National Policy Update

Presentation to GASCO

Nicolas Ferreyros
Managing Director, Policy, Advocacy, and Communications

June 10, 2022

COA Supports Community Oncology Practices & Teams

Physicians

Patients

Nurses

Fellows

Pharmacists

Administrators

- COA Administrators' Network (CAN)
  - Networking practice leadership teams
- Community Oncology Pharmacy Network (COPA)
  - Networking practice pharmacy teams
- COAnalyzer
  - Comprehensive practice performance measurement and benchmarking tool available for practices
- COA Fellows Initiative
  - Reaching the future workforce in practices
- COA Patient Advocacy Network (CPAN)
  - Educating and empowering patient advocates
- Meetings and events
  - Annual conference
  - Payer Exchange Summit
  - State of Community Oncology Briefing

Key Takeaways: What is COA Currently Focused On?

1. Watch out for destructive drug pricing reforms
   - Top priority: Keeping an eye on destructive drug pricing proposals, such as proposed in original Build Back Better (BBB) Act, Most Favored Nation, and Part B experiment (to name a few).
   - COA has a legislative fixes to most destructive proposals.
2. PBMs, PBMs, PBMs (and Insurers)
   - Stop PBMs from getting in the way of practices providing cancer care.
   - Starts with addressing DIR fees and sham "quality" programs.
   - Senate/House bill, CMS rule, FTC investigation, and requests for information
3. Reform of the broken 340B program
   - Exposing hospital excessive mark-up on oncology drugs and PBM takeover of 340B contract pharmacies
   - Developed legislation to have 340B discounts go directly to patients in need, in all settings.
4. Figuring out future of the OCM, OCF, and CMMI – while leading payment reform
   - Beware mandatory Part B models if drug price reform fails
5. Increasing our focus on the state-level action and reforms
   - Pushing back on prior authorizations, step therapy, and white/brown bagging.
   - Fostering more state legislation and tie back to federal initiatives.

DC is Focused Elsewhere, For Now…

Remember: It All Comes Back to Drug Price Reform

The New York Times

OPINION

GUEST ESSAY

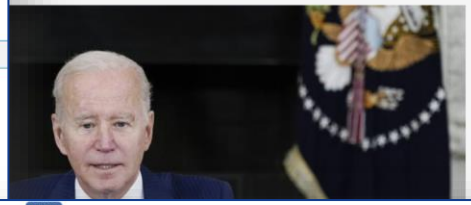
Prices for New Drugs Are Rising 20 Percent a Year. Congress Needs to Act.

June 8, 2022

Phelan M. Ebenhack/Associated Press

Biden puts focus on drug prices as he tries to revive agenda

By CHRIS MEGERIAN 2 hours ago



GEORGIA RECORDER

GOVERNMENT/POLITICS ENERGY/ENVIRONMENT EDUCATION HEALTH CRIMINAL JUSTICE CIVIL RIGHTS/IMMIGRATION

GOVERNMENT & POLITICS HEALTH

FOR THE RECORD

Warnock pushes to lower drug prices for seniors, diabetics

BY: ROSS WILLIAMS - MARCH 24, 2022 1:48 PM

KERA News for North Texas

KERA All Things Considered

News

House Speaker Nancy Pelosi visits Dallas to talk lower drug costs

KERA | By Pablo Arauz Peña

Published March 21, 2022 at 8:20 PM CDT

Drug Price Reform & Build Back Better (BBB) Disaster

- Pres. Biden's Build Back Better (BBB)
  - Massive framework including infrastructure. clean energy, health care, more.

- Beware impact of Part B reform and Medicare "negotiation"
  - Drug pricing provisions put providers in the middle of "negotiations."
  - Avalere study commissioned by COA found 42.9% cut in part B add-on payments in medical oncology.

- COA fought hard with lobbying and a multi-million-dollar ad campaign
  - Remove providers from middle of negotiations between manufacturers and government!

Specialty	Percentage Change in Part B Add-on Payment from Current Law to Medicare Negotiation
Rheumatology	-48.5%
Medical Oncology	-42.9%
Hematology/Oncology	-41.3%
Radiation Oncology	-39.7%
Interventional Pain Management	-39.4%
Gynecologist/Oncologist	-39.3%
Hematology	-38.7%
Internal Medicine	-38.4%
Ophthalmology, Otology, Laryngology, and Rhinology	-36.1%
Gastroenterology	-24.4%
All Providers	**-39.8%**

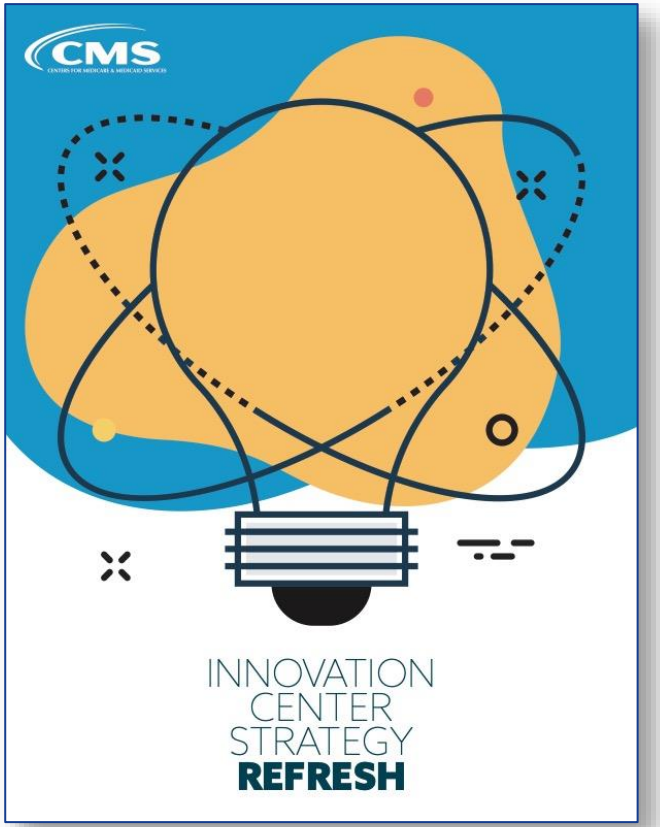
Source: Avalere Health

Drug Price Reform & Build Back Better (BBB) Disaster

- Is the BBB dead?
  - Dem leadership says no
  - Manchin says maybe
  - Remember: Election year!
- Keep an eye out for return of BBB and negotiations in some form
- Some key Congressional milestones:
  - August: Congressional recess
  - September 30: Govt. funding expires
  - November 8: Mid-term elections
- **Prediction: A very wild summer, full of surprises!**

What is the Future of the OCM, OCF, and CMMI?

