# From DC to PR: Updates on Cancer Care Issues in the USA

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*Managing Director*
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13th Annual Puerto Rico Oncology Symposium
February 3, 2024

# About the Community Oncology Alliance (COA): Who We Are and What We Do

- A non-profit dedicated to advocating for independent, community oncology practices and patients.
  - The majority of Americans with cancer are treated in independent, community oncology practices.
- What COA does:
  - Public policy advocacy and engagement
  - Patient and professional empowerment
  - Practice support, networking and community building
  - Research and education
  - Payment and delivery system transformation
- Peer-to-peer support networks and initiatives:
  - Practice leadership teams and administrators (COA Administrators' Network, CAN)
  - Pharmacy teams (Community Oncology Pharmacy Association, COPA)
  - Patients, caregivers, survivors, and advocates (COA Patient Advocacy Network, CPAN)

# COA’s Overall 2024 Policy & Advocacy Priorities

1. Ensuring Sustainable Payments and Reimbursement
2. Pharmacy Benefit Manager (PBM) Reform
3. Addressing Anti-Competitive Hospital Policies and Regulation
4. Provider Wellness and Workforce Issues
5. Prior Authorization and Utilization Management Reform to Protect Patients
6. Finding Permanent Solution to Cancer Drug Shortages
7. Supporting System Transformation and New Payment Models
8. Improving Cancer Health Equity

# Active Policy and Legislative Issues in DC on COA's Radar

Community oncology practice payment/reimbursement

Inflation Reduction Act (IRA) drug negotiation technical fix

Cancer drug shortages

"Non-profit" hospitals and 340B program

Pharmacy Benefit Manager (PBM) reform and abuses

CMS prohibiting practices from delivering cancer drugs to patients

# Political Reality: It's A Mess in Washington

- Democrats control the White House and the Senate (barely)
  - Have to work with (some) Republicans to get legislation passed
- Republicans control the House (barely)
  - Have to work with (some) Democrats to get legislation passed
- A wild year behind, and a wild year ahead
  - Government still does not have long term funding in place for 2024
    - Currently in our 3rd short term funding bill because they can't work together
  - It's an Election Season!
    - Presidential election as well as 468 seats in the Congress (33 Senate seats and all 435 House seats) are up for regular election
    - Retirement of many provider champions – Reps. Burgess, Wenstrup, Bucshon, Eschoo; Sens. Braun and Romney

# Politicians Love to Focus on Health Care and Drug Costs, Particularly in Election Years

- Drug “prices” are the biggest health care issue in Washington
  - Every elected official in the U.S. has promised to reduce the cost of drugs
- Big Pharma is punching bag for politicians – particularly with passage of Medicare drug price negotiations
  - Sen. Bernie Sanders HELP Committee hearing on high drug prices next week with CEOs of BMS, J&J, Merck
- IRA has allowed politicians to focus attention on pharmacy benefit managers (PBMs), hospitals, and insurers

# The Health Care World We Live In:
# Extreme Vertical Integration and Consolidation

## Vertical Business Relationships Among Insurers, PBMs, Specialty Pharmacies, and Providers, 2023

| | BlueCross BlueShield (private) | CENTENE Corporation (NYSE: CNC) | THE CIGNA GROUP (NYSE: CI) | CVSHealth (NYSE: CVS) | Elevance Health (NYSE: ELV) | Humana (NYSE: HUM) | UNITEDHEALTH GROUP (NYSE: UNH) |
|---|---|---|---|---|---|---|---|
| Insurer | BlueCross BlueShield | Medicaid, wellcare, ambetter | cigna healthcare | aetna | Anthem | Humana | UnitedHealthcare |
| PBM (GPO) | PRIME THERAPEUTICS | envolve Pharmacy Solutions [2] | EXPRESS SCRIPTS; Ascent [4] | CVS caremark; Zinc | carelon Rx [9] | Humana Pharmacy Solutions | OPTUM Rx; EMISAR |
| Specialty Pharmacy | allianceRx Walgreens Pharmacy [1]; accredo | AcariaHealth Specialty Pharmacy | accredo; FREEDOM FERTILITY PHARMACY | CVS specialty | CVS specialty; BioPlus Specialty Pharmacy | CenterWell Specialty Pharmacy | OPTUM Specialty Pharmacy |
| Provider Services | | USMM [3] U.S. Medical Management; Community Medical Group | EVERNORTH HEALTH SERVICES [5]; alegis care; MDLIVE [6]; VillageMD [7] | CVS minute clinic; Health HUB; Oak St Health [8]; signifyhealth [8] | CareMore HEALTH; Aspire Health | CONVIVA Care Center; CenterWell Senior Primary Care [10]; CenterWell Home Health [11] | OPTUM Care |

1. Since 2021, Prime's Blue Cross and Blue Shield plans have had the option to use Express Scripts or AllianceRx Walgreens Pharmacy for mail/specialty pharmacy services. IN Dec. 2021, Walgreens purchased Prime Therapeutics' 45% ownership interest, so this business had no PBM ownership as of 2022. Effective June 2022, the company was rebranded as AllianceRx Walgreens Pharmacy.
2. Centene has announced that it would outsource its PBM operations to Express Scripts in 2024. In 2023, Centene rebranded its pharmacy benefit subsidiary as Centene Pharmacy Sevrices.
3. In 2021, Centene sold a majority stake in its U.S. Medical Management to a group of private equity firms.
4. Since 2020, Prime has sourced formulary rebates via Ascent Health Services. In 2021, Humana began sourcing formulary rebates via Ascent Health Services for its commercial plans.
5. Previously known as Evernorth Care Group and Cigna Medical Group.
6. In 2021, Cigna's Evernorth business acquired MDLive.
7. In 2022, Cigna invested $2.7 billion for an estimated 14% ownership stake in VillageMD. Walgreens owns a majority of VillageMD.
8. In September 2022, CVS Health announced its acquisition of Signify Health. In February 2023, CVS announced its acquisition of Oak Street Health. Both transactions closed in 2023.
9. Previously known as IngenioRx.
10. In 2021, Partners in Primary Care and Family Physicians Group businesses were rebranded as Centerwell Senior Primary Care.
11. In 2022, Kindred at Home was rebranded as CenterWell Home Health. In 2022, Humana announced an agreement to divest its majority interest in Kindred at Home's Hospice and Personal Care Divisions to Clayton, Dubilier & Rice. Humana also announced plans to close a majority of its SeniorBridge home care locations.

