Legislation & Reimbursement: Where Are We?

Ted Okon
Executive Director

2018 New Orleans Summer Cancer Meeting
New Orleans, Louisiana
July 22, 2018

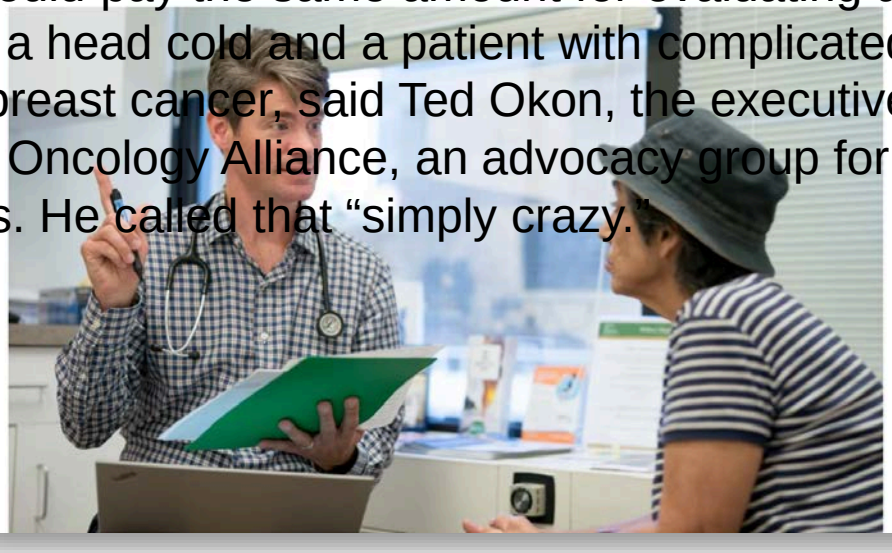
Policy Overview in One Slide

- The world of healthcare is consolidating and fundamentally changing
  - Example: Top 3 pharmacy benefit managers (PBMs) controlling 80-85% of prescription drugs will control or be controlled by #1, 3 & 4 health insurers
  - Major impact on Medicare (and private pay) reimbursement
- *It's all about drug prices in D.C.!!!*
- President's blueprint to lower drug prices contains numerous proposals, like moving Medicare Part B to D (or C)
  - Are we getting rid of the PBMs or making them more powerful in a B to D (or C) move?
- PBMs are under attack – and rightfully so!
- Big battle over fixing (or not) 340B in hospitals
- Medicare proposing to fundamentally devalue the expertise of oncologists and other specialists

Sunday New York Times

The New York Times

Sniffles? Cancer? Under Medicare Plan, Payments for Office Visits Would Be Same for Both

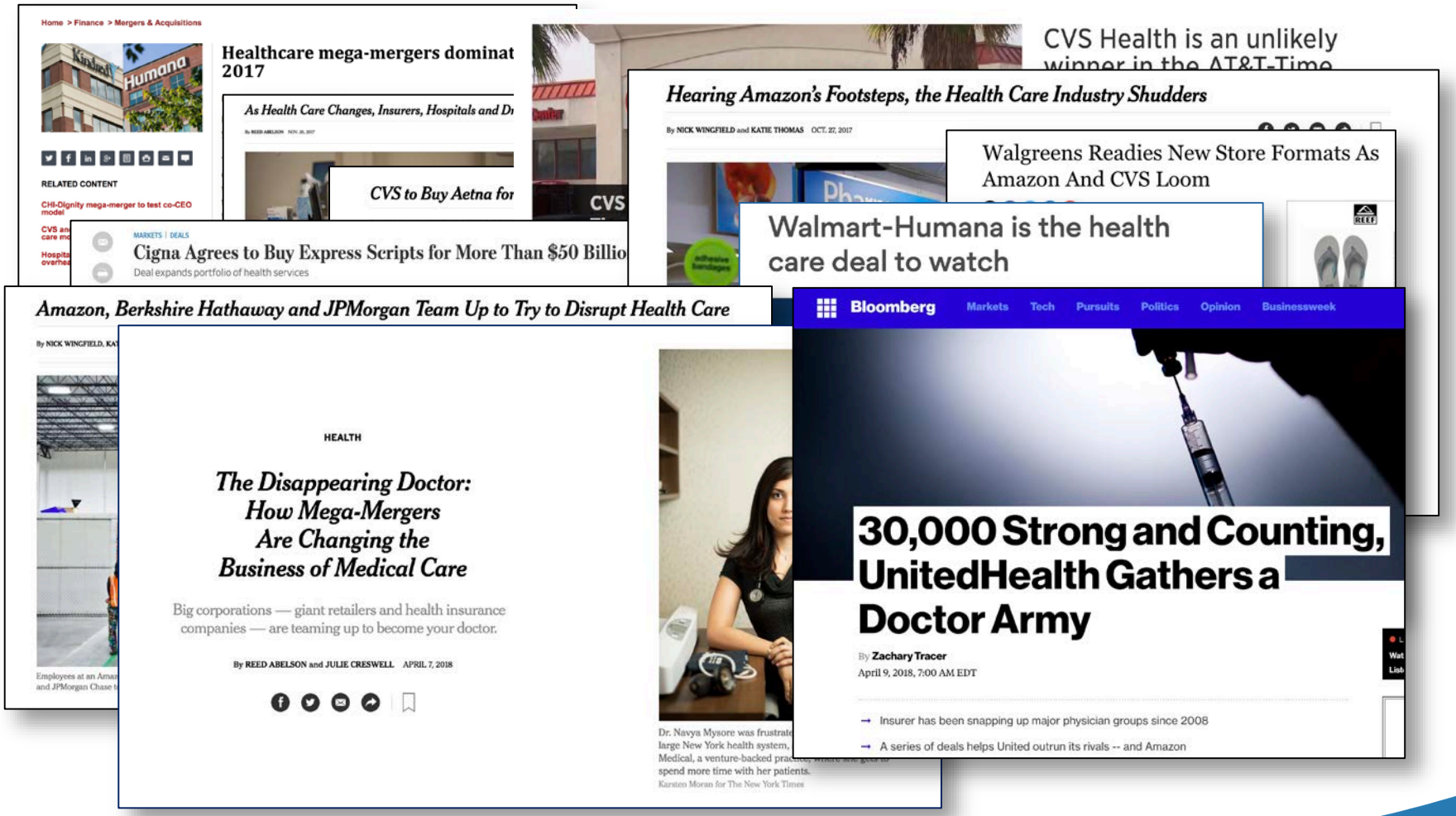


Medicare would pay the same amount for evaluating a patient with sniffles and a head cold and a patient with complicated Stage 4 metastatic breast cancer, said Ted Okon, the executive director of the Community Oncology Alliance, an advocacy group for cancer doctors and patients. He called that “simply crazy.”

