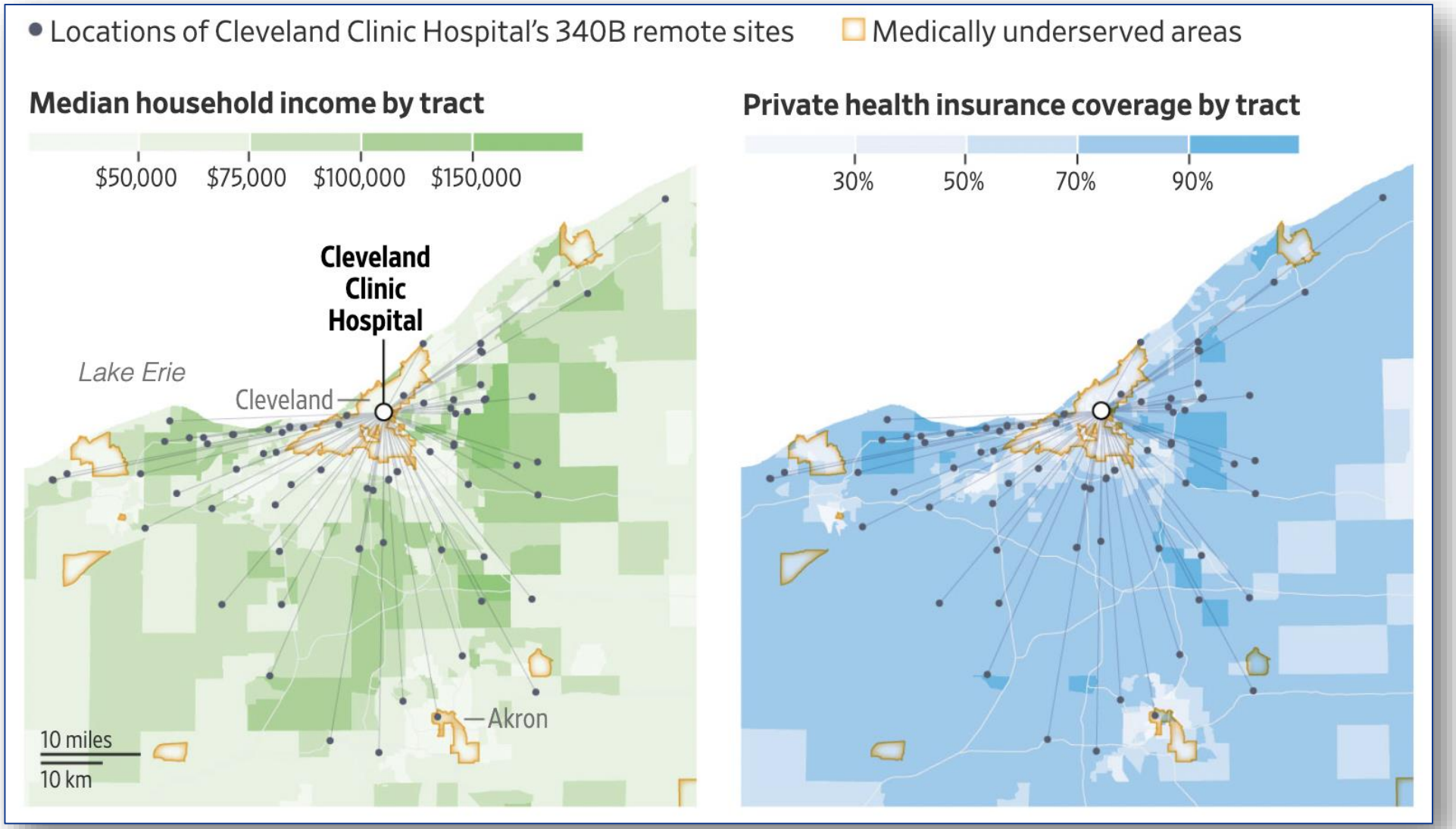


340B Has Grown Enormously, Particularly in Hospitals

- The 340B program has expanded from a handful of safety net providers to 50+% of all U.S. hospitals *(Source: USC Schaeffer Center for Health Policy Economics)*
  - WAC list price value of 340B drug purchases $106 billion in 2022 *(Source: IQVIA)*
    - Close to doubling from 2018
    - Over 15% 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)*