- Pretty clear that the OCM is dead in the water with no successor in sight
  - Very disappointing – Community oncology practices transformed the way they delivered cancer care.
  - OCM sparked 35+ other models.
  - Many practices happy, and improved quality while saving Medicare money, despite what has been said.
  - Community practices saved money vs. hospitals.
- Unclear if the OCF will ever happen or if a larger, more dramatic Part B "model" launched
  - Depends in part on what Dems can get done.
  - CMMI may be used to do something on Part B.
- CMMI looking at larger, mandatory models to make up for lost time and lack of impact



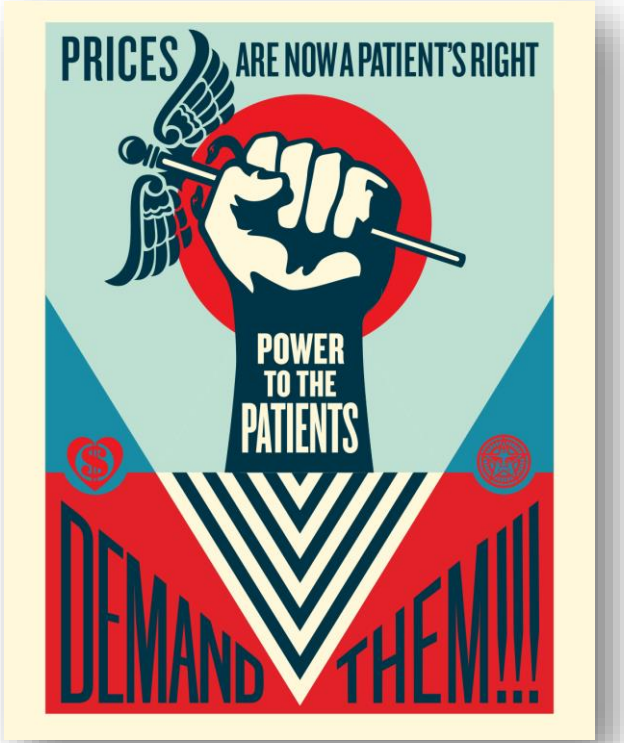
CMS Hospital Price Transparency Rule & Enforcement

- Starting Jan. 2021, CMS required hospitals to post a full list of services and prices as well as a patient-friendly tool to help shop for 300 common services

- Published prices must include:
  1. The chargemaster price
  2. Price for cash paying customers
  3. De-identified minimum and maximum negotiated prices
  4. Payer-specific negotiated charges (every payer)

- JAMA study: Less than 6% of hospitals were compliant with all components of the CMS rule
  - Why? Penalty just $300/day for non-compliance

- 18 months later and no enforcement… until yesterday
  - Northside Hospital Atlanta ($880,000)
  - Northside Hospital Cherokee ($214,000)



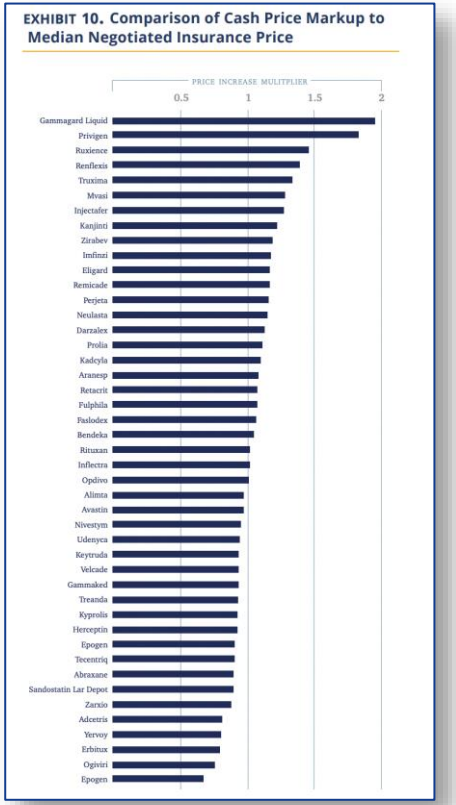
340Big: A Broken Drug Pricing Program Program

- Our position: 340B is a CRITICAL safety net program, especially for patients at some true safety net hospitals, grantees and disease specific clinics.
- But program has grown dramatically, from handful of safety net providers to 50%+ of all U.S. hospitals – and is being taken over by PBM contract pharmacies.
- 340B drug purchases at list prices reached $94 billion in 2021, 16% higher than in 2020. (14% of the U.S. pharmaceutical market's gross sales.)
- It is estimated that that **by 2026 340B be the largest federal drug program, surpassing both Medicare B, D and Medicaid.**

The explosive growth of 340B is unsustainable!

Sources: *Berkeley Research Group, Drug Channels, Masia/Columbia University & SSR Health, Berkeley Research Group)*

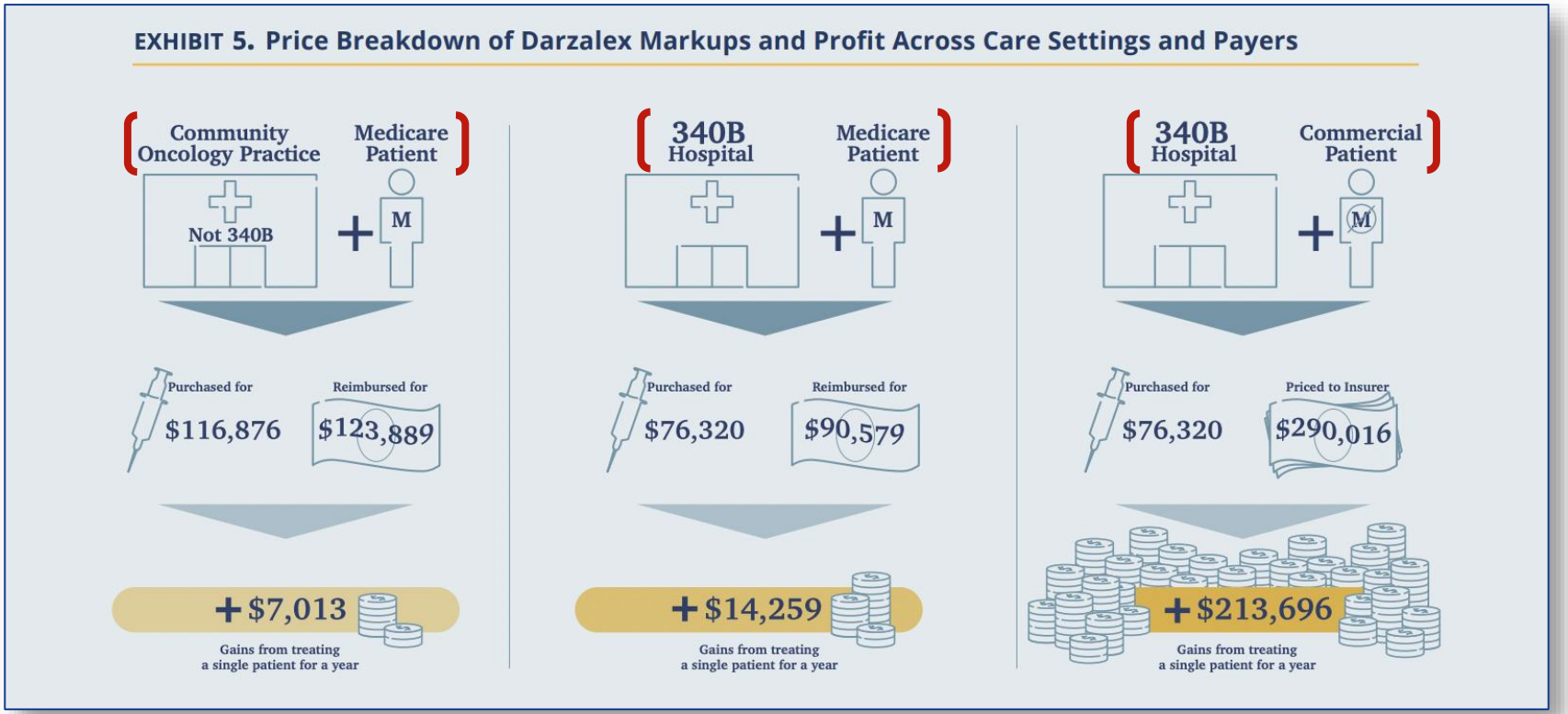
Examining 340B Hospital Drug Markups & Who Benefits?