Reimbursement in One Slide

- General strategy has been to go through providers to get to drug manufacturers on pricing
- Expect lots of attempts to negotiate (but not the government) Part B cancer and other specialty drug prices
- More cuts coming to 340B from the administration
  - Lots of 340B hearings and legislation but slow moving from the Congress
- Expect anything the administration can do to achieve site payment parity, but can only do so much without Congress
- Ratcheting down fee-for-service payments
- Huge pressure from the administration to move providers to value-based payment models with risk

Healthcare is Consolidating



What Does This All Mean?

- Consolidation, consolidation, consolidation!!!
  - Both "horizontal" and "vertical"
    - The big are not only getting bigger but have more influence over healthcare decisions
  - Example: CVS started out as a drugstore; now it wants to be everything, including the decision-maker of your medical care
- Costs have increased with consolidation, both for patients and insurers (Medicare and private insurers)
  - Hospitals buying private practices
  - Big hospitals buying smaller hospitals
  - Even bigger hospitals buying big hospitals
- Consolidation has not shown to decrease costs
  - In almost all cases, consolidation increases costs

What is CVS?

- Medical Clinic
- Benefit Plan Sponsor
- PBM
- Insurer
- What Else?

- Specialty Pharmacy
- Drug Store
- Mail Order Pharmacy

Hospital/Practice Consolidation

Policy experts
transparency
by Evan Sweeney | Jun 28, 20

Hospital mergers and physician ac
(Getty/Maudib)

BRIEF

Beth Is
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AUTHOR
Meg Bryant

PUBLISHED
July 20, 2018

How Hospital Merger and

HEALTH CARE

Tax-exempt Mayo Clinic grows, but rural patients pay a price

The famed medical center builds a grand main campus while consolidating
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By DA

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By Sayeh S. Nikpay, Michael R. Richards, and David Penson

DATAWATCH

Hospital-Physician Consolidation Accelerated In The Past Decade In Cardiology, Oncology

DOI: 10.1377/hlthaff.2017.1520
HEALTH AFFAIRS 37,
NO. 7 (2018): 1123–1127

Consolidation of physician practices by hospitals, or vertical integration, increased across all practice types in 2007–17. Rates of growth were highest among medical and surgical specialty practices and lowest among primary care practices. There was substantial variation within the specialties, ranging from 4 percentage points in dermatology to 34 percentage points in cardiology and oncology.

Increased hospital-physician consolidation, or vertical integration, is a frequent topic of concern for researchers, practitioners, and policy makers.[1–3] Vertical integration could result in greater coordination between physicians and hospitals, saving costs and improving the quality of care. But a growing body of evidence suggests that vertical integration instead increases costs, with no discernible impact on quality.[4–7] While much of the literature on vertical integration has focused on the implications for cost and quality, several basic questions remain unanswered: How has vertical integration changed over time, in which specialties is it occurring most rapidly, and how have the number of integrated practices per hospital changed over time?

Using data from a physician survey that covered 75 percent of US office-based physicians and physician practices, we found that cardiology and oncology practices had the highest rates of growth in vertical integration, increasing by about 34 percentage points from 2007 to 2017 (exhibit 1). Other practice types increased 22–29 percentage points, although dermatology increased by only 4 percentage points. At about 54 percent, oncology had the overall highest rate of vertical integration in 2017, increasing from

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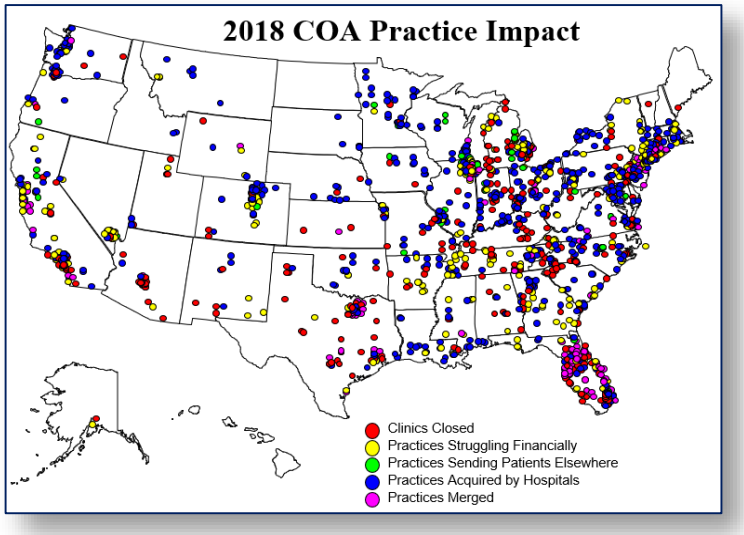
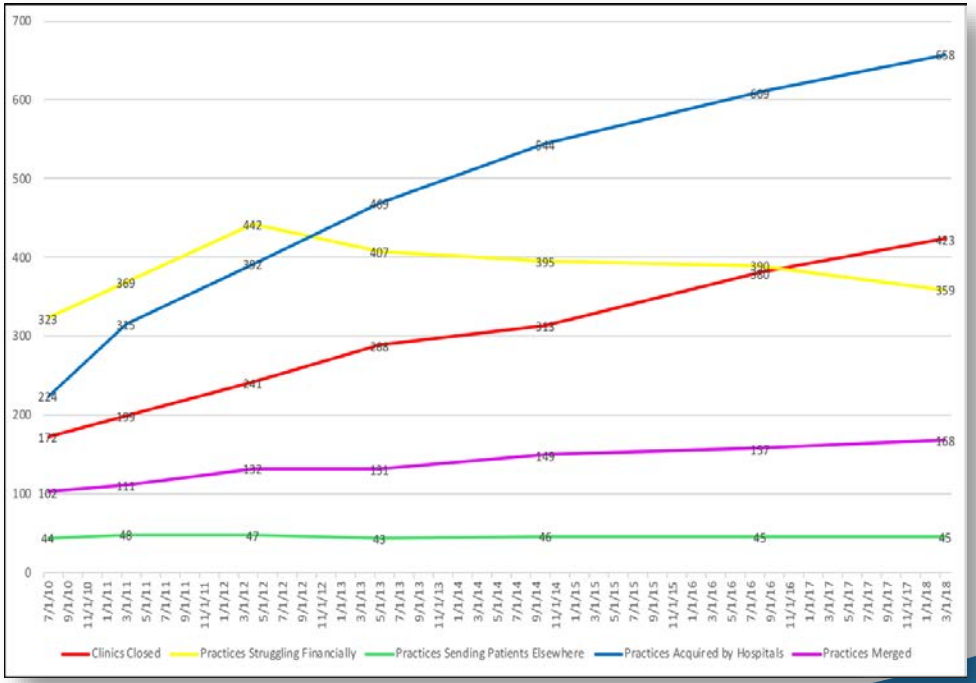
Consolidation of Cancer Care