340B Hospitals Expand into Wealthy, Insured Areas to Generate More Profits

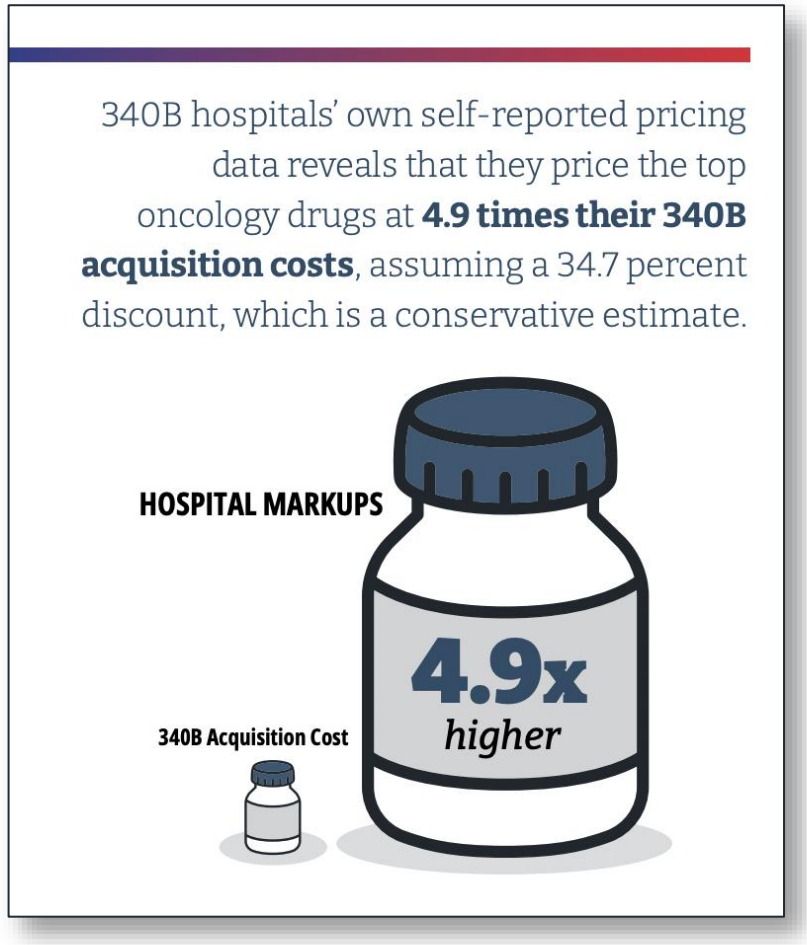


"Most of the satellite 340B sites of Cleveland Clinic's flagship hospital are in **areas with higher levels of household income and private health insurance** than its main campus. Locations can include multiple sites."

Source: Wall Street Journal.

340B Hospitals Charge Steep (5x) Markups for Cancer Drugs

- COA study using 340B hospital transparency data
- 340B hospitals make huge profits selling cancer drugs purchased at a deep discounts to patients with commercial insurance.
- 340B DSH hospitals price drugs at a median of 4.9x their 340B acquisition costs
  - The lowest average markup was 3.2 times and the highest was 11.3 times



Employers & Employees With Commercial Insurance Pay Much More

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**

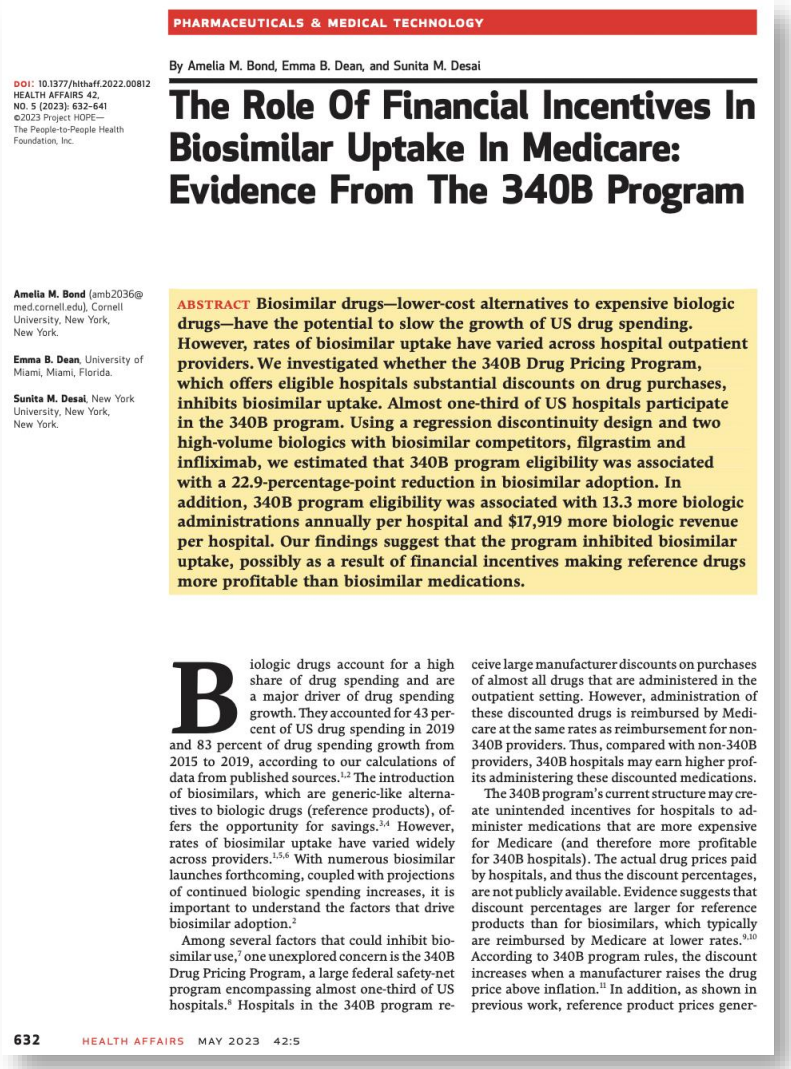
Source: COA report.

