The View from Capitol Hill

Cancer Care Policy & COA's Priorities

Ted Okon

COA Executive Director

THE 2017 COMMUNITY ONCOLOGY CONFERENCE FUELING THE CANCER MOONSHOT

The View?

Unlike this view, the view from Capitol Hill these days ain't pretty!!!

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What's Up on the Hill?

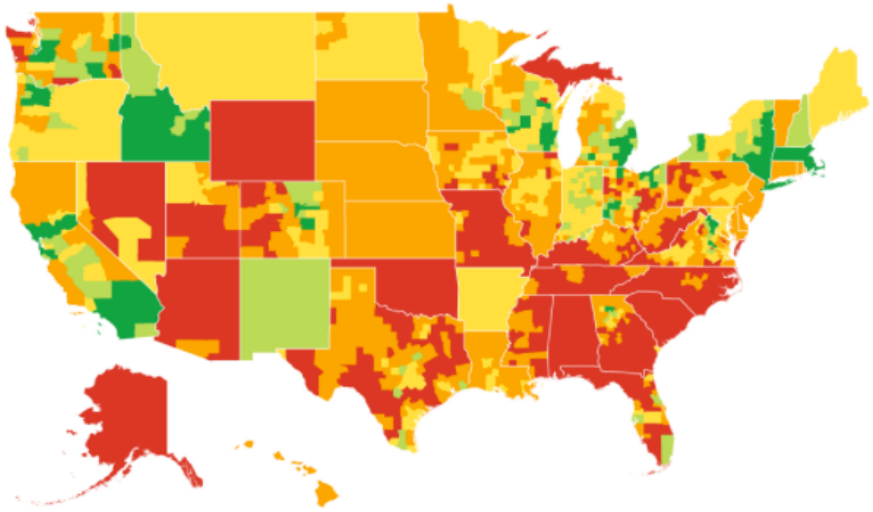
- **A little thing called Obamacare!**
  - And it's all about politics, politics & more politics!!!
- **What's the objective view on Obamacare**
  - It has real problems
    - 200 (2016) to over 1,000 (2017) U.S. counties with only 1 insurer
    - Lack of competition results in premiums rising
  - But it is engrained in the U.S. healthcare system
- **Republicans not interested in fixing it**
  - Just repeal and replace
- **Democrats not interested in fixing it**
  - Just let Republicans flounder in repeal/replace efforts

Little or No Insurer Choice in 70 Percent of Counties on Health Care Exchanges

Hootlet

In 2017, consumers in nearly 70 percent of U.S. counties have only one or two insurers selling coverage on the Obamacare exchanges. Just 11 percent of counties have four or more.

NUMBER OF INSURERS IN COUNTY	COUNTIES	SHARE OF ALL U.S. COUNTIES
1	1,030	32.8%
2	1,164	37.0%
3	599	19.1%
4	196	6.2%
5+	153	4.9%



SOURCE: Heritage Foundation calculations based on federal and state information on exchange participation, forthcoming Heritage publication.

heritage.org

Bronze Plans

Individual Age Profile	2017 Average Premium	2016 Average Premium	Increase
30 year-old	$311.17	$257.68	21%
40 year-old	$350.23	$289.88	21%
50 year-old	$489.54	$405.28	21%
60 year-old	$743.52	$615.15	21%

Silver Plans

Individual Age Profile	2017 Average Premium	2016 Average Premium	Increase
30 year-old	$364.91	$312.00	17%
40 year-old	$410.73	$351.02	17%
50 year-old	$574.10	$490.75	17%
60 year-old	$872.01	$744.99	17%

What Happens?

- **House Republicans eventually get their act together and pass a repeal/replace bill and send it to the Senate**
  - All Republicans with not one Democrat
- **Senate tries to moderate portions of the House to scrape together 50 Republican votes**
  - Won't be easy!
- **House and Senate versions end up in a "conference" to attempt to iron out differences**
  - Won't be easy!
- **Merged version sent back to the House for a vote**
- **Likely final law will push more decisions/responsibilities back on the states**

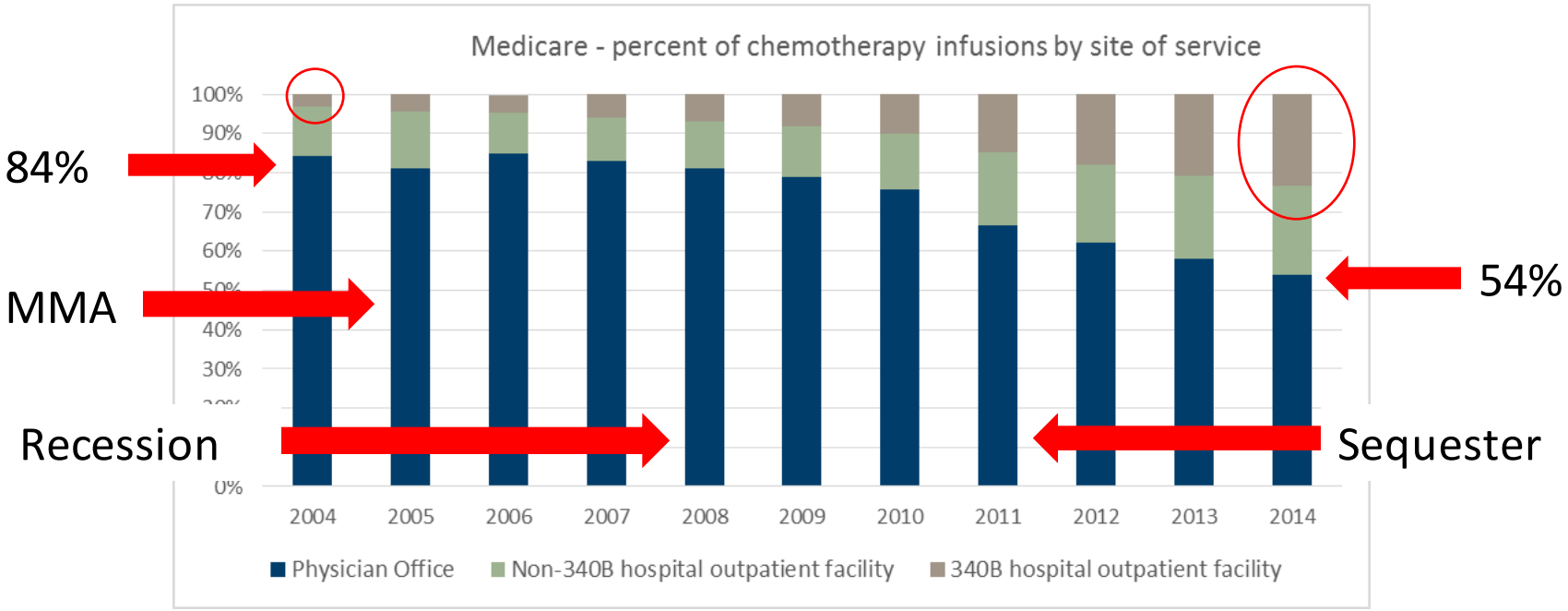
COA Priorities

- **Ensure that changes to ACA/Obamacare do not adversely impact cancer patients**
  - Preexisting conditions
  - Annual and lifetime payment caps
- **Support legislation that strengthens the community cancer care delivery system**
- **Specifically, fix the broken 340B drug discount program**
- **Specifically stop the PBM (pharmacy benefit managers) corporations from adversely impacting cancer patient care**
- **Build up an advocacy "army" to fight for cancer care fixes and advances**
- **Deal with increasing cost of cancer care**

