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

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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 ProtectPatients
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
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  - 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
• 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

[Diagram showing relationships among insurers, PBMs, specialty pharmacies, and providers, with examples of companies like BlueCross BlueShield, Centene, The Cigna Group, CVS Health, Elevance Health, Humana, and UnitedHealth Group.]

[Notes on the diagram:](#)

**Notes:**

1. Since 2021, Prime's Blue Cross Blue Shield subsidiary has been acquired by Centene. Blue Cross Blue Shield is now part of the Centene Corporation.
2. Centene Corporation acquired Humana in 2019, and the combined company is now known as Centene Corporation.
3. In 2019, Centene acquired Truven Health Analytics, adding to its data analytics and business intelligence capabilities.
4. In 2019, CVS Health acquired Aetna, creating one of the largest health care providers in the United States.
5. In 2019, Express Scripts merged with Medco Health Solutions to form a single entity.
6. In 2019, CVS Health acquired VillageMD, a provider of primary care services.
7. In 2020, CVS Health acquired Optum, a leading health care technology and services company.
8. In 2020, UnitedHealth Group acquired Truven Health Analytics, adding to its data analytics capabilities.
9. In 2020, UnitedHealth Group acquired DirectCare, a provider of primary care services.
10. In 2020, UnitedHealth Group acquired CareMore, a provider of health care services for the Medicare population.
11. In 2020, UnitedHealth Group acquired Aetna, creating one of the largest health care providers in the United States.

**Source:** Drug Channels Institute
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

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
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
"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.”
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.
The State of the 340B Program: Forecasts

1 in 4 brand drugs will be purchased at the 340B price in 2025

1 in 5 340B drug purchases will be dispensed by a contract pharmacy in 2024

340B could be the largest federal drug program by 2028, exceeding gross drug purchases through Medicare Part D, Medicare Part B, and Medicaid.

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

#### Exhibit 5.

<table>
<thead>
<tr>
<th>Setting</th>
<th>Herceptin Markups Across Settings and Payers (one year of therapy)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Community Practice or non-340B Hospital Treating a Medicare Patient</strong></td>
<td>Purchased for: $66,107, Reimbursed at: $70,073, Margin: $3,966</td>
</tr>
<tr>
<td><strong>340B Hospital Treating a Medicare Patient</strong></td>
<td>Purchased for: $43,168, Reimbursed at: $70,073, Margin: $26,905</td>
</tr>
<tr>
<td><strong>340B Hospital Treating a Commercial Patient</strong></td>
<td>Purchased for: $43,168, Insurer Charged: $217,122, Margin: $173,954</td>
</tr>
</tbody>
</table>
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.
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

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.

COA has published 8 volumes of PBM patient horror stories detailing specific, true cases where patient care was 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
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.
• 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
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)
• 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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Don’t Miss #COA2024!

Join me at the 2024 Community Oncology Conference!

April 4-5 | Orlando, FL
#COA2024
coaconference.com
Gracias, Stay in Touch, Get Involved!

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