1,654 clinics and/or practices closed, acquired by hospitals, merged, report financial struggles from 2008-2018



- 11.3% increase in closings, 8% increase in consolidations since 2016 report
- See full report at CommunityOncology.org

Drug Prices in the Spotlight

Ivan J. Miller: It's time to take prices out of the hands of mor

By Ivan J. Miller

POSTED: 06/0
UPDATED: 06/

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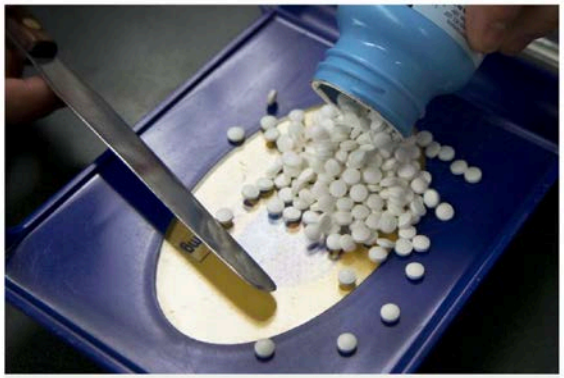
Prescription Congress to

By Nicky J

New laws take aim at prescription drug pricing in Louisiana

Updated Jun 4; Posted Jun 4



Senate panel schedules vote on controversial drug pricing bill

BY PETER SULLIVAN - 06/05/18 04:03 PM EDT

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onducted and supported by the National reatment. Novartis Pharmaceuticals Corporation

Why would a Swiss health-care company pay Michael Cohen $1.2 million? Look at drug prices.

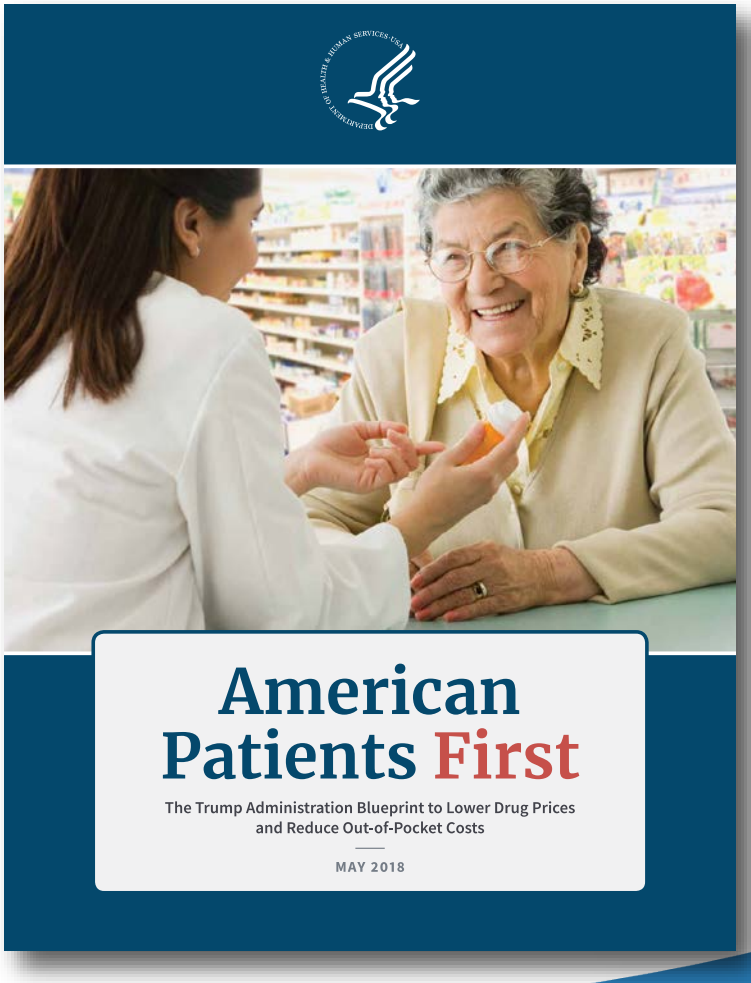
Lawyer Michael Cohen arrives at a New York City hotel on Friday. (Brendan Mcdermid/Reuters)

Importance of Drug Pricing

- Makes for great politics
  - President Trump has promised to lower drug prices
  - Democrats have made this a major issue
- Makes for great news headlines
  - Back to politics
- Drug prices, especially in cancer treatment, are unsustainable

President's Blueprint on Drugs

- Covers virtually every area of drug pricing except for direct government negotiating
- Poses 132 questions asking input on many aspects of drug pricing
- Regardless of media portrayal, pretty comprehensive



Pricing/Reimbursement Themes

- Increase drug competition
  - Speed generic and biosimilar approvals
- Facilitate manufacturer value-based contracting
- Change Medicare Part B
  - Move Part B drugs to Part D
  - Revive the Competitive Acquisition Program
- Fix "global freeloading"
- Reimburse MD practices and hospitals the same
- Address PBM situation, especially rebates
- Fix 340B
  - Move reimbursement closer to true drug acquisition cost
  - Tie 340B to charity care

Moving Medicare Part B to D

Avalere Analysis Highlights Complexities of Transitioning Medicare Part B Drugs into Part D

Matt Brow, Richard Kane | May 21, 2018

Moving certain Part B drugs to Part D, a proposal being evaluated by the Trump administration, would have disparate financial impacts on patients.