COA Legislative Priorities

- **Cancer care payment reform (identical) bills**
  - Senate (S. 463) and House (H.R. 1834) bills
    - Cancer Care Payment Reform Act
  - Creates a "demonstration project" designed to enhance the quality of cancer care and increase efficiency/affordability
  - Designed around the Oncology Medical Home
    - Makes the cancer care clinic the medical "home" for the patient
- **Bills aimed at fixing aspects of Medicare payments for cancer care**
  - Bill to eliminate "prompt pay" calculations that artificially lower drug payments
- **Bill to fix the 340B drug discount program**
- **Bills to stop the PBMs from hurting cancer care**

Consolidation of Cancer Care



- **Percent of chemotherapy administered in community oncology practices decreased from 84.2% to 54.1%**
- **Percent of chemotherapy administered in 340B hospitals increased from 3.0% to 23.1% (670% increase)**
  - 340B hospitals account for 50.3% of all hospital outpatient chemotherapy administrations

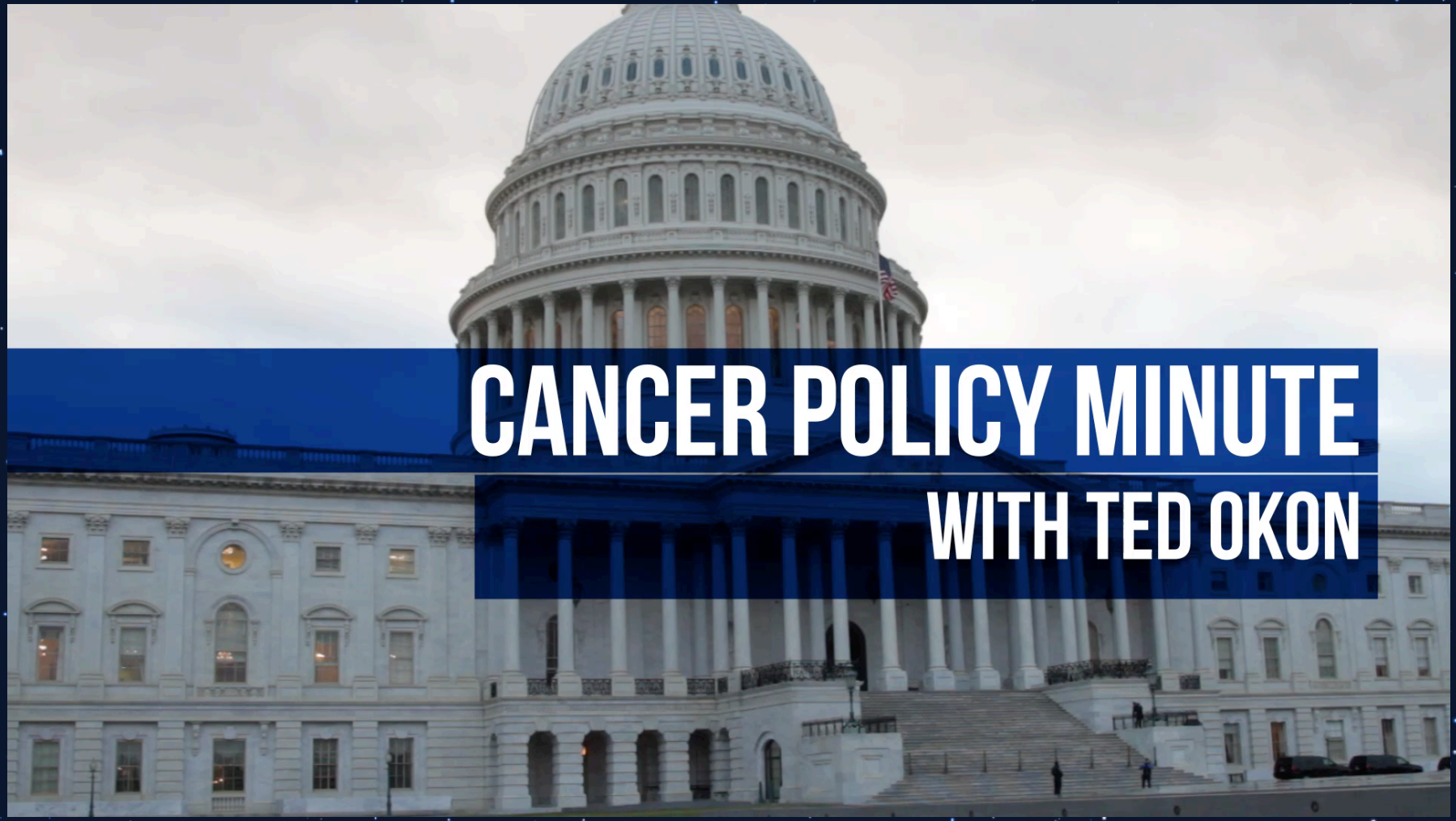
“Push” & “Pull” of Consolidation

Push

- Declining Payment for Cancer Care
- Administrative Burdens: Physicians forced to do more paperwork than treat patients
- Obstacles to Patient Care: PBMs

Pull

- Hospital Hardball Tactics: Cut off referrals to oncologists
- 340B Drug Discount Program