Source: *The 2023 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Exhibit 234. Companies are listed alphabetically by corporate name.

DRUG CHANNELS INSTITUTE

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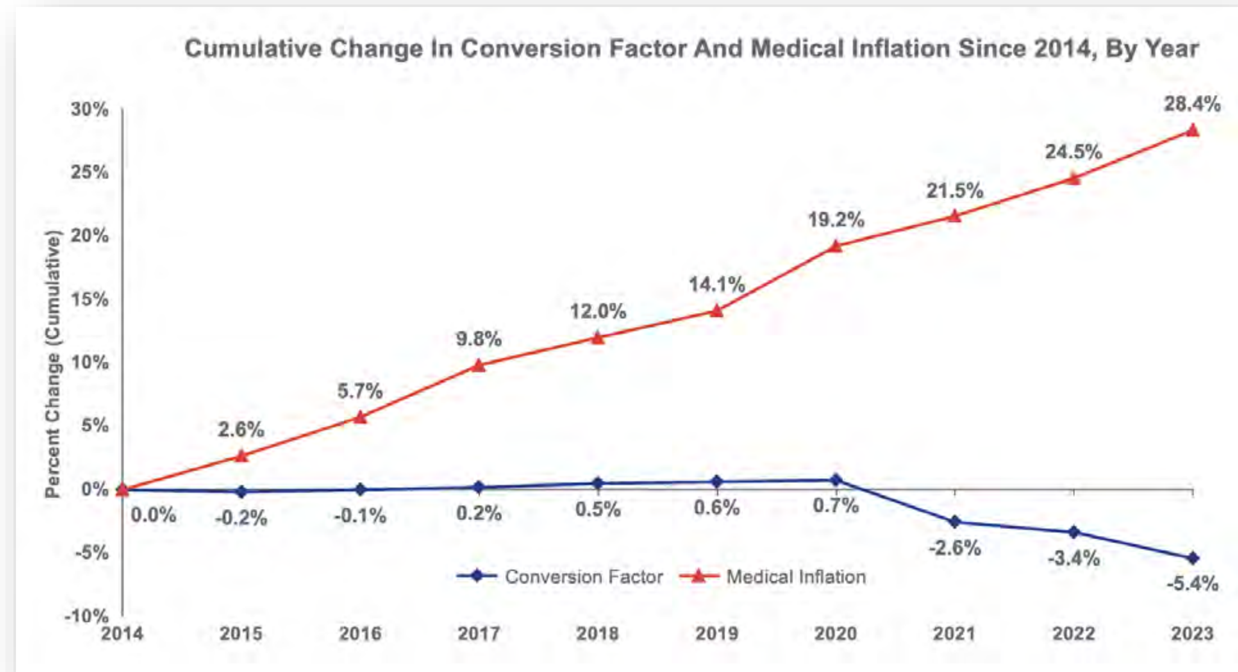
May 2023

# Medicare Payment and Reimbursement to Physicians Has Declined for 10 Years

- Payment by Medicare for cancer care services at independent practices has *decreased* over the last decade (2014-2023)
  - Medicare reimbursement (conversion factor) decreased 5.4%.
  - Compounded medical inflation increase was 28.4%.
  - This year Medicare payments were increased for all providers in 2023 EXCEPT physicians.
- Congressional fixes being considered
  - H.R. 6683: Preserving Senior's Access to Physicians Act
  - Better Mental Health, Lower-Cost Drugs and Extenders Act
- Real fix – increasing physician reimbursement – is expensive so tricky in era of tough Congressional budget negotiations



# Inflation Reduction Act (IRA): Medicare Drug Price Negotiations

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1 ness by reason of such requirements before final ac-
2 tion on such application.
3 **SEC. 138521. TERMINATION OF EMPLOYER CREDIT FOR**
4 **PAID FAMILY AND MEDICAL LEAVE.**
5 Section 45S(i) is amended by striking “December 31,
6 2025” and inserting “December 31, 2023”.
7 **Subtitle I—Drug Pricing**
8 **PART 1—LOWERING PRICES THROUGH DRUG**
9 **PRICE NEGOTIATION**
10 **SEC. 139001. PROVIDING FOR LOWER PRICES FOR CERTAIN**
11 **HIGH-PRICED SINGLE SOURCE DRUGS.**
12 (a) PROGRAM TO LOWER PRICES FOR CERTAIN
13 HIGH-PRICED SINGLE SOURCE DRUGS.—Title XI of the
14 Social Security Act is amended by adding after section
15 1184 (42 U.S.C. 1320e–3) the following new part:
16 **“PART E—PRICE NEGOTIATION PROGRAM TO**
17 **LOWER PRICES FOR CERTAIN HIGH-PRICED**
18 **SINGLE SOURCE DRUGS**
19 **“SEC. 1191. ESTABLISHMENT OF PROGRAM.**
20 “(a) IN GENERAL.—The Secretary shall establish a
21 Drug Price Negotiation Program (in this part referred to
22 as the ‘program’). Under the program, with respect to
23 each price applicability period, the Secretary shall—
24 “(1) publish a list of negotiation-eligible drugs
25 and selected drugs in accordance with section 1192;