A new analysis from Avalere finds that Medicare patients' out-of-pocket costs for new cancer therapies can vary substantially based on whether a drug is covered by Part B or Part D, due to differing benefit designs and the use of supplemental health coverage. In 2016, average out-of-pocket costs were about 33% higher for Part D-covered new cancer therapies ($3,200) than for those covered in Part B ($2,400).

Moving Medicare Part B to D (C)

- There are 15 million Americans (mostly seniors) covered by Medicare Part B who are not covered by Medicare Part D
  - Means 15 million people fall through the cracks
- Part B allows for coinsurance; Part D does not
- Middlemen like PBMs are now in the way of cancer patients getting the right drugs and on time
  - Imagine this now happening in Part B???
- Rumor making the rounds this week is moving selected Part B drugs to Part C to introduce more negotiation in Part B

Reality of Medicare Part B

- 21% of all Part B drugs analyzed have a negative estimated difference between drug acquisition cost and Medicare payment
- On average, difference is -10% per drug
- ASP for 21% of Part B drugs associated with a negative estimated difference between acquisition cost and Medicare payment increased on average by 14% between Q1 and Q3 2017
- Among the top 10 highest cost cancer drugs that account for 72% of all cancer drugs and 23% of all Part B drug spending in 2016:
  - The average estimated difference between drug acquisition cost and Medicare allowable payment amount is 2.4% or $2.50.

Source: *Avalere data on file*

PBMs Under Scrutiny/Pressure

Time To Lift the Curtain On PBM Wheeling and Dealing

They say their deals need to
consumer groups, and legisla

September 29, 2017

ROBERT CALANDRA

For all the money he spent on
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CVS Exploits PBM Role, and Taxpayers Pay

n Kentucky, lawmakers discovered that PBMs, including CVS, pocket over 40% of the state's annual Medic

PHOTO: SHA

Are PBMs putting neighborh

FIRST OPINION

What does PBM stand for? In Ohio (elsewhere), it's programs bilking mi

By SCOTT KNOER / JUNE 29, 2018

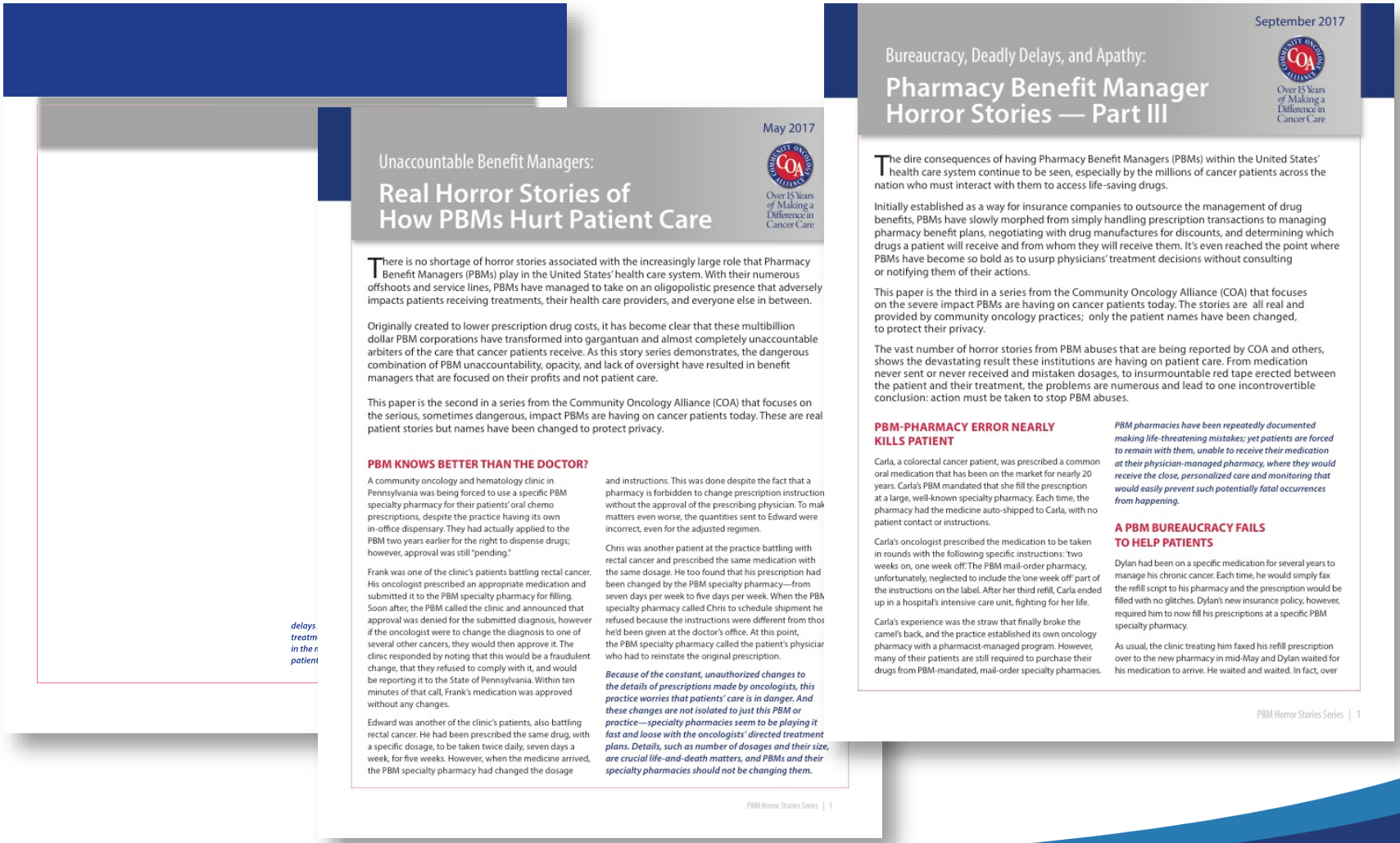
MEL EVANS/AP

In a blow to PBMs, Trump administration mulling overhaul to drug rebate safe harbor protections

by Paige Minemyer | Jul 19, 2018 4:12pm

The Trump administration could significantly overhaul safe harbor protections for drug rebates. (Pixabay)