"340B hospitals charge virtually the same median price for cash paying or uninsured patients as they do for insurers"

Source: Moto Bioadvisors

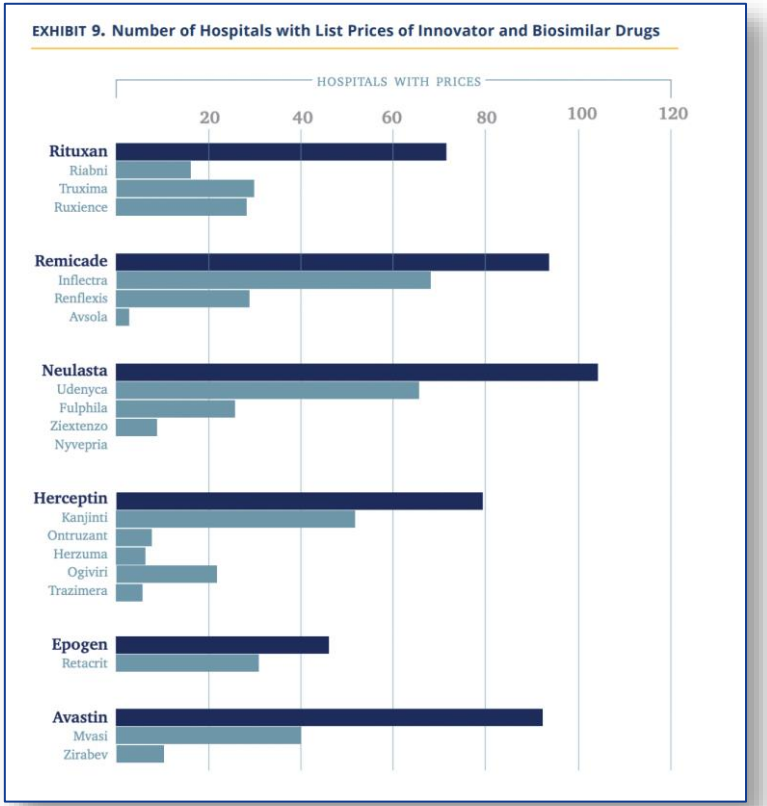
Example of 340B Profitability & Markups: Darzalex



Source: Moto Bioadvisors

340B Hospitals Using Less Biosimilars

25-56% of hospitals studied only list prices for innovator drugs, not biosimilars.



Source: Moto Bioadvisors

Will There Be 340B Reform in Washington?

- 340B is fundamentally broken and needs:
  - Transparency
  - Accountability

- COA's draft Follow-the-Patient Bill
  - Establish a patient assistance fund that all DHS hospital discounts go directly into
  - Does not impact grantees, other hospital types
  - Fund used to reduce patient cost-sharing for patients with incomes <400% FPL
  - Follow-the-patient model supports patients regardless of setting

- What appetite is there for Congress to tackle out-of-control 340B problem?

Note: Hospital Markups Endanger All Part B Providers

"Specialty pharmacies lower a patient's health care costs **by preventing hospitals and physicians from charging exorbitant fees to buy and store specialty medicines themselves."**

Americas Health Insurance Plans (AHIP)

Hospital Price Hikes:
Markups for Drugs Cost Patients Thousands of Dollars

Everyone should be able to get the medications they need at a cost they can afford. But drug prices are out of control, and hardworking families feel the consequences every day. Health insurance providers have developed innovative solutions to make prescription drugs more affordable, including leveraging lower-cost specialty pharmacies to safely distribute physician-administered drugs (sometimes called "white bagging" or "brown bagging"). These solutions help reduce Americans' out-of-pocket costs and what they pay in premiums – making health care more affordable and accessible for everyone.

Figure 1. Average Markups for Drugs in Hospitals and Physician Offices Over Pharmacies (2018-2020)

Note: Drugs with the highest total spend in 2019, which are also commonly delivered through specialty pharmacies. The drug cost estimate in physician offices and hospitals does not include the cost of administering the drugs

FEBRUARY 2022

$7,000

Costs per single treatment for drugs administered in hospitals (2018-2020) were an average of $7,000 more than those purchased through pharmacies. Drugs administered in physician offices were an average of $1,400 higher.

108%

Hospitals, on average, charged double (108%) the prices for the same drugs, compared to pharmacies. [illegible] offices [illegible] higher [illegible] the same drugs, on average.

Specialty pharmacies lower a patient's health care costs **by preventing hospitals and physicians from charging exorbitant fees to buy and store specialty medicines themselves.** Secure, direct delivery is more efficient and effective and reduces health care costs.

AHIP
Guiding Greater Health

Source: AHIP

What is a “PBM” anyway? Let’s look at CVS

Retail Store

Medical Clinic (Minute Clinic)

What Else?