Spending at 340B Hospitals is Higher

- 340B incentivizes hospitals to prescribe more drugs and/or more expensive drugs to increase their profits (Milliman, 2022)
- Per-patient spend on outpatient drugs at 340B hospitals higher than at non-340B hospitals (Government Accountability Office, 2015)
- Per-patient drug spending increased by 32.4% at hospitals that recently enrolled in 340B (Berkeley Research Group, 2019)
  - Rose by 20.6% for 340B hospitals in the first year of enrollment compared to the year prior

340B Hospitals Use Fewer Low Cost Biosimilars

- 340B eligibility associated with:
  - 22.9% reduction in biosimilar adoption
  - 13.3 more biologic administrations annually per hospital
  - $17,919 more biologic revenue per hospital
- Biosimilars have the potential to greatly reduce health care costs
  - The average price discount of biosimilars averages 30% less than their reference brand biologic.
  - 25-56% of 340B hospitals studied only listed prices for innovator drugs, not biosimilars.
- 340B discounts are percentage-based, so hospitals are less incentivized to use lower-cost biosimilars



PHARMACEUTICALS & MEDICAL TECHNOLOGY

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By Amelia M. Bond, Emma B. Dean, and Sunita M. Desai

The Role Of Financial Incentives In Biosimilar Uptake In Medicare: Evidence From The 340B Program

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ABSTRACT **Biosimilar drugs—lower-cost alternatives to expensive biologic drugs—have the potential to slow the growth of US drug spending. However, rates of biosimilar uptake have varied across hospital outpatient providers. We investigated whether the 340B Drug Pricing Program, which offers eligible hospitals substantial discounts on drug purchases, inhibits biosimilar uptake. Almost one-third of US hospitals participate in the 340B program. Using a regression discontinuity design and two high-volume biologics with biosimilar competitors, filgrastim and infliximab, we estimated that 340B program eligibility was associated with a 22.9-percentage-point reduction in biosimilar adoption. In addition, 340B program eligibility was associated with 13.3 more biologic administrations annually per hospital and $17,919 more biologic revenue per hospital. Our findings suggest that the program inhibited biosimilar uptake, possibly as a result of financial incentives making reference drugs more profitable than biosimilar medications.**

Biologic drugs account for a high share of drug spending and are a major driver of drug spending growth. They accounted for 43 percent of US drug spending in 2019 and 83 percent of drug spending growth from 2015 to 2019, according to our calculations of data from published sources.[1,2] The introduction of biosimilars, which are generic-like alternatives to biologic drugs (reference products), offers the opportunity for savings.[3,4] However, rates of biosimilar uptake have varied widely across providers.[1,5,6] With numerous biosimilar launches forthcoming, coupled with projections of continued biologic spending increases, it is important to understand the factors that drive biosimilar adoption.[2]

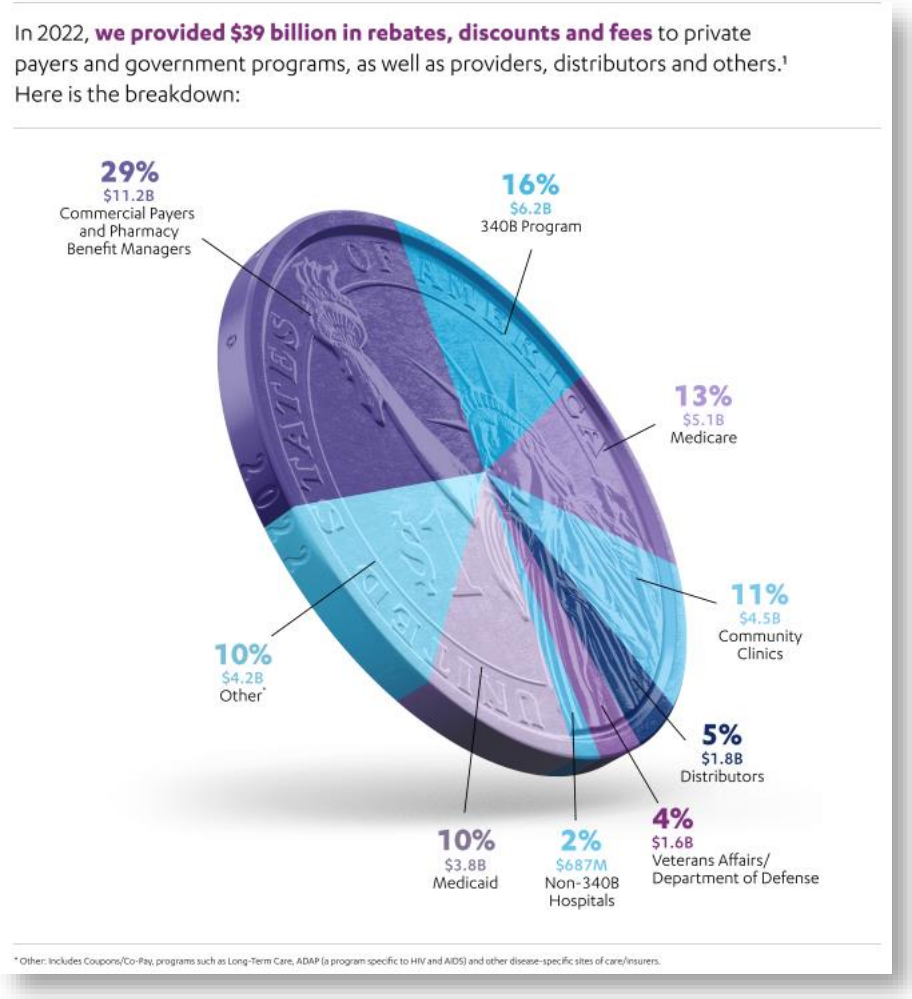
Among several factors that could inhibit biosimilar use,[7] one unexplored concern is the 340B Drug Pricing Program, a large federal safety-net program encompassing almost one-third of US hospitals.[8] Hospitals in the 340B program receive large manufacturer discounts on purchases of almost all drugs that are administered in the outpatient setting. However, administration of these discounted drugs is reimbursed by Medicare at the same rates as reimbursement for non-340B providers. Thus, compared with non-340B providers, 340B hospitals may earn higher profits administering these discounted medications.