PBM Impact on Patient Care



May 2017

Unaccountable Benefit Managers:

Real Horror Stories of How PBMs Hurt Patient Care

Over 15 Years of Making a Difference in Cancer Care

There is no shortage of horror stories associated with the increasingly large role that Pharmacy Benefit Managers (PBMs) play in the United States' health care system. With their numerous offshoots and service lines, PBMs have managed to take on an oligopolistic presence that adversely impacts patients receiving treatments, their health care providers, and everyone else in between.

Originally created to lower prescription drug costs, it has become clear that these multibillion dollar PBM corporations have transformed into gargantuan and almost completely unaccountable arbiters of the care that cancer patients receive. As this story series demonstrates, the dangerous combination of PBM unaccountability, opacity, and lack of oversight have resulted in benefit managers that are focused on their profits and not patient care.

This paper is the second in a series from the Community Oncology Alliance (COA) that focuses 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.

PBM KNOWS BETTER THAN THE DOCTOR?

A community oncology and hematology clinic in Pennsylvania was being forced to use a specific PBM specialty pharmacy for their patients' oral chemo prescriptions, despite the practice having its own in-office dispensary. They had actually applied to the PBM two years earlier for the right to dispense drugs; however, approval was still "pending."

Frank was one of the clinic's patients battling rectal cancer. His oncologist prescribed an appropriate medication and submitted it to the PBM specialty pharmacy for filling. Soon after, the PBM called the clinic and announced that approval was denied for the submitted diagnosis, however if the oncologist were to change the diagnosis to one of several other cancers, they would then approve it. The clinic responded by noting that this would be a fraudulent change, that they refused to comply with it, and would be reporting it to the State of Pennsylvania. Within ten minutes of that call, Frank's medication was approved without any changes.

Edward was another of the clinic's patients, also battling rectal cancer. He had been prescribed the same drug, with a specific dosage, to be taken twice daily, seven days a week, for five weeks. However, when the medicine arrived, the PBM specialty pharmacy had changed the dosage and instructions. This was done despite the fact that a pharmacy is forbidden to change prescription instruction without the approval of the prescribing physician. To mak matters even worse, the quantities sent to Edward were incorrect, even for the adjusted regimen.

Chris was another patient at the practice battling with rectal cancer and prescribed the same medication with the same dosage. He too found that his prescription had been changed by the PBM specialty pharmacy—from seven days per week to five days per week. When the PBM specialty pharmacy called Chris to schedule shipment he refused because the instructions were different from thos he'd been given at the doctor's office. At this point, the PBM specialty pharmacy called the patient's physician who had to reinstate the original prescription.

Because of the constant, unauthorized changes to the details of prescriptions made by oncologists, this practice worries that patients' care is in danger. And these changes are not isolated to just this PBM or practice—specialty pharmacies seem to be playing it fast and loose with the oncologists' directed treatment plans. Details, such as number of dosages and their size, are crucial life-and-death matters, and PBMs and their specialty pharmacies should not be changing them.

PBM Horror Stories Series | 1

September 2017

Bureaucracy, Deadly Delays, and Apathy:

Pharmacy Benefit Manager Horror Stories — Part III

Over 15 Years of Making a Difference in Cancer Care

The dire consequences of having Pharmacy Benefit Managers (PBMs) within the United States' health care system continue to be seen, especially by the millions of cancer patients across the nation who must interact with them to access life-saving drugs.

Initially established as a way for insurance companies to outsource the management of drug benefits, PBMs have slowly morphed from simply handling prescription transactions to managing pharmacy benefit plans, negotiating with drug manufactures for discounts, and determining which drugs a patient will receive and from whom they will receive them. It's even reached the point where PBMs have become so bold as to usurp physicians' treatment decisions without consulting or notifying them of their actions.

This paper is the third in a series from the Community Oncology Alliance (COA) that focuses on the severe impact PBMs are having on cancer patients today. The stories are all real and provided by community oncology practices; only the patient names have been changed, to protect their privacy.

The vast number of horror stories from PBM abuses that are being reported by COA and others, shows the devastating result these institutions are having on patient care. From medication never sent or never received and mistaken dosages, to insurmountable red tape erected between the patient and their treatment, the problems are numerous and lead to one incontrovertible conclusion: action must be taken to stop PBM abuses.

PBM-PHARMACY ERROR NEARLY KILLS PATIENT

Carla, a colorectal cancer patient, was prescribed a common oral medication that has been on the market for nearly 20 years. Carla's PBM mandated that she fill the prescription at a large, well-known specialty pharmacy. Each time, the pharmacy had the medicine auto-shipped to Carla, with no patient contact or instructions.

Carla's oncologist prescribed the medication to be taken in rounds with the following specific instructions: 'two weeks on, one week off.' The PBM mail-order pharmacy, unfortunately, neglected to include the 'one week off' part of the instructions on the label. After her third refill, Carla ended up in a hospital's intensive care unit, fighting for her life.

Carla's experience was the straw that finally broke the camel's back, and the practice established its own oncology pharmacy with a pharmacist-managed program. However, many of their patients are still required to purchase their drugs from PBM-mandated, mail-order specialty pharmacies.

PBM pharmacies have been repeatedly documented making life-threatening mistakes; yet patients are forced to remain with them, unable to receive their medication at their physician-managed pharmacy, where they would receive the close, personalized care and monitoring that would easily prevent such potentially fatal occurrences from happening.

A PBM BUREAUCRACY FAILS TO HELP PATIENTS

Dylan had been on a specific medication for several years to manage his chronic cancer. Each time, he would simply fax the refill script to his pharmacy and the prescription would be filled with no glitches. Dylan's new insurance policy, however, required him to now fill his prescriptions at a specific PBM specialty pharmacy.