Insurer (Aetna)

PBM (CVS Caremark & Zinc)

Specialty Pharmacy (CVS Specialty)

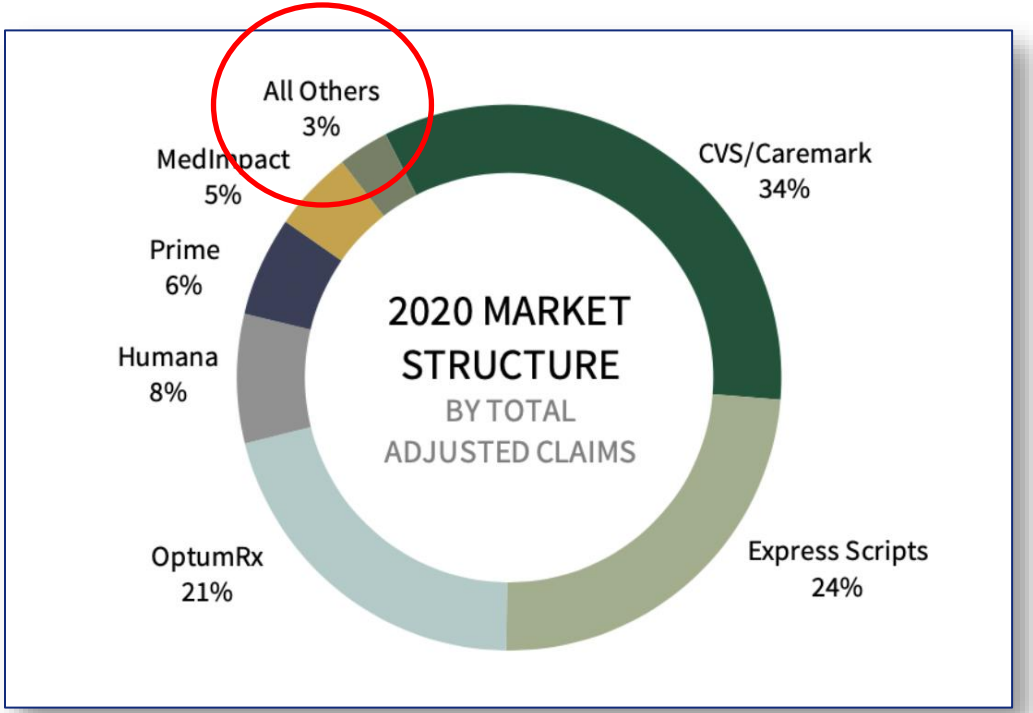
Vertical Business Relationships Among Insurers, PBMs, Specialty Pharmacies, and Providers, 2021

1. Cigna partners with providers via its Cigna Collaborative Care program. However, Cigna does not directly own healthcare providers.
2. AllianceRx Walgreens Prime is jointly owned by Prime Therapeutics and Walgreens Boots Alliance.
3. Since 2020, Prime sources formulary rebates via Ascent Health Services. In 2021, Humana began sourcing formulary rebates via Ascent Health Services for its commercial plans.

Source: Drug Channels Institute research; Companies are listed alphabetically by insurer name.

This chart appears as Exhibit 210 in *The 2021 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*. Available at http://drugch.nl/pharmacy

PBM Market is Incredibly Consolidated

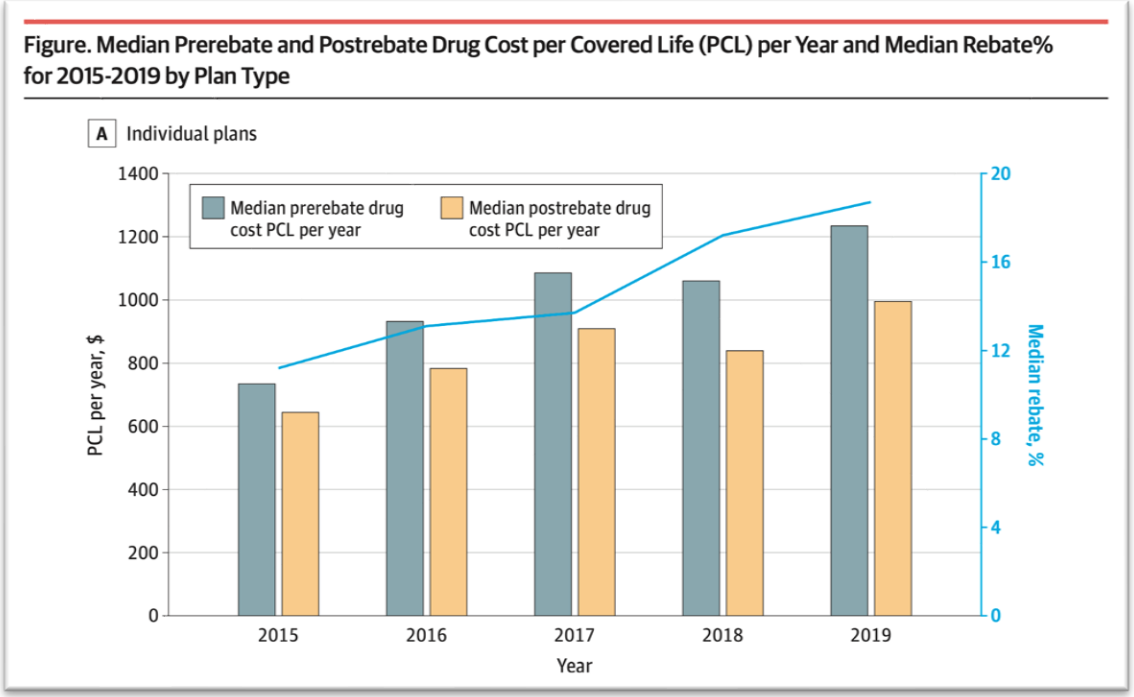


Three companies dominate with control of 79% of market:

1. CVS Health (including Caremark and Aetna)
2. Express Scripts business of Cigna
3. OptumRx business of UnitedHealth Group