The 340B program's current structure may create unintended incentives for hospitals to administer medications that are more expensive for Medicare (and therefore more profitable for 340B hospitals). The actual drug prices paid by hospitals, and thus the discount percentages, are not publicly available. Evidence suggests that discount percentages are larger for reference products than for biosimilars, which typically are reimbursed by Medicare at lower rates.[9,10] According to 340B program rules, the discount increases when a manufacturer raises the drug price above inflation.[11] In addition, as shown in previous work, reference product prices gener-

340B Leads to Consolidation/Higher Costs

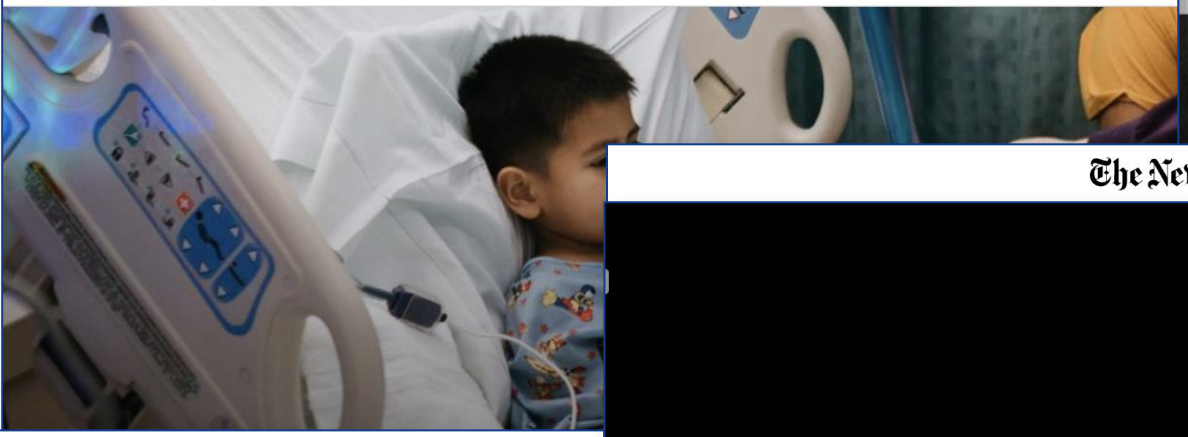
340B Discounts Are Priced In & Drive Drug Prices Up for Everyone

- Drug manufacturers account for 340B discounts and PBM rebates in setting drug list prices
- At J&J, nearly 50% of the average drug dollar accounted for by 340B discounts and PBM rebates
- Excessive scope and magnitude of 340B discounts (and PBM rebates) are fueling drug list prices
  - List prices are what employers and employees pay off of
- There is no free lunch – discounts and rebates are accounted for in drug prices



Increased Media Attention on 340B

THE WALL STREET JOURNAL.