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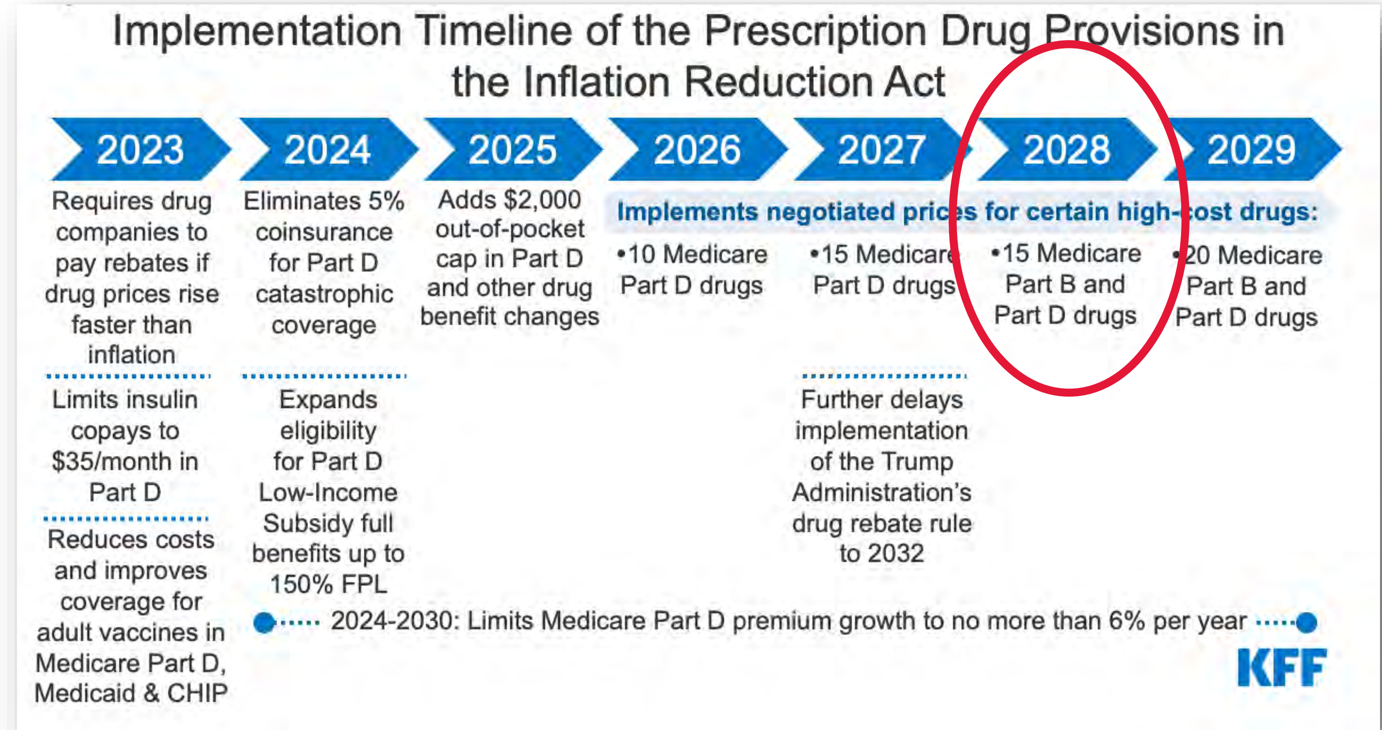
November 3, 2021 (12:14 p.m.)




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

# IRA Drug Negotiations Will Have Significant Negative Impact on Providers

- Current ASP will become MFP (Maximum Fair Price) negotiated
- Will result in minimum cut of 47% to Part B add-on payments (*Avalere analysis for COA*)
- Technical fix in Congress:
  - The Protecting Patient Access to Cancer and Complex Therapies Act
  - S. 2764, H.R. 5391

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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).

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# Additional Issues With IRA Drug Negotiations

- Negotiations won't *really* make an impact on for 3-4 years!
- Impact on drug development
  - Many cancer drugs receive post-approval indications – who will invest in that?
  - "Pill penalty" for small molecule drugs (only 9 years protection from negotiations) – shift development into higher-cost biologics
- Only impacts 60 million Medicare beneficiaries, not rest of insured
  - Beware spillover effects to commercial contracts
- Drug launch prices will likely increase to account for negotiations
  - Manufacturers will protect products that may end up facing "negotiations" and from inflation caps
- Doesn't stop hospitals, especially large 340B hospitals, from marking up prices to patients with commercial insurance or no insurance
  - The more Medicare reduces reimbursement the more hospitals will try make up for difference

# How IRA Drug Negotiations Might Play Out

- Where we are today
  - This week CMS sent initial offers for 10 Part D drugs selected for price negotiations
- A lot will happen before full (Part B and D) implementation in 2028
  - A lot can and will happen in the next four years
- CMS has no experience "negotiating" drug prices – steep learning curve
  - The wheels of government turn slowly, brain power moves around
- Politics, politics, politics
  - Republicans focus on dragging CMS/CMMI, Democrats celebrating negotiations
  - If 2024 elections leave Republican in charge it will absolutely impact negotiations
- Fate of IRA will likely be decided by the Courts
  - At least 7 lawsuits so far…
  - First ruling denied Chamber of Commerce effort for preliminary injunction
  - Likely to be decided by Supreme Court over constitutional issues