Source: Health Industries Research

PBM Rebates Not Getting to Patients in Need

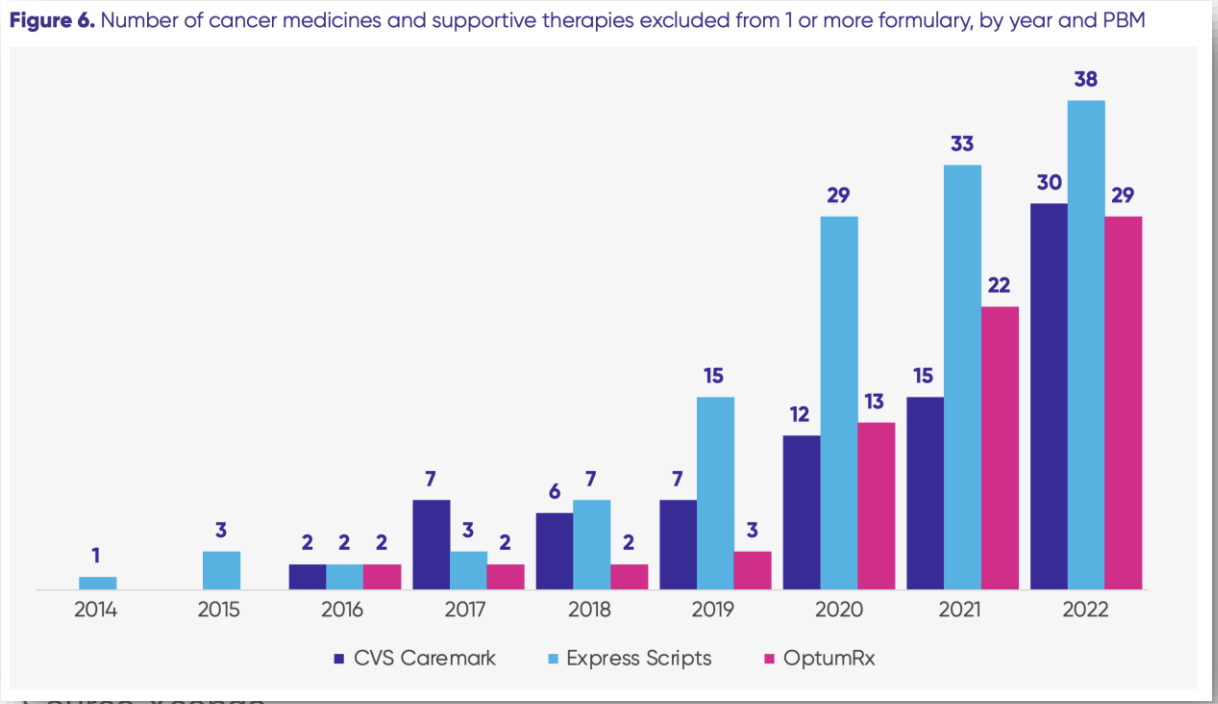


Rebates from drugmakers to commercial health plans are increasing faster than list prices.

Sick patients paying more for drugs based on inflated list prices, while rebates go back to the plan to reduce premiums for the healthy.

Source: JAMA Health Forum

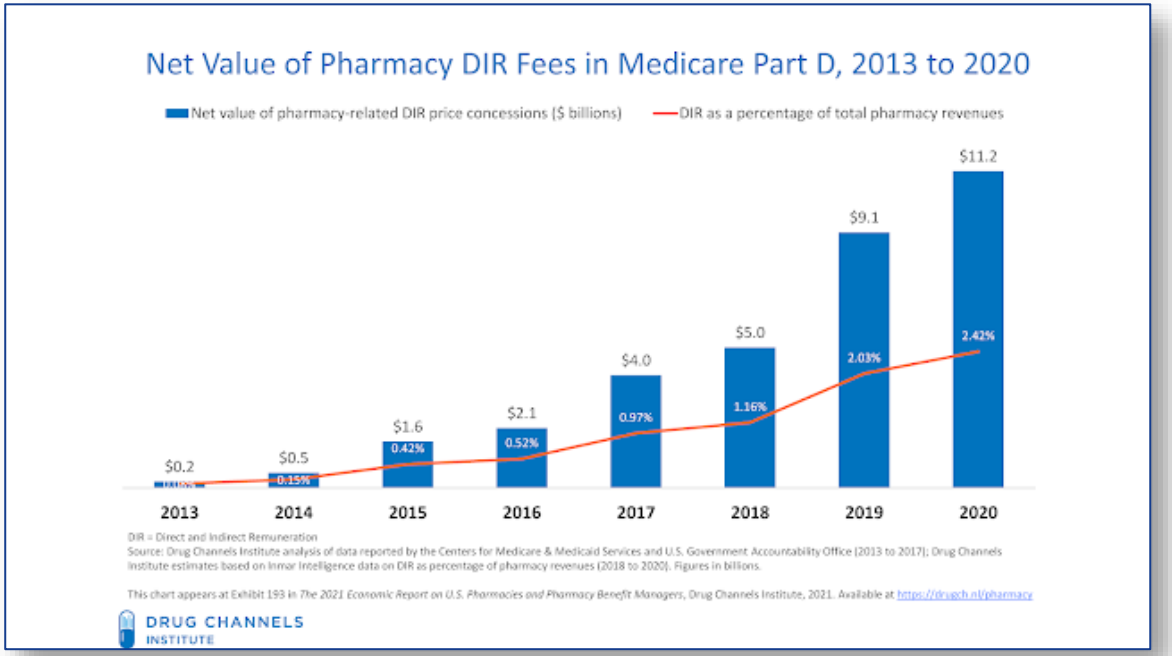
PBM Formulary Exclusion Lists Growing



Source Xcenda

- Formulary exclusions used by PBMs to negotiate with manufacturers.
- Dramatic growth in formulary exclusions.
- Specialty exclusions (incl. oncology) are routine.
- Biosimilar exclusions slowing down cost saving efforts.

PBM DIR Fees Are Exploding



- DIR stands for "Direct and Indirect Remuneration"
  - Fees charged to pharmacies based on performance on "quality" measures.
  - Unpredictable, non-negotiable, and often "clawed back" 6+ months after prescription dispensed.
- In oncology often based on irrelevant "quality" metrics.
- Patients pay inflated list price cost at counter.

PBM DIR Fees Are Exploding

TABLE 2: PHARMACY PRICE CONCESSIONS BY YEAR (2010–2020)

Contract Year	Total Pharmacy Price Concessions	% Change
2010	$ 8,869,347	–
2011	$8,582,354	-3.2%
2012	$68,086,163	693.3%
2013	$228,573,206	235.7%
2014	$538,421,239	135.6%
2015	$1,719,179,214	219.3%
2016	$2,125,460,000	23.6%
2017	$ 4,001,741,355	88.3%
2018	$6,339,517,817	58.4%
2019	$8,130,024,785	28.2%
2020	$9,535,197,775	17.3%

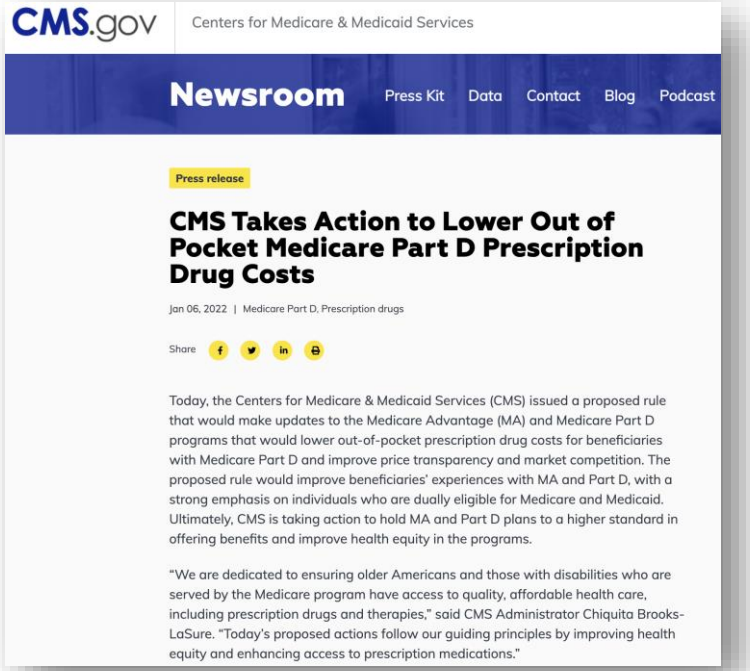
Source: Summary Direct and Indirect Remuneration Report Data, 2010–2020.