As usual, the clinic treating him faxed his refill prescription over to the new pharmacy in mid-May and Dylan waited for his medication to arrive. He waited and waited. In fact, over

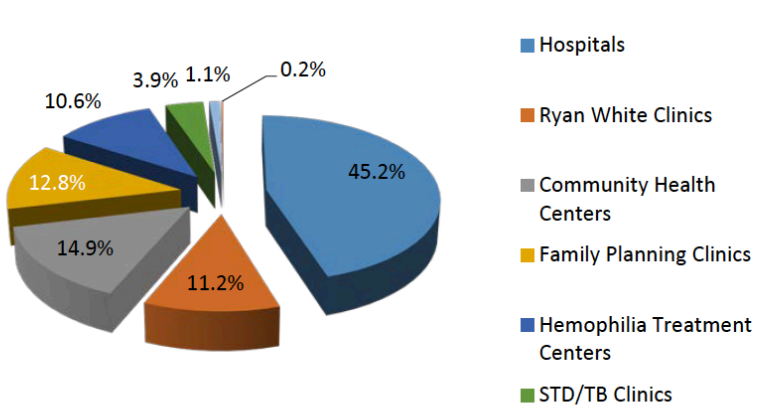
PBM Horror Stories Series | 1

340B Debate

- ***340B is a critical safety-net program to catch patients in need from falling through the "treatment cracks"***
  but…
  - 340B has had explosive growth in the hospital sector versus with federal grantees
    - Tied to the hospital growth has been equally explosive growth in contract pharmacies
  - Questions about how 340B savings are being used in hospitals
    - Getting to patients in need or funding buildings and CEO bonuses?
  - Concern about lack of transparency and accountability in hospitals versus with federal grantees
  - Research that 340B is a motivating force behind cancer care consolidation
  - Indications that 340B is fueling drug prices

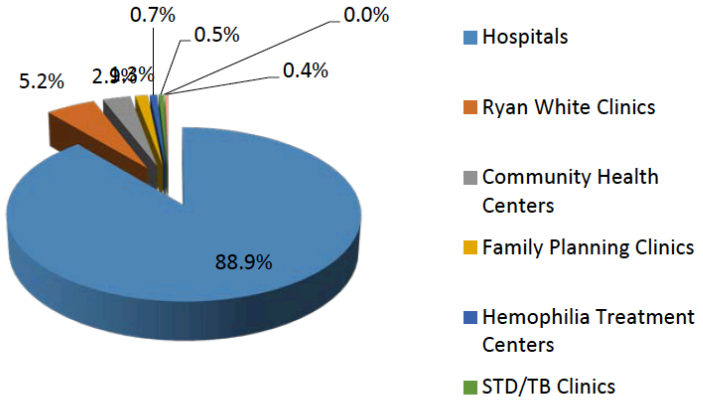
340B Growth by Entity Type

340B Purchases by Entity Type (2004)



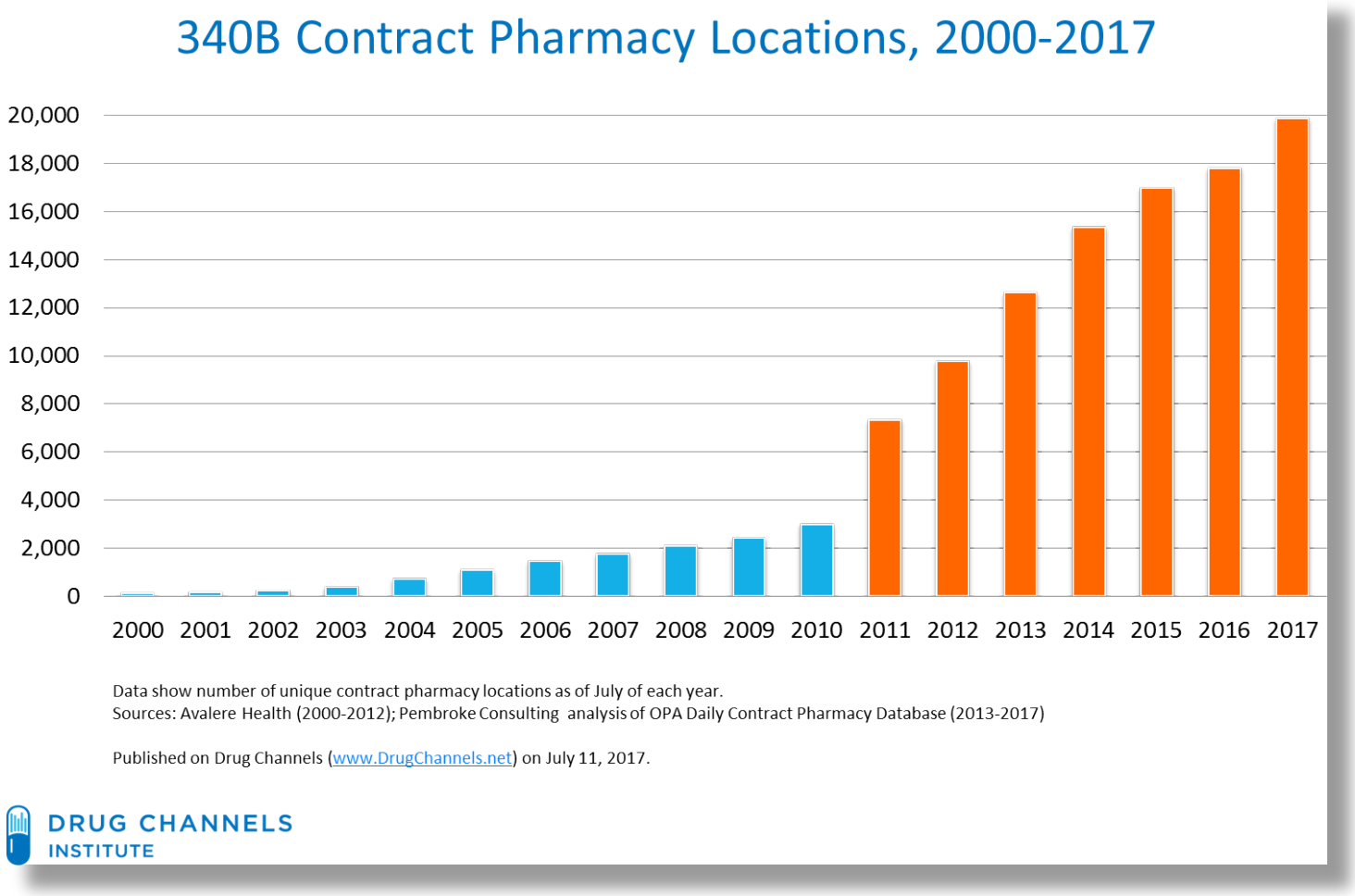
Source: Mathematica, *The PHS 340B Drug Pricing Program: Results of a Survey of Eligible Entities,* August 2004