# Cancer Drug Shortages Crisis: Déjà Vu

- Cancer drug shortages remain a big and recurring problem in our health care system
  - Patient care being delayed or cancelled
  - COA has testified multiple times – and also 12 years ago!
- **Root cause: Broken financial and economics of the generic sterile injectable drug market**
  - Low reimbursement and increasing system discounts for generic sterile injectables = underinvestment and loss of manufacturing capacity
- Doesn't look like Washington has the will to *really* fix it
  - Politicians not willing to address economics, increase payments
    - Soft ideas like FDA reporting, more "studies", proposals for stockpiles
  - Senate Committee on Finance white paper last week
  - House Energy & Commerce legislative proposal ("discussion draft")
  - Ways & Means hearing next Tuesday, COA testifying

**Preventing and Mitigating Generic Drug Shortages: Policy Options Under Federal Health Programs**

Senate Committee on Finance

January 25, 2024

CNN health · Life, But Better · Fitness · Food · Sleep · Mindfulness · Relationships

**US cancer centers still see 'widespread' shortages of life-saving chemo drugs, survey finds**

By Jacqueline Howard, CNN
4 minute read · Published 9:00 AM EDT, Thu October 5, 2023

# Hospitals, “Non-Profit” Hospitals and 340B Scrutiny

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

LOCAL NEWS

## Virginia senator calls NYT investigation troubling: 'Bon Secours needs to have an answer'

TYLER LAYNE
MELISSA HIPOLIT

The New York Times investigation alleges Bon Secours is failing to use the savings to help underserved populations, putting new scrutiny on the program.

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

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“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.”

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.

# The State of the 340B Program: Key Statistics

**$54.6B** in discounted 340B program sales, which equates to **$126.3B** in gross sales

**169%** growth in 340B sales over last 5 years

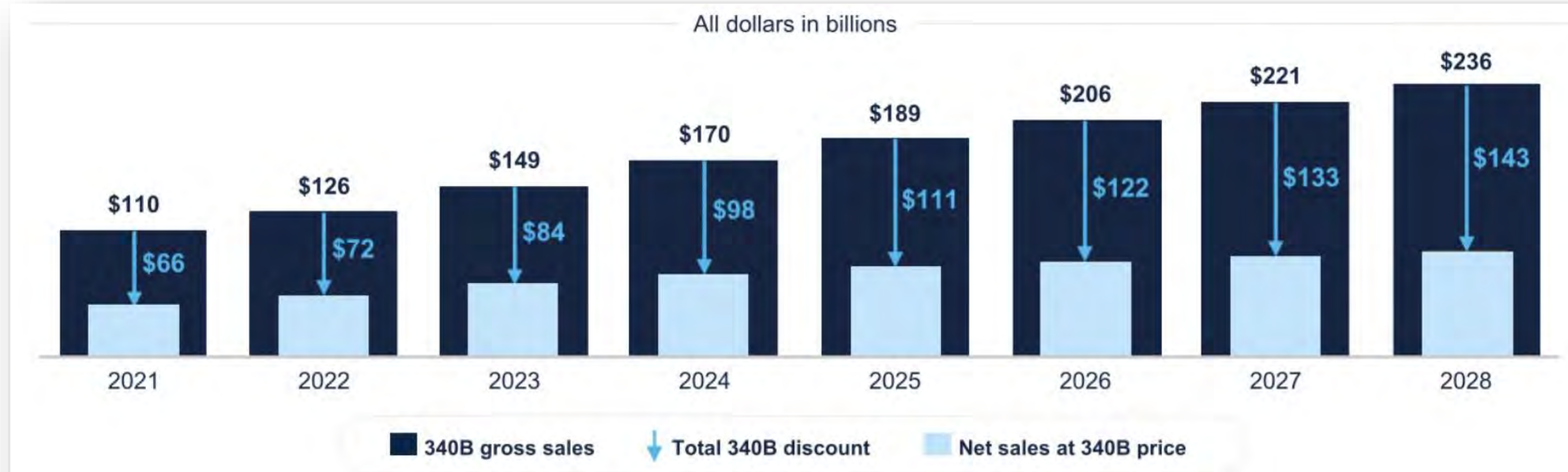
Contract pharmacies account for an estimated **10%** of 340B sales of physician-administered drugs

The average discount off list price for drugs purchased at 340B price in 2022 was **57%**

340B purchases represented **18%** of outpatient branded drug sales for 2022

Contract pharmacy arrangements grew by **153%** between 2018 and 2022

# The State of the 340B Program: Forecasts




**1 in 4**

brand drugs will be purchased at the 340B price in 2025

**340B could be the largest**

federal drug program by 2028, exceeding gross drug purchases through Medicare Part D, Medicare Part B, and Medicaid.

**1 in 5**

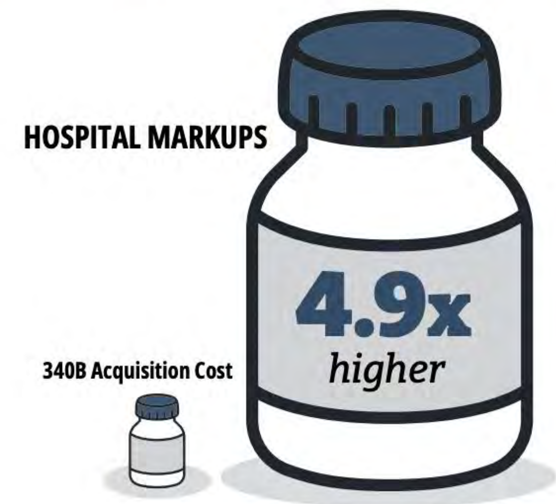
340B drug purchases will be dispensed by a contract pharmacy in 2024

**By 2027,** the average discount off list price for drugs purchased at the 340B price will exceed **60%**

# Why is 340B in Hospitals Controversial? Outrageous 340B Drug Markups

- 340B hospital make huge profits buying cancer drugs at discount, selling them with enormous markups to to patients.
  - Not required to pass on savings to patients (e.g., lower costs)
  - No serious free/charity care requirements or oversight!
- **COA study: median markup for drugs at 340B DSH hospitals was 4.9x their discounted 340B acquisition costs**
  - The lowest average markup was 3.2 times and the highest was 11.3 times.
- Wide variation in prices charged between 340B hospitals, and even between different payers/insurers within the same hospital.