CMS: DIR fees have **exploded by 107,400 percent between 2010 and 2020.**

A dramatic increase from the 45,000 percent growth that CMS reported between 2010 and 2017.

CMS Rule to "Fix" PBM DIR Fees… Starting in 2024

- CMS rule to fix retroactive DIR fees
  - Move all pharmacy price concessions, including retroactive DIR fees, to the point-of-sale to benefit patients.
  - Estimates it would reduce seniors and people with disabilities' out-of-pocket expenses by $21.3 billion over 10 years.
- Passed **but**… pushed back to 2024!
- Good first step, **but**… PBMs will just shift profit making strategies to other areas
  - E.g. the new ESI contract AWP – 26.3%, and will collect $0.75 bonus fee on every claim



CMS.gov Centers for Medicare & Medicaid Services

Newsroom Press Kit Data Contact Blog Podcast

Press release

CMS Takes Action to Lower Out of Pocket Medicare Part D Prescription Drug Costs

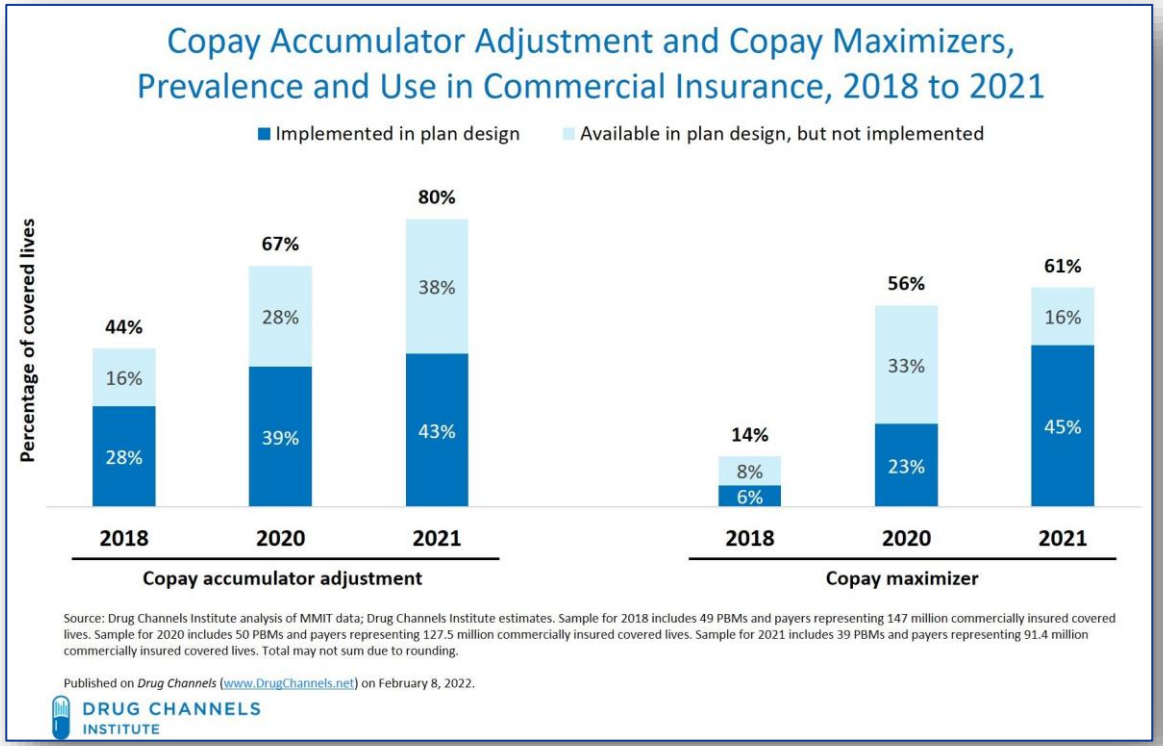
Jan 06, 2022 | Medicare Part D, Prescription drugs

Share

Today, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule that would make updates to the Medicare Advantage (MA) and Medicare Part D programs that would lower out-of-pocket prescription drug costs for beneficiaries with Medicare Part D and improve price transparency and market competition. The proposed rule would improve beneficiaries' experiences with MA and Part D, with a strong emphasis on individuals who are dually eligible for Medicare and Medicaid. Ultimately, CMS is taking action to hold MA and Part D plans to a higher standard in offering benefits and improve health equity in the programs.

"We are dedicated to ensuring older Americans and those with disabilities who are served by the Medicare program have access to quality, affordable health care, including prescription drugs and therapies," said CMS Administrator Chiquita Brooks-LaSure. "Today's proposed actions follow our guiding principles by improving health equity and enhancing access to prescription medications."

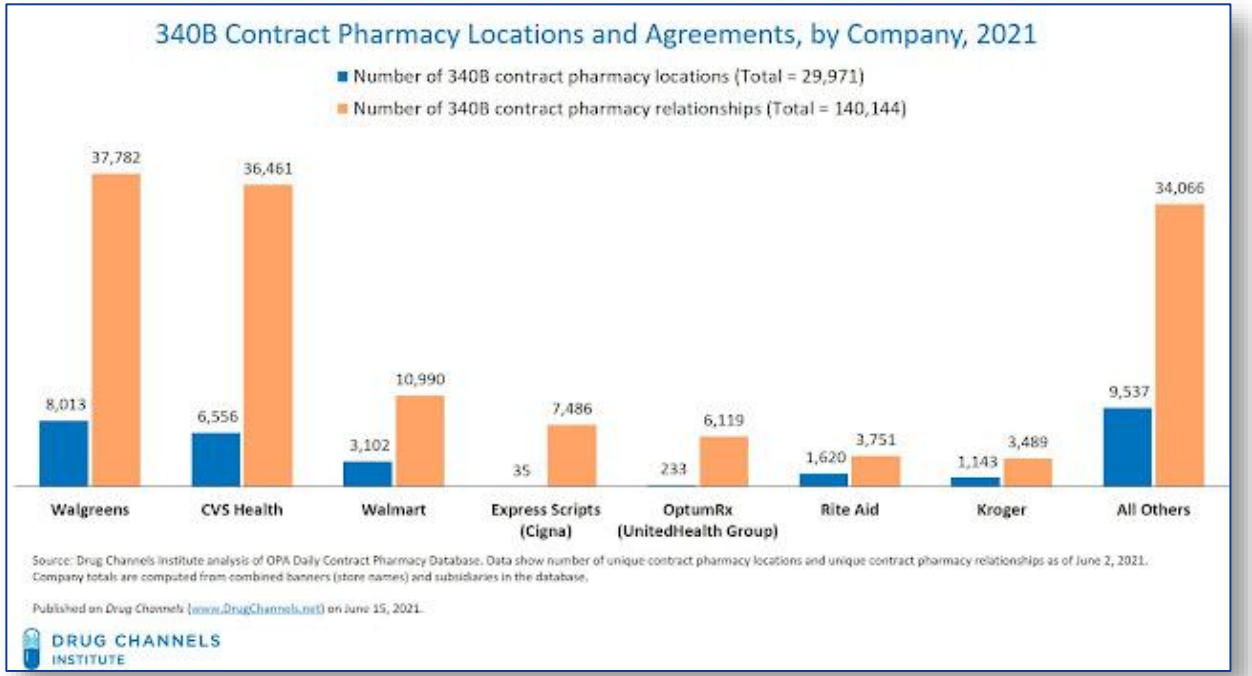
PBM Use of Copay Accumulators & Maximizers Exploding