340B Purchases by Entity Type (2011 - 2013)

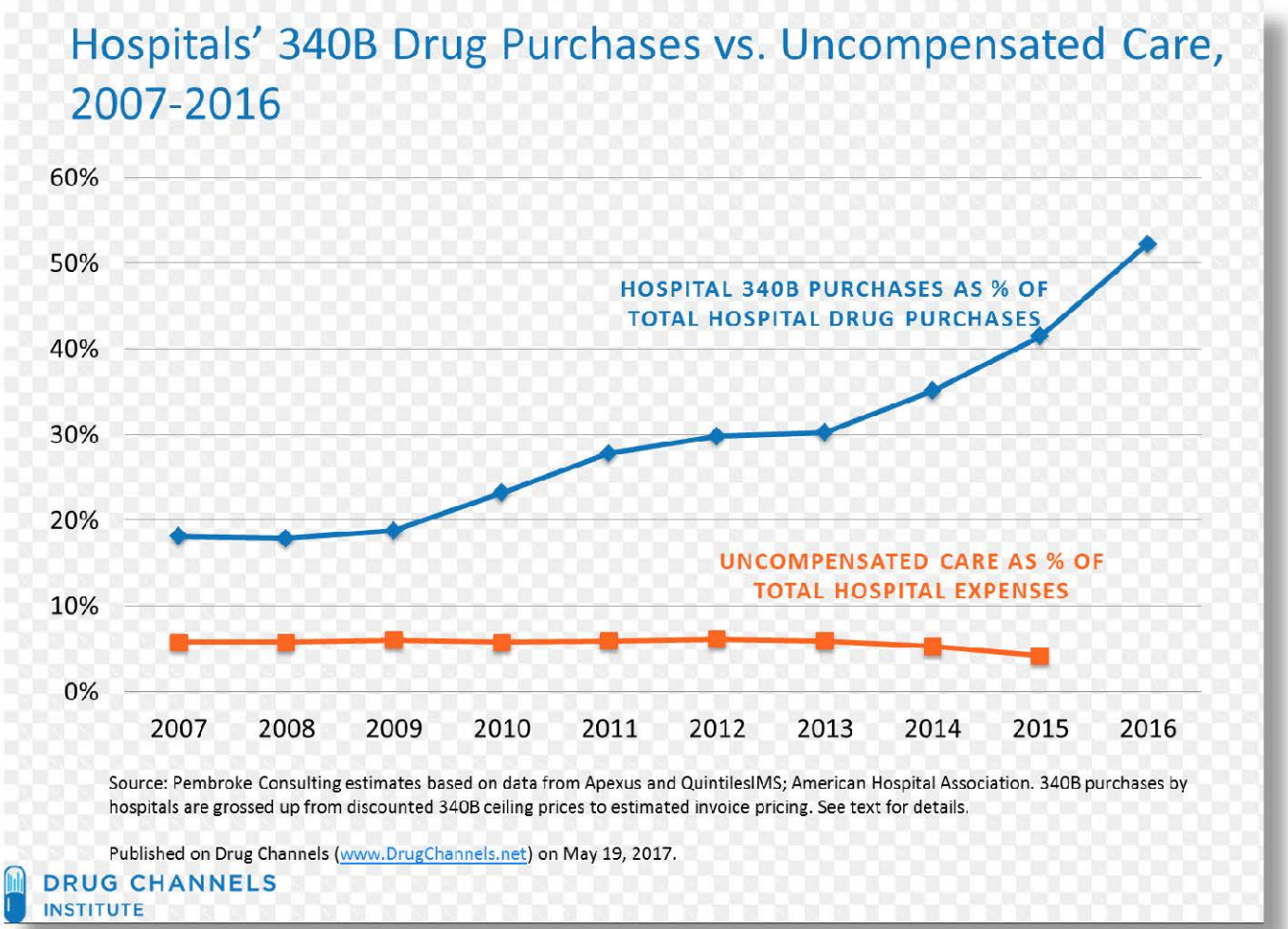


Source: Berkeley Research Group analysis of $7.1B in manufacturer 340B sales data for the period 2011 to 2013.