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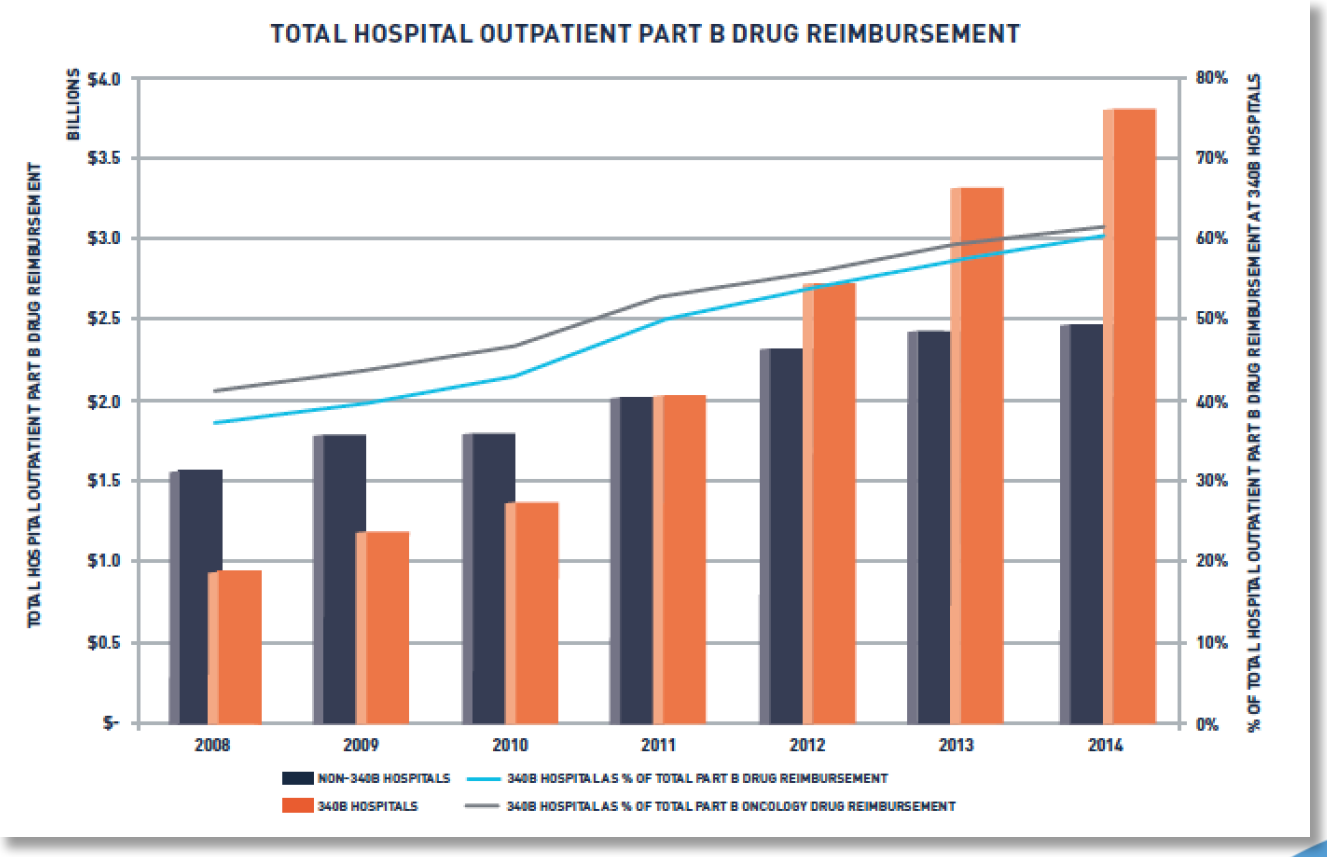
340B Overview

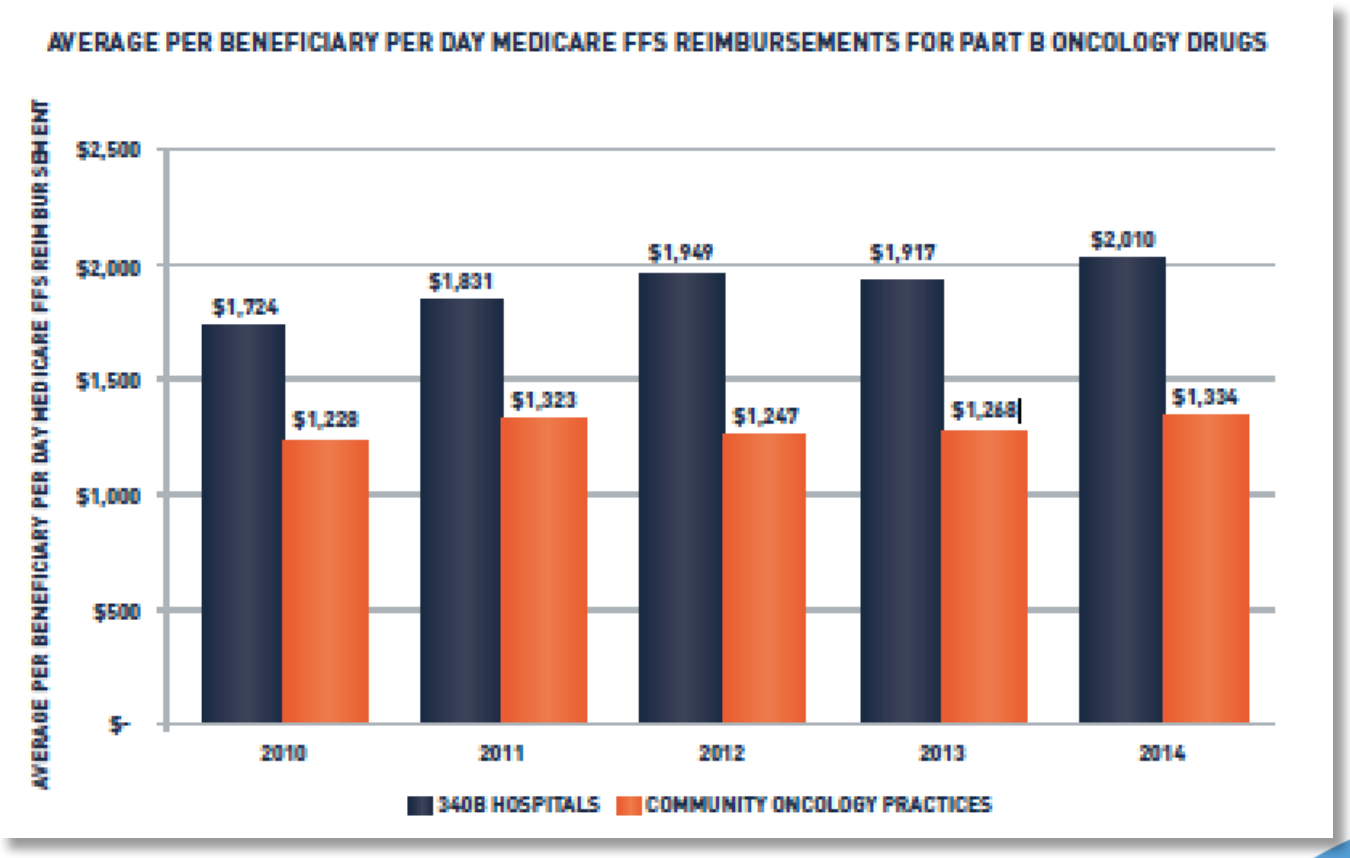
- ***340B is a CRITICAL safety net program, including for cancer patients who are underinsured or not insured***
- **Program has grown tremendously in the hospital sector**
  - 62% of all oncology drugs in the hospital outpatient setting are discounted by 340B
  - Close to 25% of all Medicare Part B is now discounted by 340B
  - Close to 30% of all Part B oncology drugs are discounted by 340B
- **340B profits (upwards of 100% margins on cancer drugs) are fueling consolidation of cancer care into the hospital setting**
- **Problem with consolidation is that hospital outpatient cancer care costs patients, Medicare, and taxpayers more**
  - 340B hospitals cost Medicare 51% more for cancer care than community cancer clinics