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

110 Shares | Share | Tweet | Email

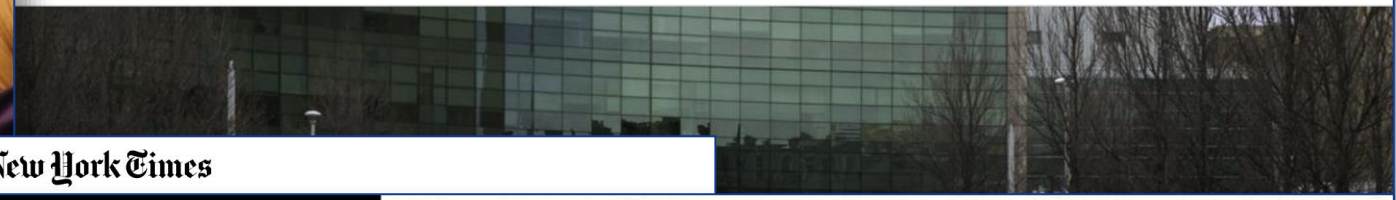
by: Garrett Bergquist

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.

THE WALL STREET JOURNAL.

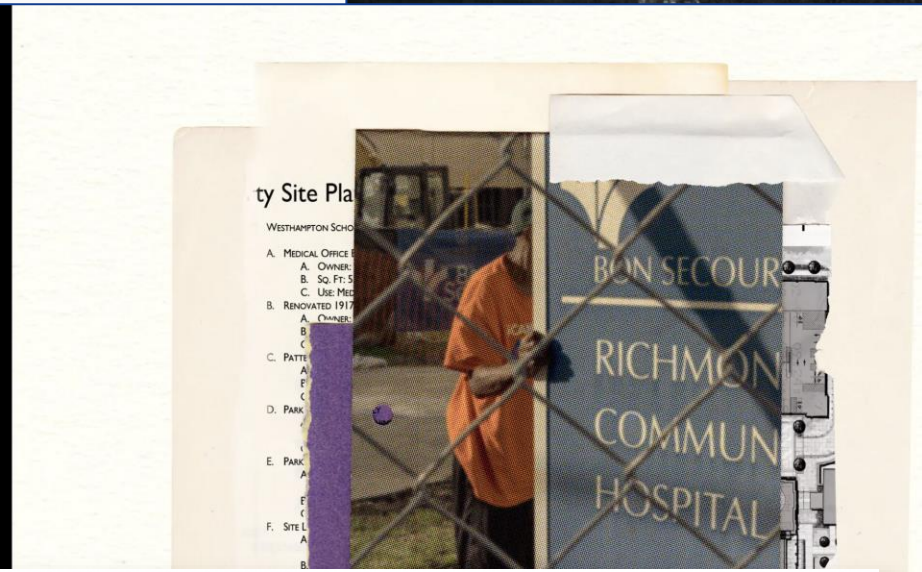


The New York Times

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."