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.



# Why is 340B in Hospitals Controversial? Outrageous 340B Drug Markups

*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** |

# What's Next for 340B and COA Focus

- Hospitals under scrutiny and 340B being examined like never before
- 340B has historically been a very partisan issue in Washington,
  - Democrats completely unwilling to examine it
- Some community clinics have distanced themselves from hospitals
  - ASAP 340B Coalition, and COA is a member
- Pharma has won one suit allowing companies to restrict sales to multiple contract pharmacies
  - COA filed two amicus briefs on PBM intrusion into 340B
- **Big news this week: Senate Discussion Draft**
  - Bipartisan discussion draft released on Thursday
  - COA providing input on legislation to create greater transparency/accountability in 340B hospitals

# Breaking News: Senate 340B Discussion Draft

- "Supporting Underserved and Strengthening Transparency, Accountability and Integrity Now and for the Future of 340B Act"
  - The SUSTAIN 340B Act
- Legislative discussion draft is a response to RFI Senators put out in 2023
  - Released yesterday, responses due April 1, 2024
- Bipartisan group of senior, serious Senators
- After years of effort, this is the biggest opportunity for 340B reform ever

***"We believe it is necessary to pass legislation in the 118th Congress that provides clarity, transparency, and accountability in the 340B program to ensure the program remains strong, long into the future."***

# What Are Pharmacy Benefit Managers (PBMs)?

PBMs are **large, often for-profit corporations** hired to as middlemen **manage prescription drug benefits** on behalf of health insurers, Medicare Part D drug plans, large employers, and other payers.

**Middlemen** | The role of pharmacy-benefit managers

Individuals pay premiums to their employer/plan sponsor or health insurer.

**Consumers**

Individuals cover their prescription-drug copay, or pay cash to the pharmacy.

**Pharmacy**

The pharmacy negotiates with the drug maker or a wholesaler for drug costs, as well as discounts and rebates based on the volume of drugs the pharmacy handles.

Pharmacy-benefit manager

The PBM negotiates with the pharmacy over reimbursement for drugs and dispensing fees.

The insurance company pays the PBM to manage its drug costs, and get rebates from manufacturers. (The PBM often retains a portion of the rebate.)

The PBM also negotiates prices with the manufacturer, which then pays rebates to the PBM for preferred placement on a plan's formulary.

**Insurance company**

**Manufacturer**

Source: Avalere Health LLC

# PBMs, PBMs, PBMs:
# Major PBM Problems COA Focused On

- Most people don't know about PBMs because they are middlemen, not always visible to patients.
  - Silently control what, when, and where patients access prescription drugs.
- PBMs impact on patients
  - Delaying and denying cancer patients from getting their drugs
  - Forced use of mail order pharmacy
  - Using "fail first" step therapy, prior auth, and other utilization management to ensure most profitable (to the PBM) drugs used
- PBMs impact on practices
  - Underwater reimbursement in post-DIR Fee world
  - Excluding pharmacies from PBM networks
  - Moving medical benefit drugs to pharmacy benefit

# COA Horror Story Series: Impact of PBM Abuses

Playing Games with Patient Lives:
**Pharmacy Benefit Manager Horror Stories – Part VIII**

Once hailed as a problem-solving initiative that would hasten the process of patients receiving their prescription authorizations and even help to lower patient cost, PBMs have in many cases become the problem themselves.

Today, PBMs often take on every role of a vertically integrated system, controlling every step between patient and insurance company, insurance company and pharmaceutical manufacturer, and even the insurance company and the pharmacy where patients can access their medication.

Today, PBMs often take on every role of a vertically integrated system, controlling every step between patient and insurance company, insurance company and pharmaceutical manufacturer, and even the insurance company and the pharmacy where patients can access their medication.

With PBMs having manipulated their way into a position where they can mandate that patients purchase their medication from a particular distributor – one that they own – it is no wonder that the three largest PBMs in the US are more profitable than some pharmaceutical companies.

monitor her condition, changing the line of treatment whenever the disease showed signs of progression. In June, a checkup revealed that the cancer had metastasized to Belinda's neck, upper abdomen, and liver. Time was critical, and her doctor immediately prescribed a common oral chemotherapy with instructions that the PBM-mandated specialty pharmacy deliver the medication directly to Belinda's home. It was a standard request, yet the medicine had not arrived three and a half weeks later.

Calling the specialty pharmacy, the oncology clinic's office manager learned that the prescription was still pending approval by Belinda's insurance company. Five days later, the pharmacy requested clarification of the pill dosage and quantity. The clinic complied and still