Growth of the 340B Program



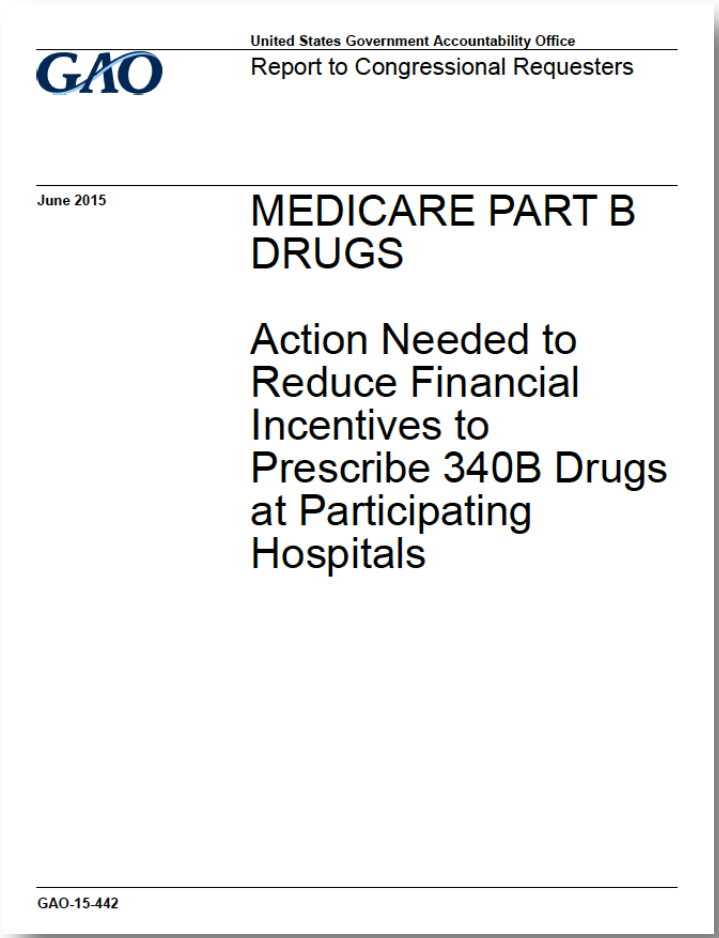
Source: *340B Growth and the Impact on the Oncology Marketplace: Update*, Berkeley Research Group, December 2015.

340B Hospitals Cost 51% More



Source: *340B Growth and the Impact on the Oncology Marketplace: Update*, Berkeley Research Group, December 2015.

Government Investigation



United States Government Accountability Office

GAO

Report to Congressional Requesters

June 2015

MEDICARE PART B DRUGS

Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals

GAO-15-442

"The financial incentive to maximize Medicare revenues through the prescribing of more or more expensive drugs at 340B hospitals also raises concerns… Not only does excess spending on Part B drugs increase the burden on both taxpayers and beneficiaries who finance the program through their premiums, it also has direct financial effects on beneficiaries who are responsible for 20 percent of the Medicare payment for their Part B drugs. Furthermore, this incentive to prescribe these drugs raises potential concerns about the appropriateness of the health care provided to Medicare Part B beneficiaries."

June 2015

340B Myths Vs. Reality

April 2017

The 340B Drug Discount Program in Review:

A Look at the Data and Evidence to Date

Over 15 Years of Making a Difference in Cancer Care

Since its inception, the 340B Drug Discount Program has been the subject of countless research studies, white papers, and analyses looking at its substantial growth and role in the United States' health care system. This paper seeks to provide a review of the data and evidence provided by studies of the 340B program to better understand how it has changed over the last 25 years. A necessary and important program for America's most vulnerable patients, 340B has morphed into a substantial profit-generating program for most hospitals that is very different from the noble, original program intended to help patients in need.

A series of legislative missteps has been responsible for the tremendous growth of the 340B program in hospitals. Most of these hospitals make tremendous profits from the program; provide incredibly low levels of charity care; are much more expensive for patients and taxpayers; and are shrinking our nation's cancer care system. 340B has become a classic case of well-intentioned policy causing unintended consequences that adversely affect patient care.

340B is a Good Idea

340B is a federal program that requires drug manufacturers to provide outpatient drugs at significantly reduced prices to eligible health care organizations, known as covered entities, that are supposed to treat high numbers of indigent and uninsured patients. Eligible participants include non-profit hospitals, community health centers, Ryan White HIV/AIDS clinics, black lung clinics, and other designated facilities that treat indigent and uninsured patients. The original concept of the 340B program was that by providing access to deeply discounted drugs (upwards of 50 percent), participants would be able to use savings to provide needed services and medication for the indigent, uninsured, and underserved patient populations they treat.

What Went Wrong?

When it started, the 340B program was aimed at a very small subset of safety-net providers. According to a report by the Medicare Payment Advisory Commission (MedPAC) to Congress, 340B grew very slowly to include just 583 participants after its first 13 years of existence (1992 – 2005).

Since then, however, 340B has exploded, with most of the growth being driven by hospitals.[1] By 2014 there were 2,140 hospitals participating in 340B, a 367 percent increase in just nine years after the Medicare Modernization Act (MMA).

> **By 2014 there were 2,140 hospitals participating in 340B, a 367 percent increase in just nine years after the Medicare Modernization Act (MMA).**

Today approximately 45 percent of all acute care hospitals participate in the 340B program. [2]

The catalyst for the explosive growth of hospitals in 340B was the passage of the MMA, which was signed into law in late 2003. The MMA fundamentally changed reimbursement for Medicare Part B prescription drugs (those drugs administered by physicians in clinics, hospitals, and other clinical settings) from 95 percent of Average Wholesale Price (AWP) to Average Sales Price (ASP) plus 6 percent.[3]