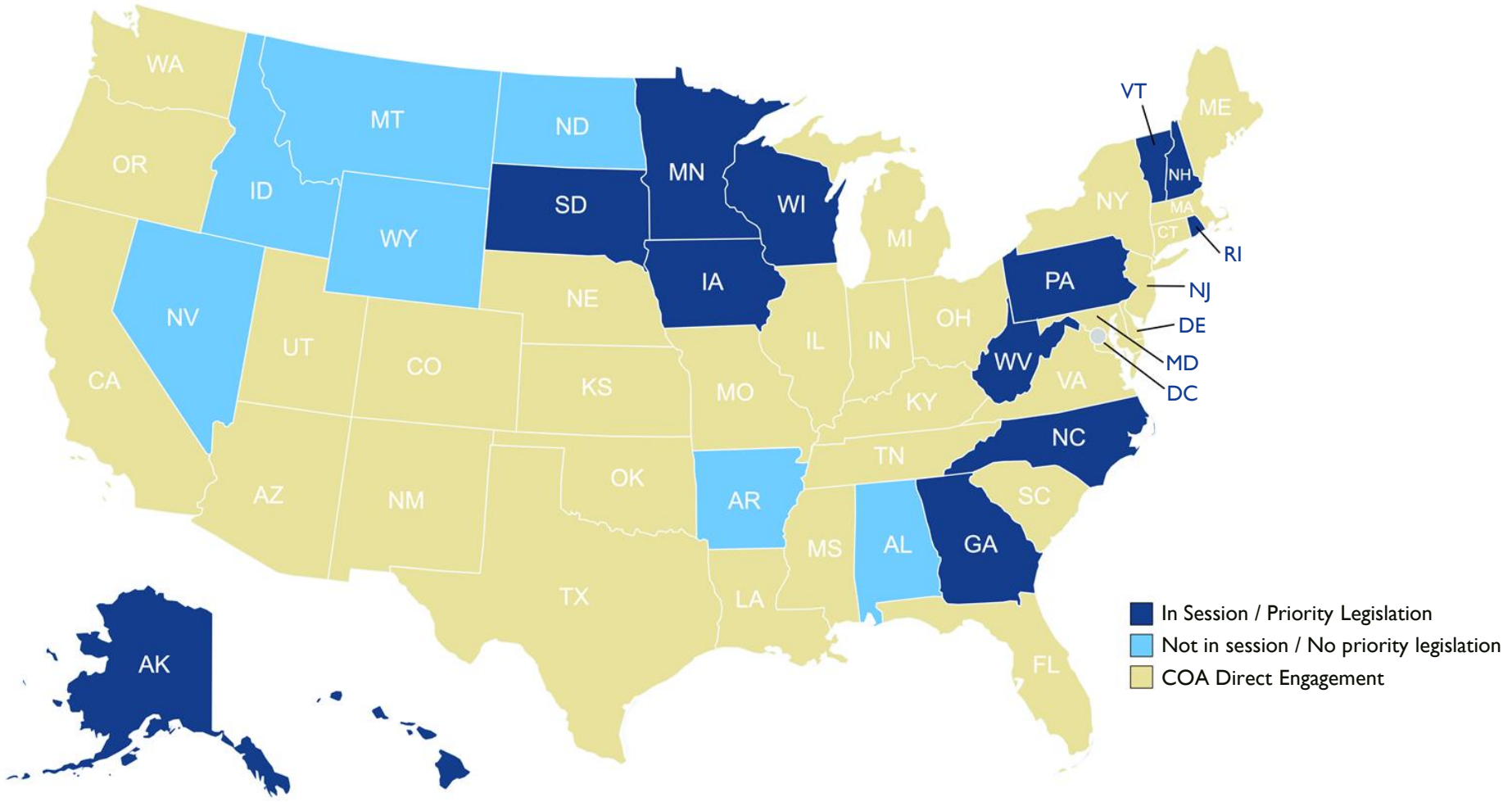
What's Next for 340B & Solutions

- 340B is a more partisan issue than PBM reform but Democrats have had to acknowledge program has flaws.
- Congressional (House) bill already introduced that would create more accountability and transparency relating to 340B in hospitals
  - More legislation likely coming
- 21 drug companies have restricted sales to multiple 340B PBM contract pharmacies
  - CVS has disclosed this has hit earnings
  - One court case won by industry; two more to be decided
    - Likely heading to the Supreme Court
- Solutions to reform 340B
  1. Improved transparency and reporting of 340B and hospital discounts.
  2. Accountability and true oversight of how money is being used by hospitals.
  3. Should 340B discounts follow the patient – directly benefit them?

State Policy Updates

James Lee
Senior Manager
Community Oncology Alliance

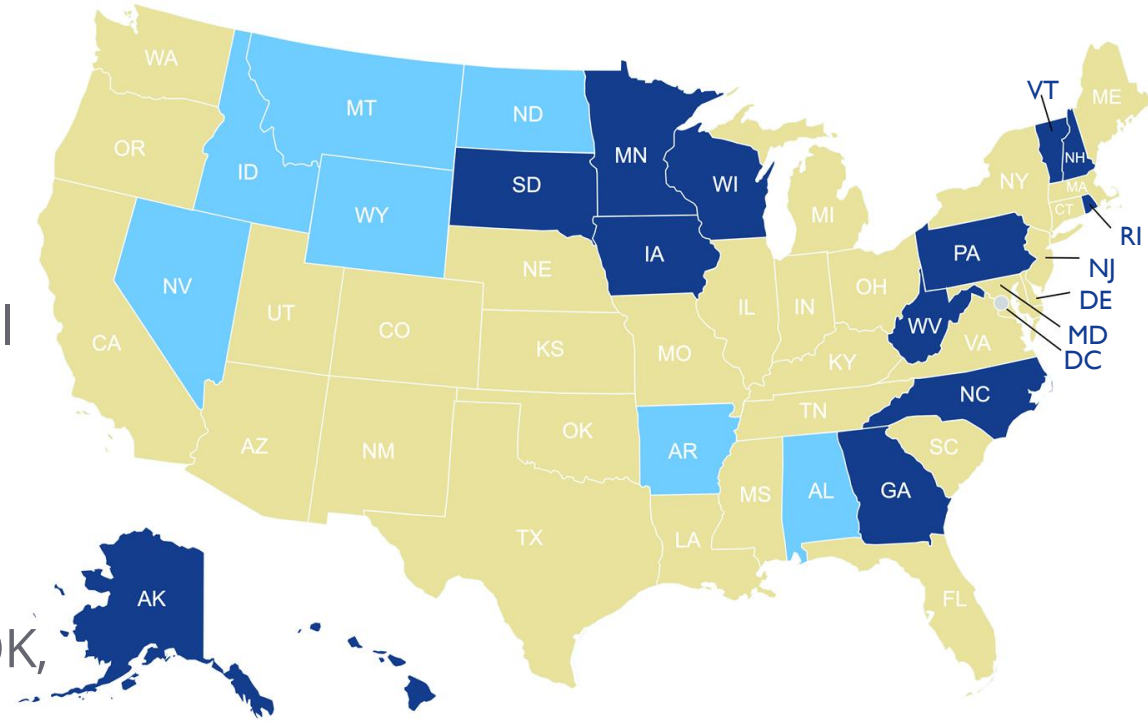
2022 State Impact



2022 State Impact

Directly Engaged 30/41 States

- 46 States in Session
- 41 States with Priority Legislation
- 350+ Bills Monitored Across All States
- 20% State Passage Rate vs 3-4% Federal