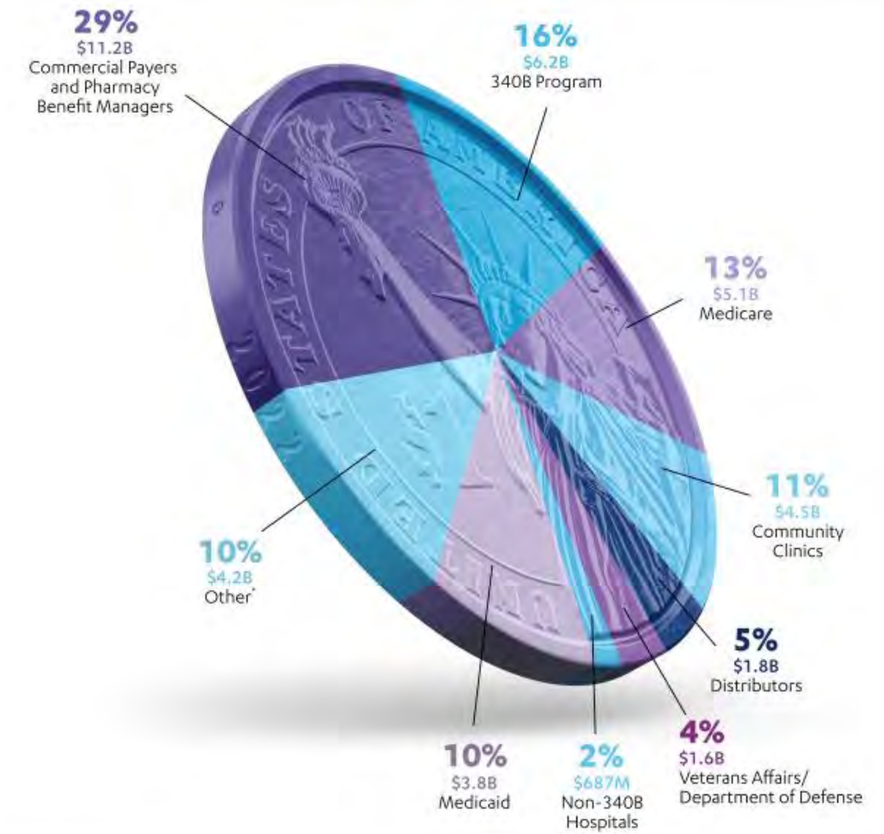
PBM Horror Stories Series | 1

COA has published 8 volume of PBM patient horror stories detailing specific, true cases where patient care delayed, denied, or worse.

https://mycoa.communityoncology.org/education-publications/pbm-horror-stories

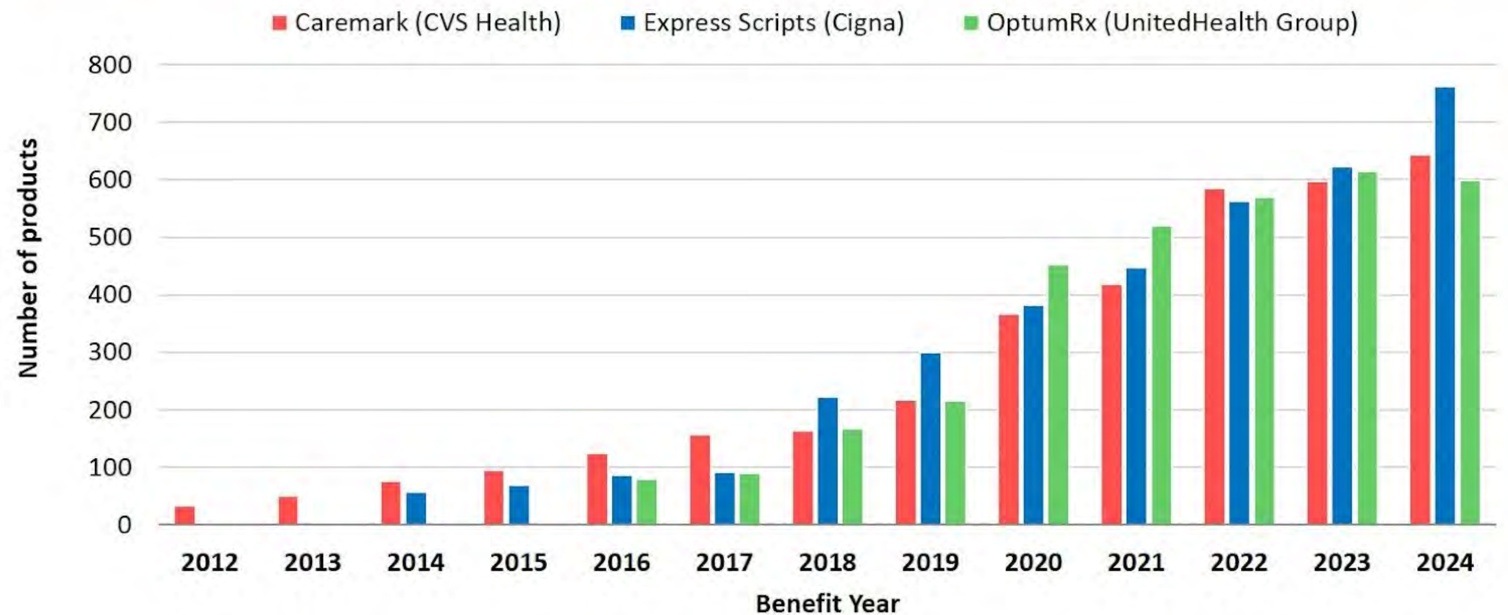
# Growing Scale of PBM Rebates & Discounts Drive Up Drug Prices

- Drug manufacturers account for PBM rebates and other discounts in setting drug list prices
  - At one manufacturer, 29% of the average drug dollar accounted for PBM rebates
- Excessive scope and magnitude of PBM rebates and other discounts are fueling drug list prices that patients pay
  - "List prices" are what employers and employees pay on!
  - Rebates are threatening the viability of the biosimilar market
- **There is no free lunch** – discounts and rebates are accounted for in drug prices



# PBM Formulary Exclusion Lists Growing

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



# Sea Change on PBMs in Washington: Reform is in the Air!

- Pre-COVID and pre-IRA, PBMs were happy in the shadows
  - Democrats – Barely acknowledged PBMs, focused on “big pharma”
  - Republicans - Acknowledged PBM issues but were not a major focus
- Post-COVID and IRA: PBMs in the spotlight
  - At least 21 PBM-focused bills being pushed
  - FTC working on a major PBM report
  - GAO report on PBM rebates
- Bipartisan action on PBMs underway
  - Multiple (with more to come) hearings putting PBMs in hot seat
  - Seven congressional committees have worked on and combined various PBM bills
  - House: Energy & Commerce, Ways and Means, Education & Workforce Committees
  - Senate: Finance, Health Education, Labor and Pensions (HELP), Commerce Committees
- **Stage is set for PBM reform from Congress in 2024**
  - 20+ PBM bills in Congress right now
  - Need legislative package/vehicle for reforms to proceed
  - Hope not to stop the momentum