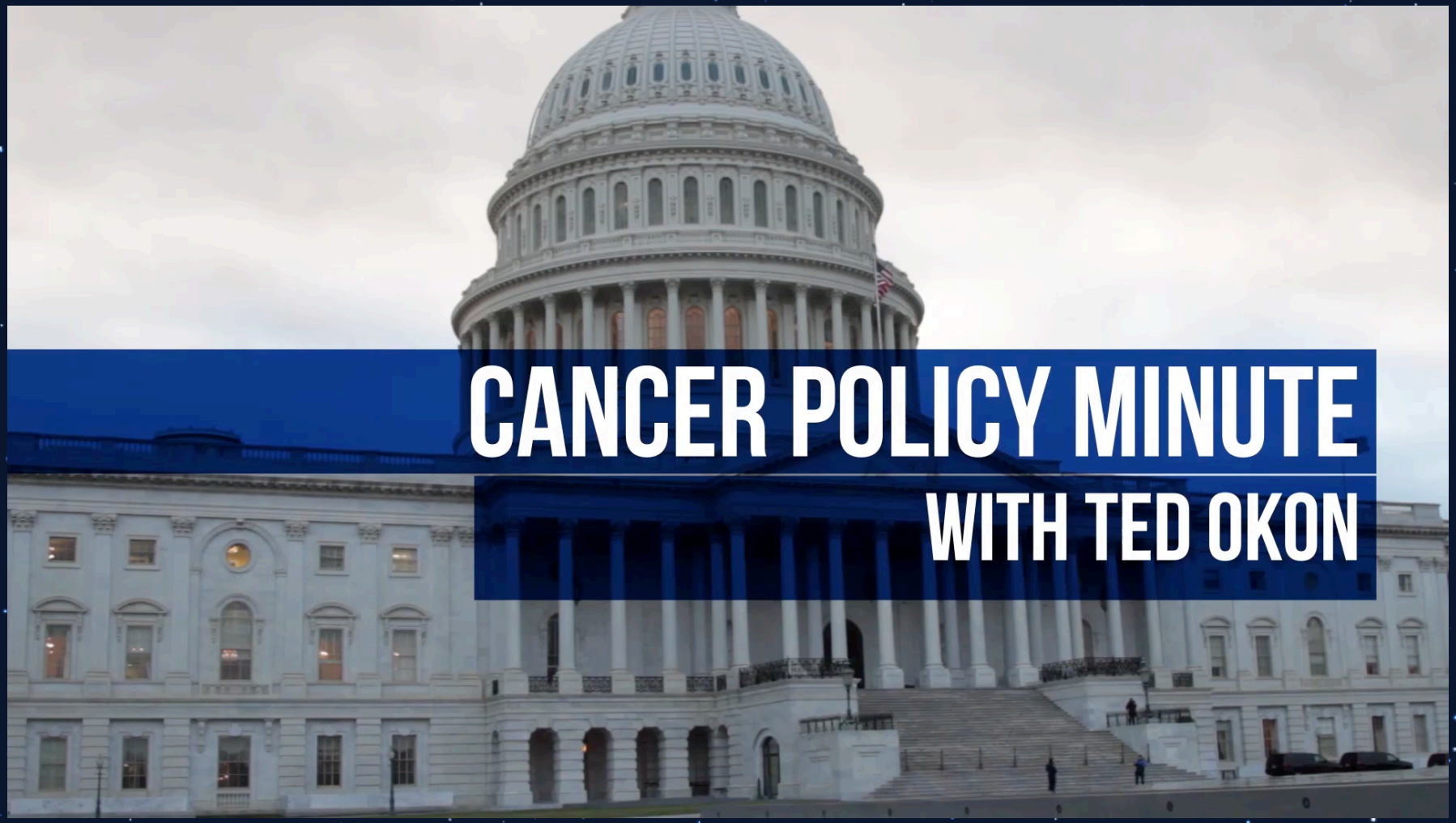
The shift from AWP to ASP-based reimbursement significantly lowered drug reimbursement for everyone in Part B. However, hospitals soon discovered that the 340B program gave them a loophole that actually allowed them to realize substantial profits from Part B drugs. Hospitals that would have seen significant decreases in payments under the new ASP-based system offset those losses by joining the 340B program and gaining access to tremendously discounted drugs.

At the same time, the severe MMA reimbursement cut forced a significant number of oncology practice closures and mergers into hospital systems. 340B hospitals seized on the

- **340B Marketing Myths**
  - Only costs pharmaceutical companies
  - Benefits patients in need
  - Has no impact on drug prices
- **340B Stark Reality**
  - Costs patients, Medicare, private payers & taxpayers
  - Only 24% of 340B hospitals account for 80% of charity care in all 340B hospitals
  - Fuels drug prices

SAVE 340B Bill

- **Exempts federal grantees and rural hospitals**
  - Lessens the political push-back and gives members cover
    - Very, very important!!!
- **Defines a patient**
  - Makes clear the patient must be under the (real) treatment of the hospital; not just getting drugs.
- **Limits contract pharmacies**
  - Number (5) and location
  - Moratorium on any further expansion
- **Requires a report from GAO on better eligibility metric than DSH**
  - Moratorium on new DSH main & child sites
  - Child sites must be wholly-owned
- **New reporting requirements in line with federal grantees**
- **Gives the HHS Secretary more power to enforce the program**
- **Requires reports to Congress**
- **Assesses a user fee not to exceed 0.1% of total drug purchases**



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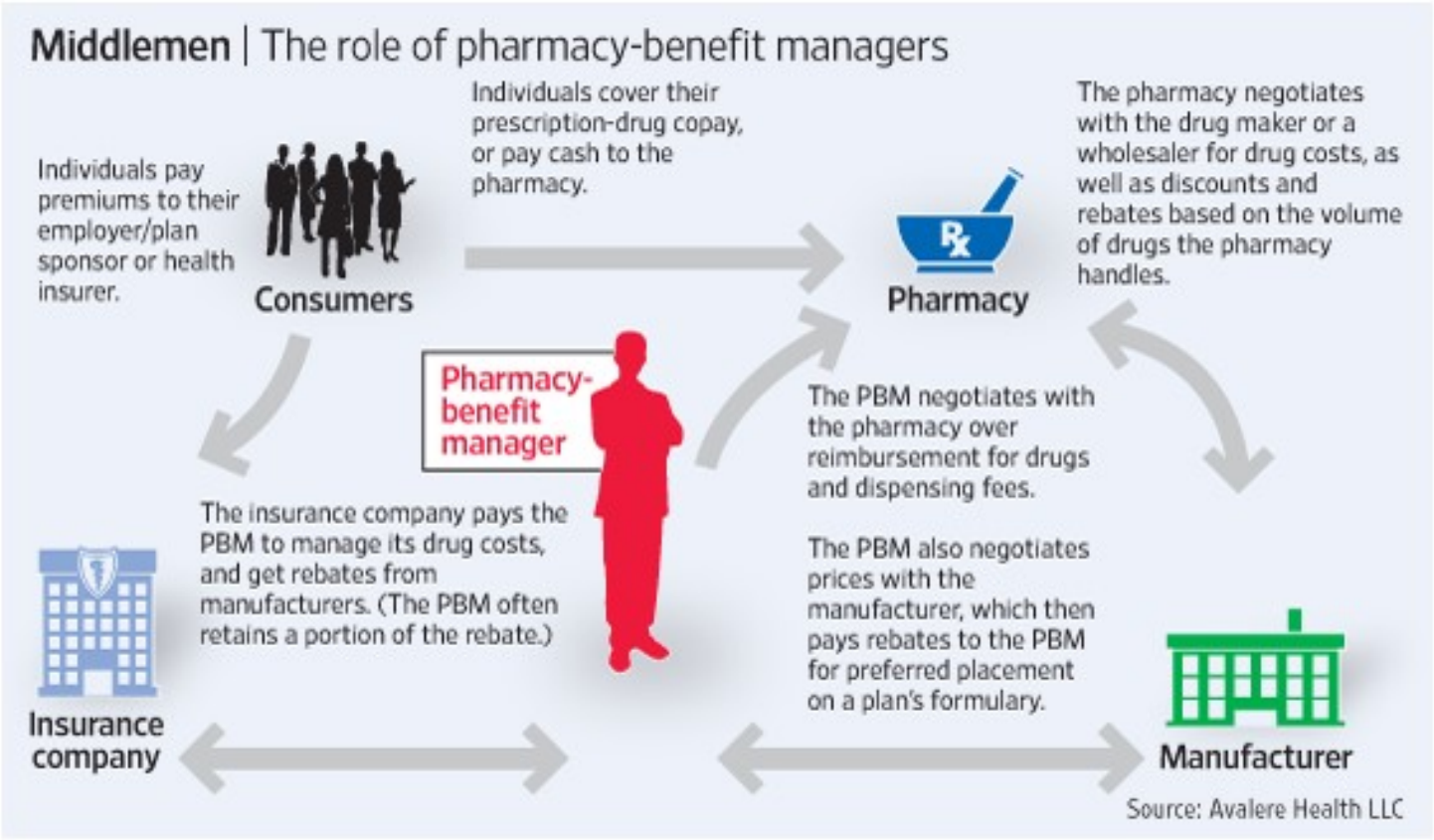
PBMs: The Middlemen