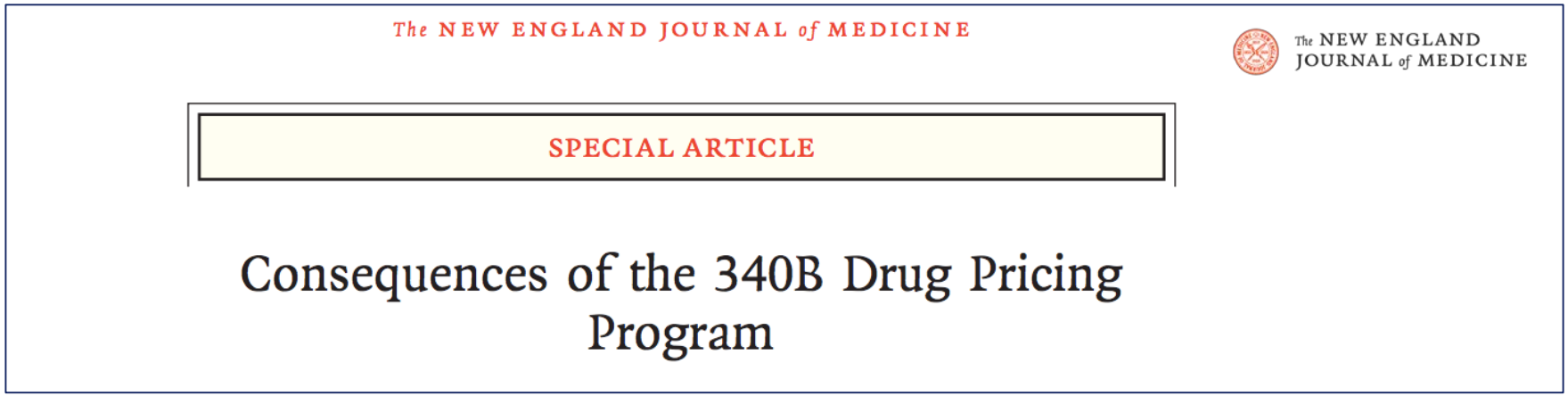
Contract Pharmacy Growth



Growth of 340B vs Charity Care

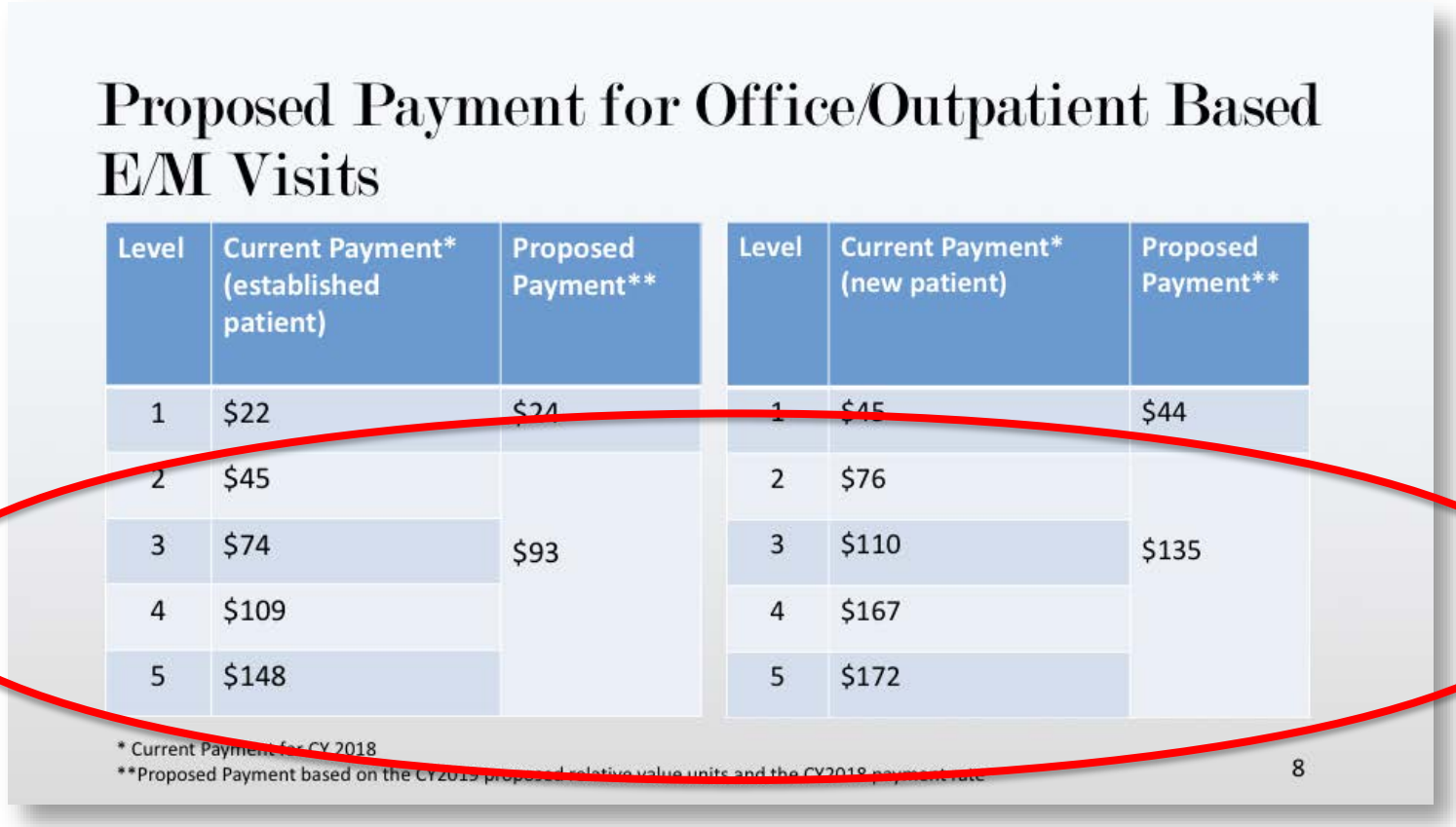


340B Studies



- Study in NEJM about impact of 340B in consolidating cancer care
- Conducted <u>independently</u> by Harvard & NYU researchers, and funded by HHS agency (Health Resources and Services Administration)
- Found that 340B program associated with:
  - "hospital–physician consolidation in hematology–oncology"
  - "more hospital-based administration of parenteral drugs in hematology–oncology"
  - ***No "clear evidence of expanded care or lower mortality among low-income patients"***

Fundamental Payment Change



Proposed Payment for Office/Outpatient Based E/M Visits

Level	Current Payment* (established patient)	Proposed Payment**	Level	Current Payment* (new patient)	Proposed Payment**
1	$22	$24	1	$45	$44
2	$45	$93	2	$76	$135
3	$74		3	$110	
4	$109		4	$167	
5	$148		5	$172	

* Current Payment for CY 2018
**Proposed Payment based on the CY2019 proposed relative value units and the CY2018 payment rate

8

"Their scheme to pay a physician the same amount for evaluating a case of sniffles and a complex brain cancer simply defies all logic. It is the antithesis of value-based healthcare and cheapens the medical care seniors are entitled to under Medicare," Ted Okon, executive director of COA, said in a **statement**, posted the day after CMS released the proposed rule.

2019 COA Conference

Thanks!!!

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