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

HEARINGS

Bringing Transparency and Accountability to Pharmacy Benefit Managers

Related Links

February 16, 2023

Press Release Published: May 16, 2023

Comer Announces First Hearing on Pharmacy Benefit Managers’ Role in Rising Health Care Costs

UNITED STATES SENATE COMMITTEE ON FINANCE

Full Committee Hearing

Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers

Date: Thursday, March 30, 2023
Time: 10:00 AM
Location: 215 Dirksen Senate Office Building

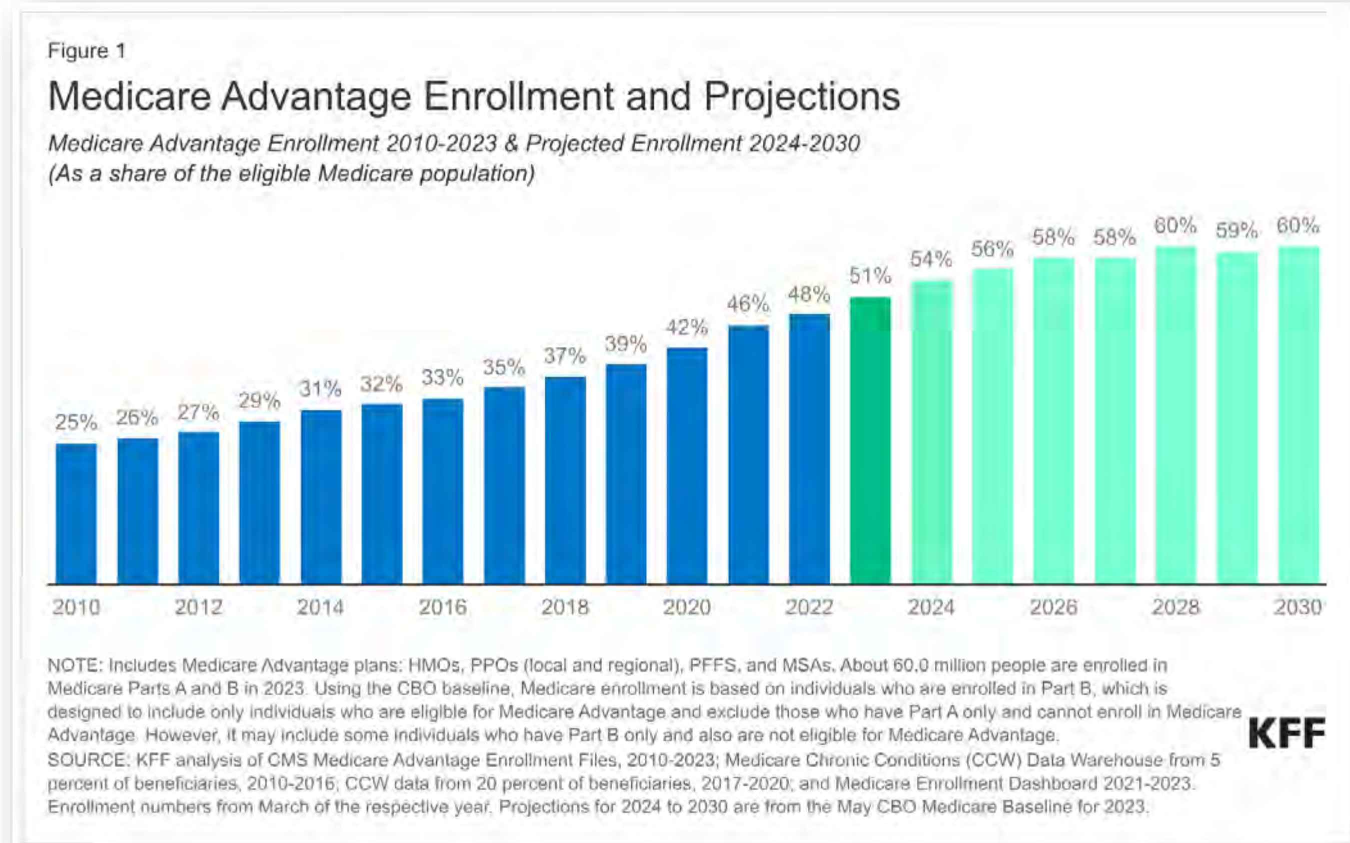
Jonathan E Levitt
Founding Partner
Frier Levitt Attorneys at Law
Pine Brook, NJ
Download Testimony

# Recap of PBM Reforms on the Table in Congress

1. Transparency
   - Reporting requirements on drug prices, rebates, formulary, benefit design.
2. Banning Spread Pricing
   - When PBMs reimburse pharmacies less than what they make from drug plans and keep the “spread” as profit.
3. Rebate Passthrough
   - Requiring PBMs to pass on 100% of rebates, fees, discounts to plan sponsors.
4. Reduce Patient Out-of-Pocket Costs
   - Tie cost-sharing to the negotiated net price, instead of the list price.
5. Delinking drug prices from PBM profits
   - Prohibiting PBMs from earning a profit based on drug list price. Instead, must be flat dollar service amount.