Who Are These PBMs?

PBM Mergers and Consolidations in Last Five Years

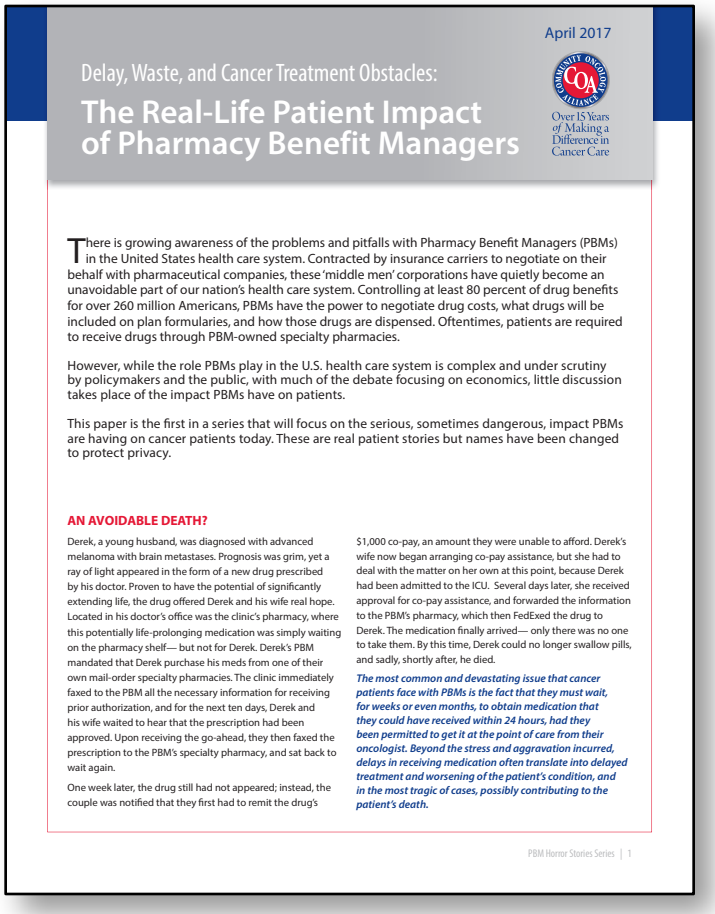
What Are PBMs Supposed to Do?

- **Serve as the middlemen to negotiate lower drug costs by using competitive means to get lower drug pricing from manufacturers**
  - Combination of discounts and rebates
- **Return lower drug costs to the "plan sponsors" who in turn are increasingly part of the same corporation**
- **Help processes at the pharmacy level**
- **Streamline the system among drug manufacturers, pharmacies, and plan sponsors**

What PBMs Are Doing

- **Extracting more rebates from drug manufacturers but unclear who is benefitting from those rebates**
  - PBMs say they benefit the plan sponsors but PBMs increasingly tied to their brother/sister corporate plan sponsors
- **Gap between real net drug prices (including discounts and rebates) and "list" prices growing**
  - Problem for patients and payers because they pay off of the "list" drug price
    - Medicare patients enter the "donut hole" faster and assume higher costs
    - Medicare pays more as patients exit the "donut hole" faster
- **Charging pharmacies – including community cancer clinics – for all types of fees**

PBMs Hurting Patients



April 2017

Delay, Waste, and Cancer Treatment Obstacles:

The Real-Life Patient Impact of Pharmacy Benefit Managers

Over 15 Years of Making a Difference in Cancer Care

There is growing awareness of the problems and pitfalls with Pharmacy Benefit Managers (PBMs) in the United States health care system. Contracted by insurance carriers to negotiate on their behalf with pharmaceutical companies, these 'middle men' corporations have quietly become an unavoidable part of our nation's health care system. Controlling at least 80 percent of drug benefits for over 260 million Americans, PBMs have the power to negotiate drug costs, what drugs will be included on plan formularies, and how those drugs are dispensed. Oftentimes, patients are required to receive drugs through PBM-owned specialty pharmacies.

However, while the role PBMs play in the U.S. health care system is complex and under scrutiny by policymakers and the public, with much of the debate focusing on economics, little discussion takes place of the impact PBMs have on patients.

This paper is the first in a series that will focus on the serious, sometimes dangerous, impact PBMs are having on cancer patients today. These are real patient stories but names have been changed to protect privacy.

AN AVOIDABLE DEATH?

Derek, a young husband, was diagnosed with advanced melanoma with brain metastases. Prognosis was grim, yet a ray of light appeared in the form of a new drug prescribed by his doctor. Proven to have the potential of significantly extending life, the drug offered Derek and his wife real hope. Located in his doctor's office was the clinic's pharmacy, where this potentially life-prolonging medication was simply waiting on the pharmacy shelf— but not for Derek. Derek's PBM mandated that Derek purchase his meds from one of their own mail-order specialty pharmacies. The clinic immediately faxed to the PBM all the necessary information for receiving prior authorization, and for the next ten days, Derek and his wife waited to hear that the prescription had been approved. Upon receiving the go-ahead, they then faxed the prescription to the PBM's specialty pharmacy, and sat back to wait again.