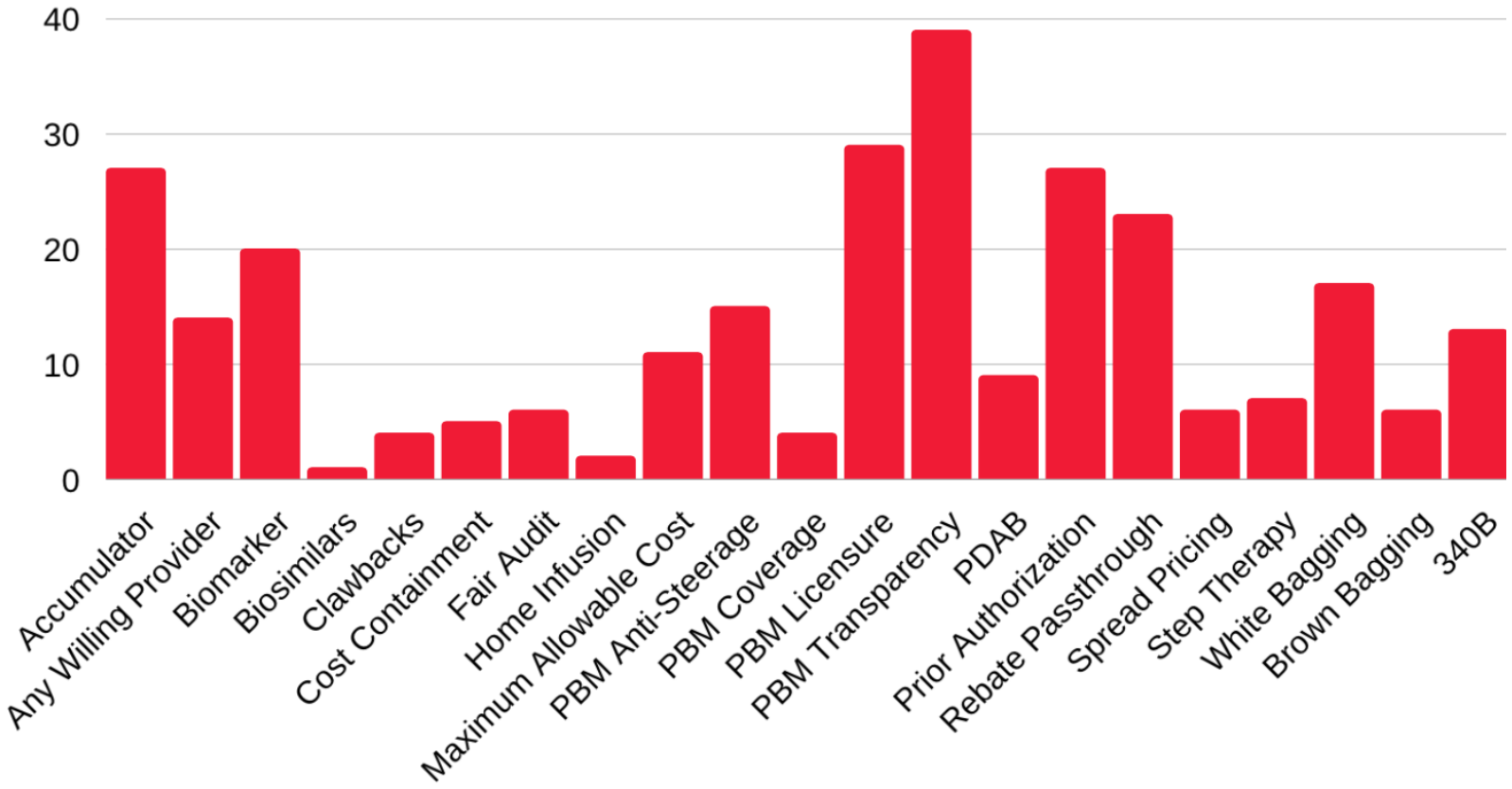


Practice and Partner Work

AZ, CA, CO, CT, DE, FL, IL, IN, KS, KY, LA, ME, MD, MA, MI, MS, MO, NE, NJ, NM, NY, OH, OK, OR, SC, TN, TX, UT, VA, WA

PBM State Policy Developments

State Policy Trends - Filed Legislation



PBM State Policy Developments

State lawmakers have identified insurer and PBM business policies as contributing factors to delayed care and higher costs across healthcare markets.

The following state proposals have been introduced to improve patient outcomes and combat increased health care spending.

1. PBM Transparency and Licensure Bills
2. Prior Authorization Reform
3. PBM White Bagging Prohibitions
4. Biomarker Testing Coverage
5. PBM 340B Oversight and Transparency

PBM State Policy Developments

PBM Transparency

Requires a Pharmacy Benefit Manager to:

- Report to a regulatory body or agency on an annual or biannual basis.
- Disclose information (rebates, formulary changes, pharmacy ownership, etc) with consumers or state regulatory bodies.