Estimate of covered lives in commercial plans impacted by copay accumulators and maximizers:

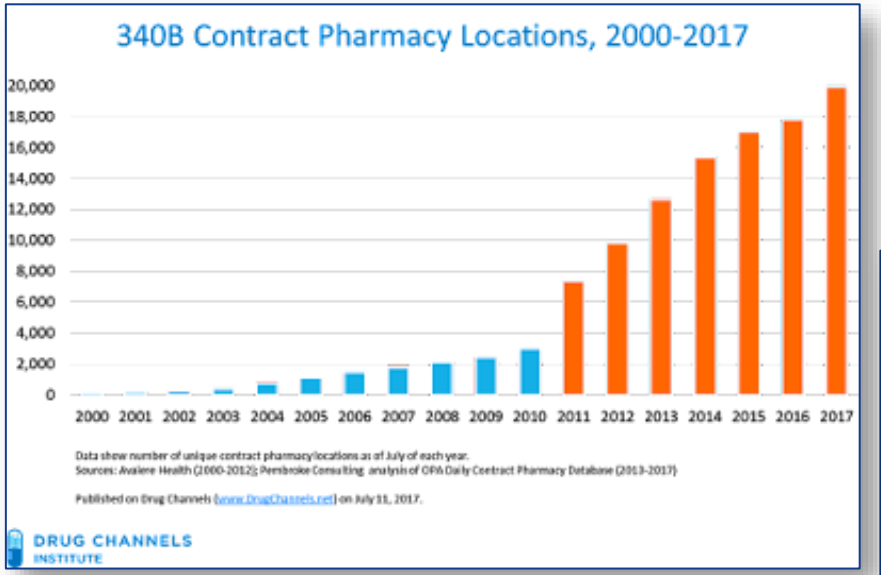
- 43% of are in plans that have implemented accumulators
- 45% are in plans that have implemented maximizers.

PBMs Have Discovered the 340B Program



Top 3 PBM <u>non-retail</u> pharmacies now account for 18% of 340B pharmacy relationships.

340B Program & Growth of PBM Contract Pharmacies



Source: Drug Channels

340B Very Lucrative to PBMs & Corporate Pharmacies

340B Drug Pricing Program – The 340B Drug Pricing Program allows eligible Covered Entities to purchase prescription drugs from manufacturers at a steep discount, and is overseen by the HHS and the Health Resources and Services Administration ("HRSA"). In 2020, a number of pharmaceutical manufacturers began programs that limited Covered Entities' participation in the program through contract pharmacies arrangements. In May 2021, HRSA sent enforcement letters to

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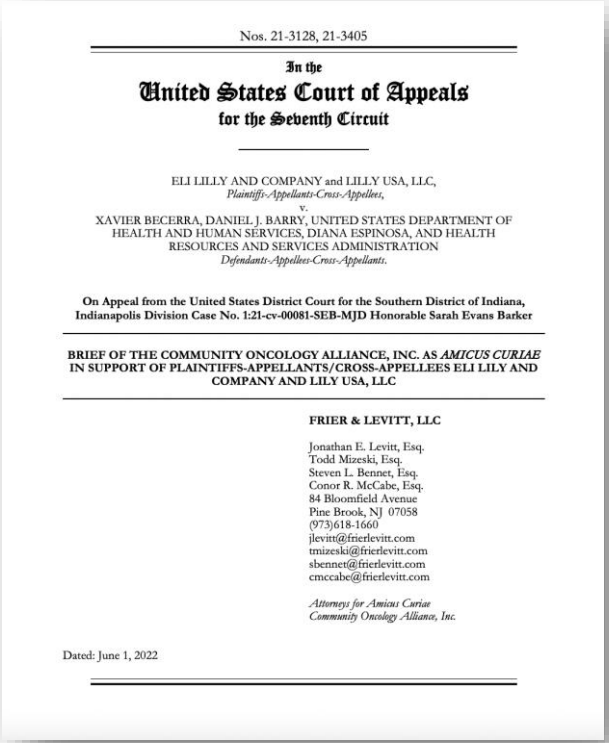
multiple manufacturers to curb these practices. In September 2021, HRSA forwarded the enforcement actions to the OIG for potential imposition of civil monetary penalties. Those enforcement actions are currently subject to ongoing litigation. A reduction in Covered Entities' participation in contract pharmacy arrangements, as a result of the pending enforcement actions or otherwise, a reduction in the use of the Company's administrative services by Covered Entities, or a reduction in drug manufacturers' participation in the program could materially and adversely affect the Company.

Source: 2021 CVS Health 10K

COA Amicus Brief on PBM 340B Contract Pharmacies

- The explosion in 340B contract pharmacy arrangements with for-profit PBMs has fundamentally mutated the program.
- Billions of dollars in 340B discounts are retained by PBMs as profits, not passed on to patients in need.
- Collectively, the leading PBM-owned or affiliated contract pharmacies are conservatively estimated to retain upwards of $2.58 billion in 340B discounts in 2022.
- PBM contract pharmacy arrangements are fueling the broader PBM takeover of the pharmaceutical system – harming patients through higher drug costs and barriers to accessible, affordable health care.



Nos. 21-3128, 21-3405

In the

United States Court of Appeals

for the Seventh Circuit

ELI LILLY AND COMPANY and LILLY USA, LLC,
Plaintiffs-Appellants-Cross-Appellees,
v.
XAVIER BECERRA, DANIEL J. BARRY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIANA ESPINOSA, AND HEALTH RESOURCES AND SERVICES ADMINISTRATION
Defendants-Appellees-Cross-Appellants.

On Appeal from the United States District Court for the Southern District of Indiana, Indianapolis Division Case No. 1:21-cv-00081-SEB-MJD Honorable Sarah Evans Barker

BRIEF OF THE COMMUNITY ONCOLOGY ALLIANCE, INC. AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFFS-APPELLANTS/CROSS-APPELLEES ELI LILY AND COMPANY AND LILY USA, LLC

FRIER & LEVITT, LLC

Jonathan E. Levitt, Esq.
Todd Mizeski, Esq.
Steven L. Bennet, Esq.
Conor R. McCabe, Esq.
84 Bloomfield Avenue
Pine Brook, NJ 07058
(973)618-1660
jlevitt@frierlevitt.com
tmizeski@frierlevitt.com
sbennet@frierlevitt.com
cmccabe@frierlevitt.com

Attorneys for Amicus Curiae Community Oncology Alliance, Inc.