One week later, the drug still had not appeared; instead, the couple was notified that they first had to remit the drug's $1,000 co-pay, an amount they were unable to afford. Derek's wife now began arranging co-pay assistance, but she had to deal with the matter on her own at this point, because Derek had been admitted to the ICU. Several days later, she received approval for co-pay assistance, and forwarded the information to the PBM's pharmacy, which then FedExed the drug to Derek. The medication finally arrived— only there was no one to take them. By this time, Derek could no longer swallow pills, and sadly, shortly after, he died.

The most common and devastating issue that cancer patients face with PBMs is the fact that they must wait, for weeks or even months, to obtain medication that they could have received within 24 hours, had they been permitted to get it at the point of care from their oncologist. Beyond the stress and aggravation incurred, delays in receiving medication often translate into delayed treatment and worsening of the patient's condition, and in the most tragic of cases, possibly contributing to the patient's death.

PBM Horror Stories Series | 1

- **Slows patients from getting their cancer drugs**
- **Changes the dosing and/or schedule without the oncologists OK**
- **Changes the drugs**
- **Refuses the prescription**

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PBM Legislation

- **Griffith bill H.R.1038 - Improving Transparency and Accuracy in Medicare Part D Spending Act**
  - Stops retroactive DIR fees
  - Problematic because could establish DIR fees in statute
- **Collins (Doug) bill H.R.1316 - Prescription Drug Price Transparency Act**
  - Requires greater PBM MAC pricing transparency
  - Restricts PBMs from exclusively steering business to subsidiaries or corporate brother/sister entities
- **Bilirakis bill (in progress)**
  - Would make DIR quality performance programs 2-sided
  - Restrictions on quality metrics, measurements, etc.

THE BUFFALO NEWS | Opinion

Another Voice: Benefit managers contribute to high drug prices

By Another Voice

Published Mon, Apr 24, 2017

By Ted Okon

For a professor of pharmaceutical ethics, John Jones' recent Another Voice column, "Blame drugmakers for high-priced drugs," is a disappointing example of the kind of ethical blindness that has left our health care system with the problem of insanely high drug costs.

There is no doubt that drugmakers share the blame for high drug prices. But they are just one part of a larger drug system that is broken. If our country truly wants to lower drug prices, then it should take a long hard look at the role played by pharmacy benefit managers (PBMs).

It is no longer a secret that PBMs are a dominant player in the U.S. health care system. Today, just three PBMs control prescription drug benefits for 80 percent of Americans. They make billions of dollars in profits as middlemen in our health care system while delivering no actual patient care. In fact, what they do to the patients forced to use them often feels like just the opposite.
Every day my inbox is flooded with pleas for help from cancer clinics across the country struggling to help patients stuck in the bureaucratic purgatory of PBMs.

Medication delays that often last over a month, denials of lifesaving treatments and endless hours spent on the phone with unaccountable PBM representatives are the norm, not the exception.
Stuck in the middle of all this are very real and sick Americans who just want to get better.

Drug Price Issue

How the U.S. could cure drug-price insanity

by Peter B. Bach, MD SEPTEMBER 17, 2015, 8

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Christine Rushton,

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Mylan CEO to Def Increase Before C

By ALANA ABRAMSON
Sep 20, 2016, 6:01 PM ET

THE WALL STREET JOURNAL.

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Trump Attacks Drugmakers on Pricing

He vows to 'save billions of dollars' by changing how the U.S. buys its drugs

President-elect Donald Trump criticized the pharmaceutical industry during his press conference on Wednesday. *PHOTO: JUSTIN LANE/EUROPEAN PRESSPHOTO AGENCY*

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Drug Prices

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older patients on ealth, and take sts for this Modernization Act, which created Medicare's prescription drug program.

MARTIAN

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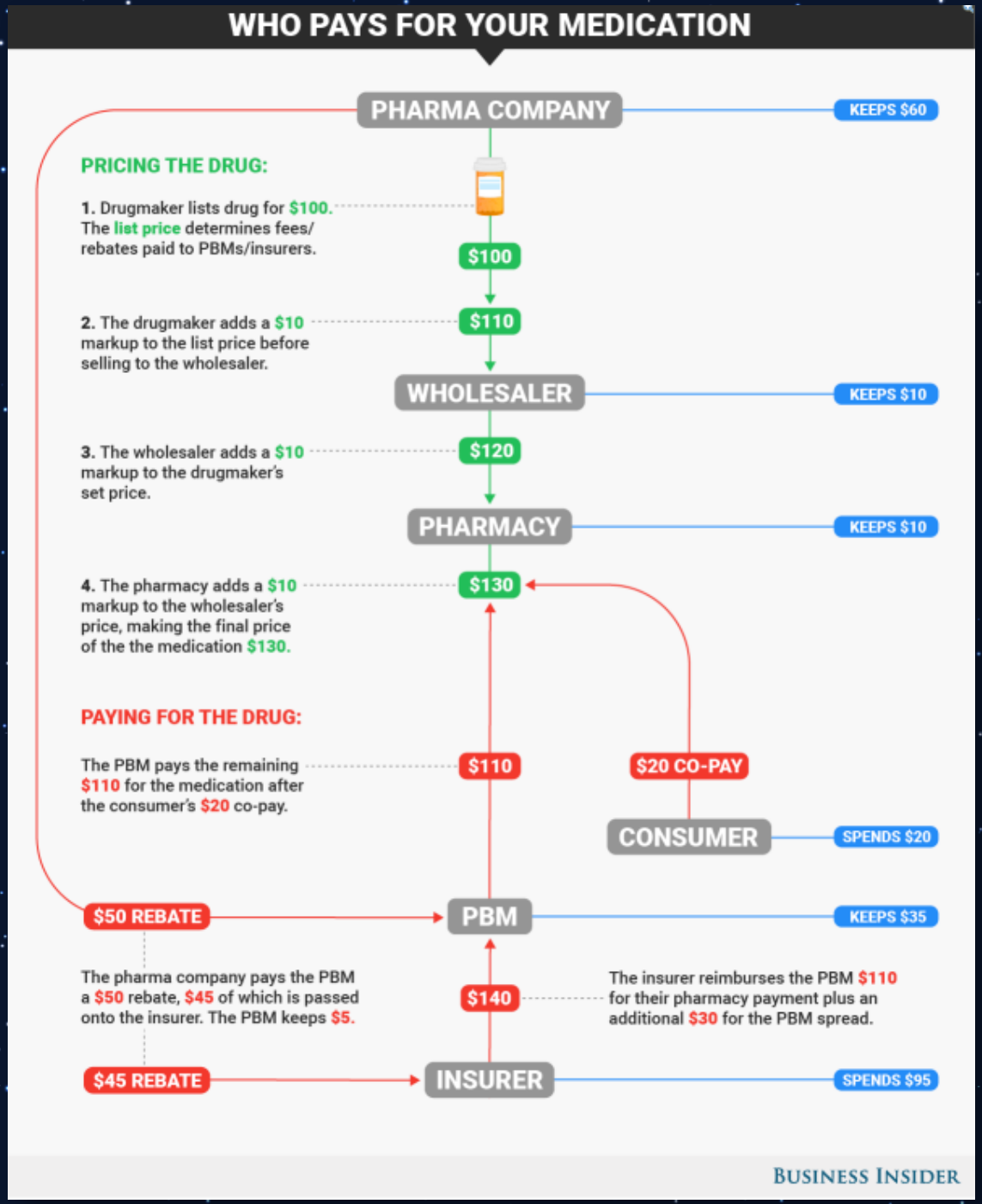
Breaking Down Drug Prices