Example

- Connecticut SB 1159
  - Authorizes DOI to assess PBM practices, including spread pricing and rebate allocations, and report to the General Assembly.
- Louisiana HB 673
  - Creates a PBM monitoring advisory council responsible for monitoring PBMs and advising the legislature, commissioner of insurance, and Board of Pharmacy on the regulation of PBMs.

PBM State Policy Developments

PBM Licensure

A regulatory tool utilized by the state to identify pharmacy benefit managers operating within the state and enforce laws on the books.

- Extends upon the work of a transparency law
- Allows a PBM's license to be suspended or revoked
- Provides enforcement options for a regulatory agency or in some cases another state authority
- Example
  - Florida SB 1550
    - Requires PBMs to apply for a certificate of authority to operate in the state of Florida. Certification is handled by the Office of Insurance Regulation.

PBM State Policy Developments

Prior Authorization Reform

Prevent pharmacy benefit managers from implementing prior authorization protocols that unnecessarily delay treatment and increase costs.

- Streamlining Electronic System: Cut down on the time prior authorization takes away from patients and providers, establishing streamlined prior authorization systems that can receive requests

- Gold Card Rating: Providers that have met an average approval rating issued a status for a short timeframe. Typically 6-12 months

PBM State Policy Developments

White Bagging Prohibition

Prohibiting white bagging as a condition of coverage for infusion drugs.

- Patients have the right to obtain clinician-administered drugs from their chosen provider without interference from a PBM.
- Example
  - North Dakota SB 2378
    - Defines a "clinician-administered drug" as an outpatient prescription drug that cannot be self-administered by the patient, certain vaccines administered by authorized healthcare providers, or specialty drugs.
    - The availability of clinician-administered drugs cannot be limited or excluded solely based on not being dispensed by a mail-order pharmacy or PBM affiliate, as long as the drug would otherwise be covered for patients.

PBM State Policy Developments

White Bagging Prohibition

- Example (Continued)
  - North Dakota SB 2378
    - Participating providers should not be penalized or have their payments reduced for administering clinician-administered drugs obtained from a source other than a mail-order pharmacy or PBM affiliate, as long as the drugs are medically necessary.
    - The law prohibits requiring a pharmacy designated by a PBM or third-party payer to dispense medication to a patient for the purpose of transporting it to a healthcare setting for administration by a participating provider.

PBM State Policy Developments

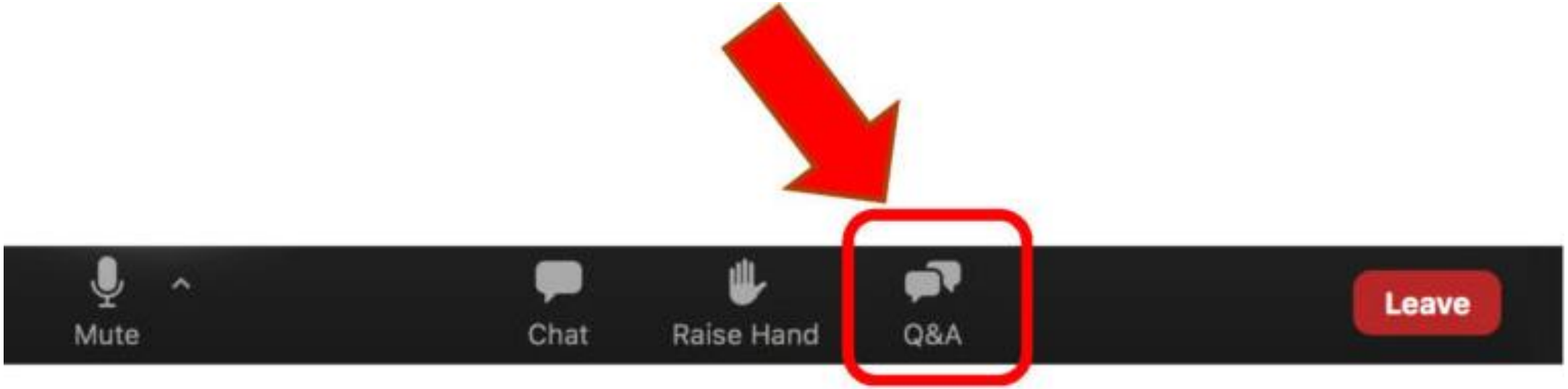
PBM 340B Transparency

Establish reporting requirements for 340B Hospitals.

- Require participating hospitals to disclose how it uses 340B drug savings to benefit the residents of the geographic area covered by the hospital
- Requires participating hospitals to disclose its estimated savings, comparing the 340B drug pricing program acquisition price to the group purchasing organization price
- Examples
  - VA HB 2472 *The 340B Covered Entity Commitment to Good Stewardship Principles Annual Report*
  - IN HB 1291 Reporting median reimbursements received for 340B drugs

Questions?

- Type questions into Q&A area at bottom or top of screen.



National Cancer Treatment Alliance™

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Thank you and stay in touch!

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