# Insurer Challenges: Medicare DIS-Advantage

- Rapid growth of Medicare Advantage enrollment in past decade
  - In 2023, 49 percent of Medicare beneficiaries were enrolled in MA plans
- MA presents new challenges for oncology patients and practices
  - Restrictive networks and formularies
  - Burdensome prior authorization and utilization management
  - Increased spending vs. traditional Medicare
  - *Many within COA call MA Medicare DISAdvantage*
- There is increasing scrutiny of MA in Washington
  - CMS published extremely broad RFI on MA data this week



# Copay Accumulator/Maximizer Programs: Harmful Insurer Strategies to "Save" on Drug Costs

- Copay Accumulator Programs
  - Exclude manufacturer copay assistance from deductibles
  - Patient forced to be responsible for full deductible
  - Plan double-dipping, gets to capture two full deductibles
- Copay Maximizer Programs
  - Patients out-of-pocket is maximized to full value of copay assistance from manufacturer
  - Plan gets to capture manufacturer copay assistance
  - Less copay assistance available for patients in need
- Alternative Funding Programs
  - Eliminate plan coverage for specialty drugs
  - Denied coverage, patients with insurance are pushed into manufacturer assistance programs

## COPAY ACCUMULATORS HARM PATIENTS

Patients are being harmed by copay accumulator adjustment policies (CAAPs) that bar copay assistance from counting towards a patient's deductible or out-of-pocket maximum. These policies hurt patients who depend on medicines by:

**Exposing Vulnerable Patients to Large, Unexpected Costs**

CAAPs disproportionately impact patients suffering from serious illness, particularly those who are low income or persons of color. These patients rely on copay assistance, but accumulators cut that lifeline and leave patients exposed.

**Interrupting Necessary Treatment**

Nearly all copay assistance is used to pay for medicines without generic alternatives. When more costs are transferred to the sick and vulnerable, those patients often lose access to needed medications—driving down drug adherence and resulting in other more costly health issues. CAAPs create an unnecessary barrier that interrupts the course of critical treatment for patients.

**Undermining Patient Protections**

The Affordable Care Act provided minimum standards for coverage and protections against high out-of-pocket costs, particularly for those with pre-existing health conditions. CAAPs erode these protections and harm patients with serious, chronic health conditions.

# CMS Reinterpretation of Drug Delivery: A Stark Law Violation?

- CMS "FAQ" saying practices not allowed to deliver oral drugs to patients. Must be picked up in-person
  - Friends, family, caregivers also not allowed to pick up
  - Allowed during COVID, stopped with end of PHE
  - A Stark law violation against self-dealing (how???)
- CMS' says beneficiaries can get drugs through mail order from Part D plan sponsor (aka PBMs)
  - PBM mail order endless source of problems and delays
- A nightmare for patients and practices
  - PBMs trolling for patients
  - Prescriptions being abandoned
- COA lawsuit against CMS (ongoing)
- Working on legislative fix with Congress
  - Seniors' Access to Critical Medications Act (H.R. 5526 & S. 3458)

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HEALTH

**Some Cancer Patients Must Travel Hundreds of Miles for Medication**

Health emergency's end means independent cancer doctors can't send prescriptions directly to their Medicare patients

By Stephanie Armour Follow

June 12, 2023 9:00 am ET

Gift unlocked article

# Keep an Eye on CMMI & Federal Reform Models

- Yes, we have the Enhancing Oncology Model (EOM), but…
- CMMI is a "toolbox" for reform that Administrations can turn to for pet projects/issues
  - Past mandatory CMMI demonstration projects (see previous Part B demos) proposed
  - If a model such as EOM is demonstrated to "save money" it can become law. What are parameters or guardrails?
- Keep a close eye on CMMI

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**COA Continues Effort to Stop Most Favored Nation Model**

Dec 21, 2020
Rose McNulty

Article

**Doctors' Groups Spar Over Proposed Medicare Part B Drug Model**

*By Kerry Young, CQ Roll Call*

May 5, 2016 – A group with roots in an effort by medical students to help elect Barack Obama president in 2008 is backing the president in one of his last major fights over health policy. The nonprofit Doctors for America is running a grassroots campaign in support of a proposal to alter how Medicare pays for drugs administered in doctors' offices, putting it at odds with much larger medical associations.

# Active Policy and Legislative Issues in DC on COA's Radar

Community oncology practice payment/reimbursement

Inflation Reduction Act (IRA) drug negotiation technical fix

Cancer drug shortages

"Non-profit" hospitals and 340B program

Pharmacy Benefit Manager (PBM) reform and abuses

CMS prohibiting practices from delivering cancer drugs to patients

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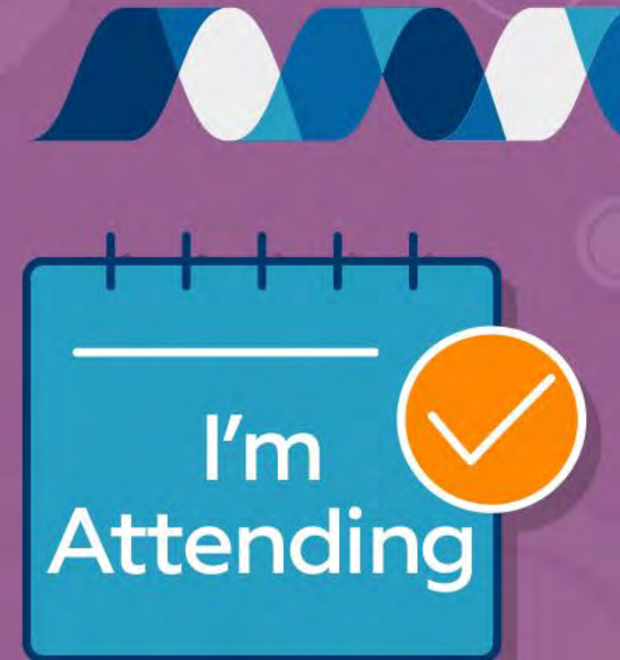

# Gracias, Stay in Touch, Get Involved!

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