- **Escalating drug prices are a problem and not sustainable**
  - Pharma/bio companies part of the problem and need to get innovative with solutions
- **Escalating drug prices only part of the problem of increasing cancer care costs**
  - Only 18-20% of the cost of cancer care relates to drugs
    - Pharma/bio an easy target for the media, politicians, and academics
  - Technology advances and demographics are a large part of the problem
    - Better diagnosis and treatment keeping people alive
    - Shifting demographics and health behaviors increasing cancer cases and costs
- **Everyone part of the problem — *and everyone needs to be part of the solution!!!***
  - FDA
  - Pharmaceutical/biotechnology companies
  - Insurers — private and Medicare
  - PBMs
  - Community oncology
  - Hospitals, including 340B and cancer hospitals with special Medicare exemption



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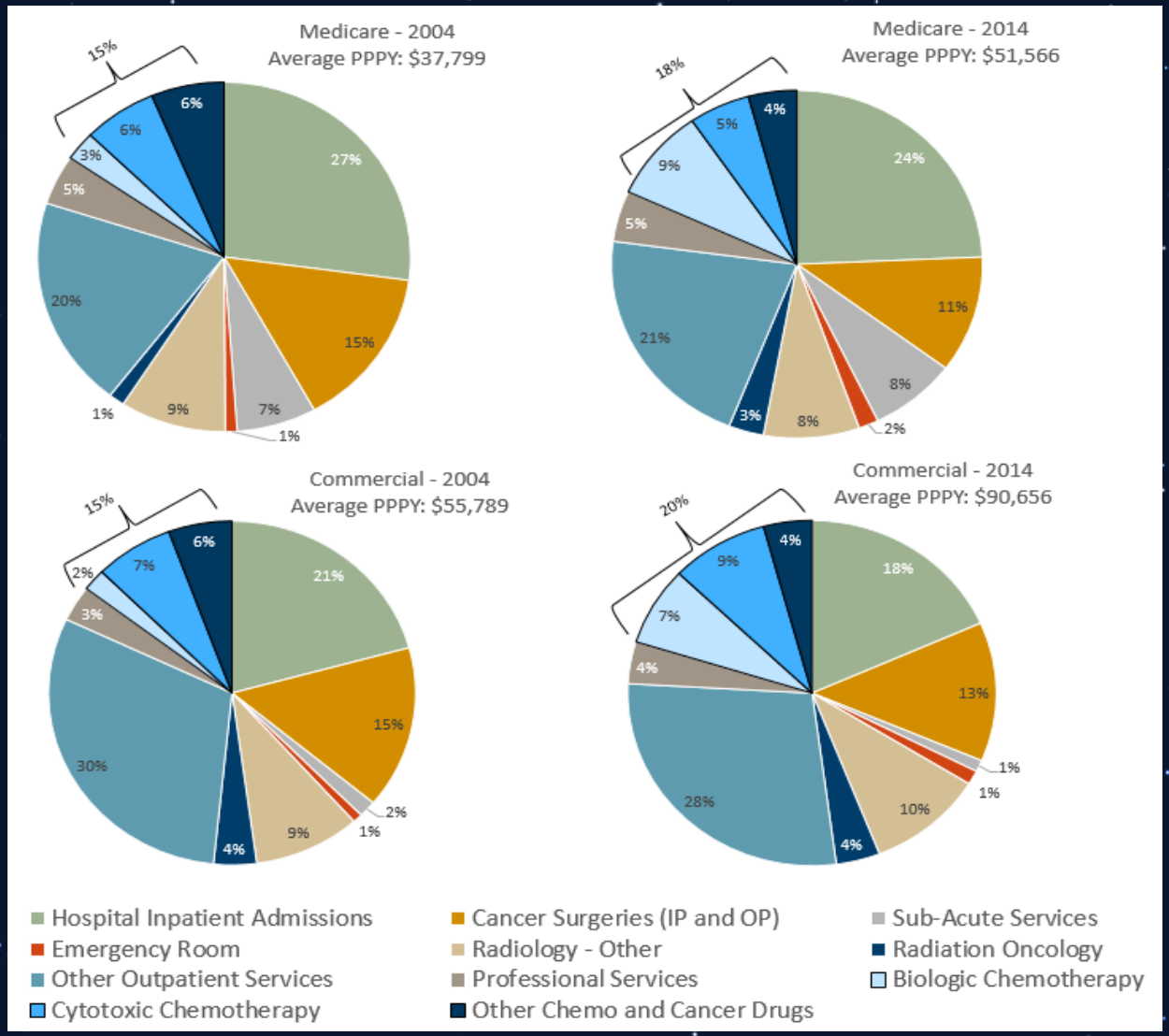

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Cost Drivers of Cancer Care

Service Category	2004-2014 PPPY Cost Trends	
	Medicare	Commercial
Hospital Inpatient Admissions	22%	44%
Cancer Surgeries (inpatient and outpatient)	0%*	39%
Sub-Acute Services	51%	15%
Emergency Room	132%	147%
Radiology – Other	24%	77%
Radiation Oncology	204%	66%
Other Outpatient Services	48%	49%
Professional Services	40%	90%
Biologic Chemotherapy	335%	485%
Cytotoxic Chemotherapy	14%	101%
Other Chemo and Cancer Drugs	-9%	24%
Total PPPY Cost Trend	**36%**	**62%**

I Am Community Oncology

- **Major nationwide campaign from COA to:**

Educate

Engage

Empower

- **Show & tell the story of community oncology**
  - Personal cancer treatment that patients need.
  - Provided by compassionate, expert professionals.
  - Delivered close to home, in your community.

Community Oncology TV

- **National waiting room TV network**
  - Telling YOUR stories
- **Variety of programming including:**
  - Cancer Policy Minute
  - Spotlight on Cancer Care
  - Know Your Cancer Care
  - Message from Our Sponsors
- **Interspersed with local news, weather, and pop culture programming**
- **Practices can customize/add own content**
  - Doctor/staff features, event invitations, appointment reminders, etc.

CPAN + I Am Community Oncology = A Stronger Advocacy Voice

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