Dated: June 1, 2022

Pressure is Growing on PBMs in Washington and Beyond

- Congressional bills
  - Grassley & Cantwell bill
  - TACT Act (72-hour bill)
  - Eliminating retroactive DIR fees bill (Tester)
  - DIR Quality Measures bill
- Agency action
  - CMS rule on DIR Fees
  - FTC action – Investigation and RFI
- COA focused on PBMs
  - Horror stories series and PBM abuses campaign
  - Testified before House Oversight & Reform Committee hearing/forum on PBMs (next week!)
  - Major expose paper from Frier Levitt
  - Working at the State Level on PBMs

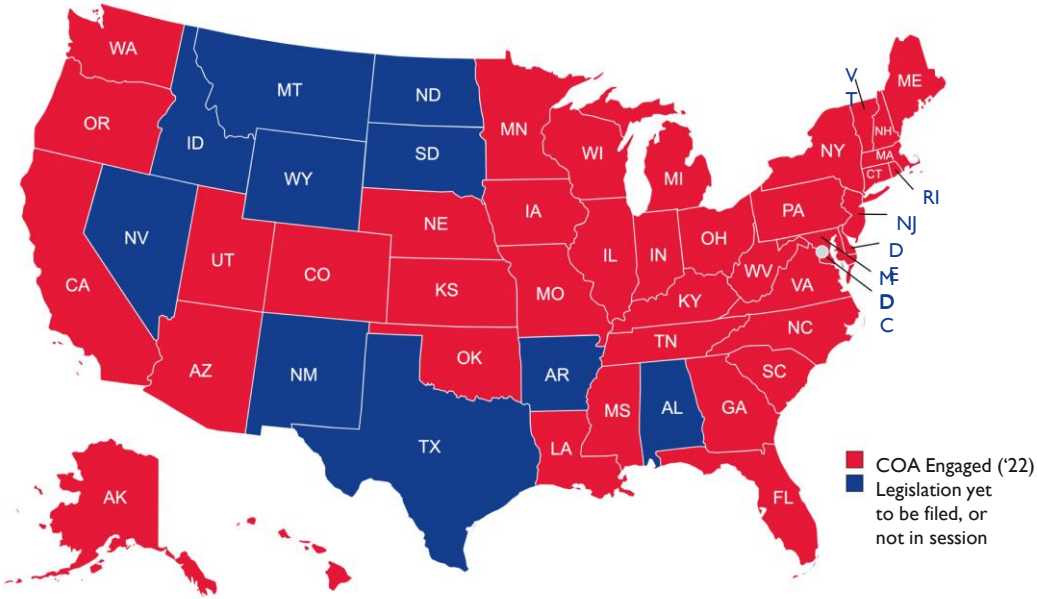
Breaking news: FTC Vote to Study PBMs!

- FTC unanimously voted to study pharmacy benefit managers.
- Sent subpoenas for info to CVS Caremark; Express Scripts.; OptumRx.; Humana; Prime Therapeutics; and MedImpact.
- The FTC study will look at PBMs fees/clawbacks, rebates, use of prior authorizations and other administrative restrictions, as well as the use of specialty drug lists and surrounding specialty drug policies.

Increasing Action at State Level

- COA's state team is monitoring 350+ bills in the 2022 legislative cycle.
  - State team has followed 60 hearings and participated in 20 legislative engagements across all states.
  - Activity in 20 states including AZ, CA, CT, FL, GA, IL, KY, MD, ME, MI, MO, OH, NC, NJ, SC, TN, TX, VA, WA, WV.

- State legislative agenda priorities:
  - DIR Fees
  - PBM licensure
  - Prior Authorization
  - Step therapy
  - White bagging/brown bagging
  - Copay accumulators and maximizers



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   - COA has a legislative fixes to most destructive proposals.
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   - Pushing back on prior authorizations, step therapy, and white/brown bagging.
   - Fostering more state legislation and tie back to federal initiatives.

What Can *You* Do? Help Pop the DC Bubble!

Participate, participate, participate

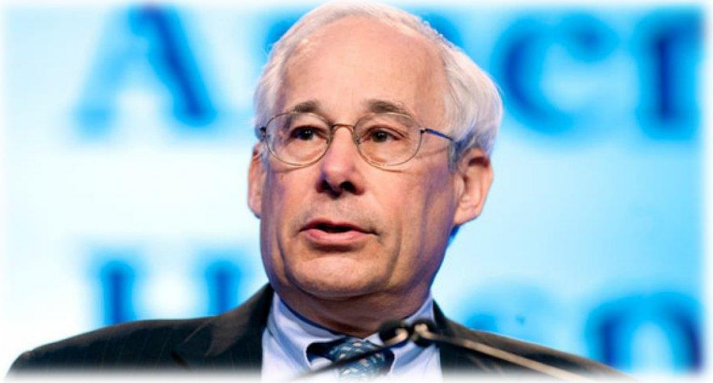
1. Hill Day's and visits
2. Submit comments on proposals
3. Contact your elected officials
4. Engage with our state team

Stay in touch with COA

- Latest papers, comment letters, alerts
- Subscribe to our emails and newsletter
- Create a MyCOA account

Join COA's FREE professional networks

- COA Administrators' Network (CAN)
- Community Oncology Pharmacy Association (COPA)
- COA Patient Advocacy Network (CPAN)



It is chilling to see the great institutions of health care, hospitals, physician groups, and scientific bodies assume that the seat of a bystander is available. That seat is gone. To try to avoid the "political fray" through silence is impossible, because silence is now political. Either engage, or assist the harm. There is no third choice.

Donald M. Berwick, MD, MPP
Moral Choices for Today's Physician – JAMA 2017

DONATE NOW

Humanitarian Aid for Ukraine

The **Community Oncology Alliance** has made it easier than ever to show your support for the people of Ukraine. Refugees fleeing the ongoing fighting need food, shelter, and medical aid, including cancer care. We have vetted four organizations that are providing these items and services to Ukrainian refugees.

The Organizations

Americares

Direct Relief

Doctors Without Borders

International Medical Corps

How It Works

Scan the QR code or visit the URL:

communityoncology.org/coa-cares-humanitarian-aid-committee

Then, select the organization of your choice and follow the instructions on screen. It's that easy.

Every donation, no matter how big or small, can help provide medical care and critical care to those in need. **Please donate today.**


2023 COMMUNITY ONCOLOGY CONFERENCE
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THE DATE
MARCH 23–24, 2023
GAYLORD PALMS Kissimmee, FL
COMMUNITY ONCOLOGY ALLIANCE
COA
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Thank you and stay in touch!

Nicolas Ferreyros
Managing Director
Policy, Advocacy, Communications
Community Oncology Alliance

Email: nferreyros@COAcancer.org
Phone: (713) 377-0689