


The View from Capitol Hill

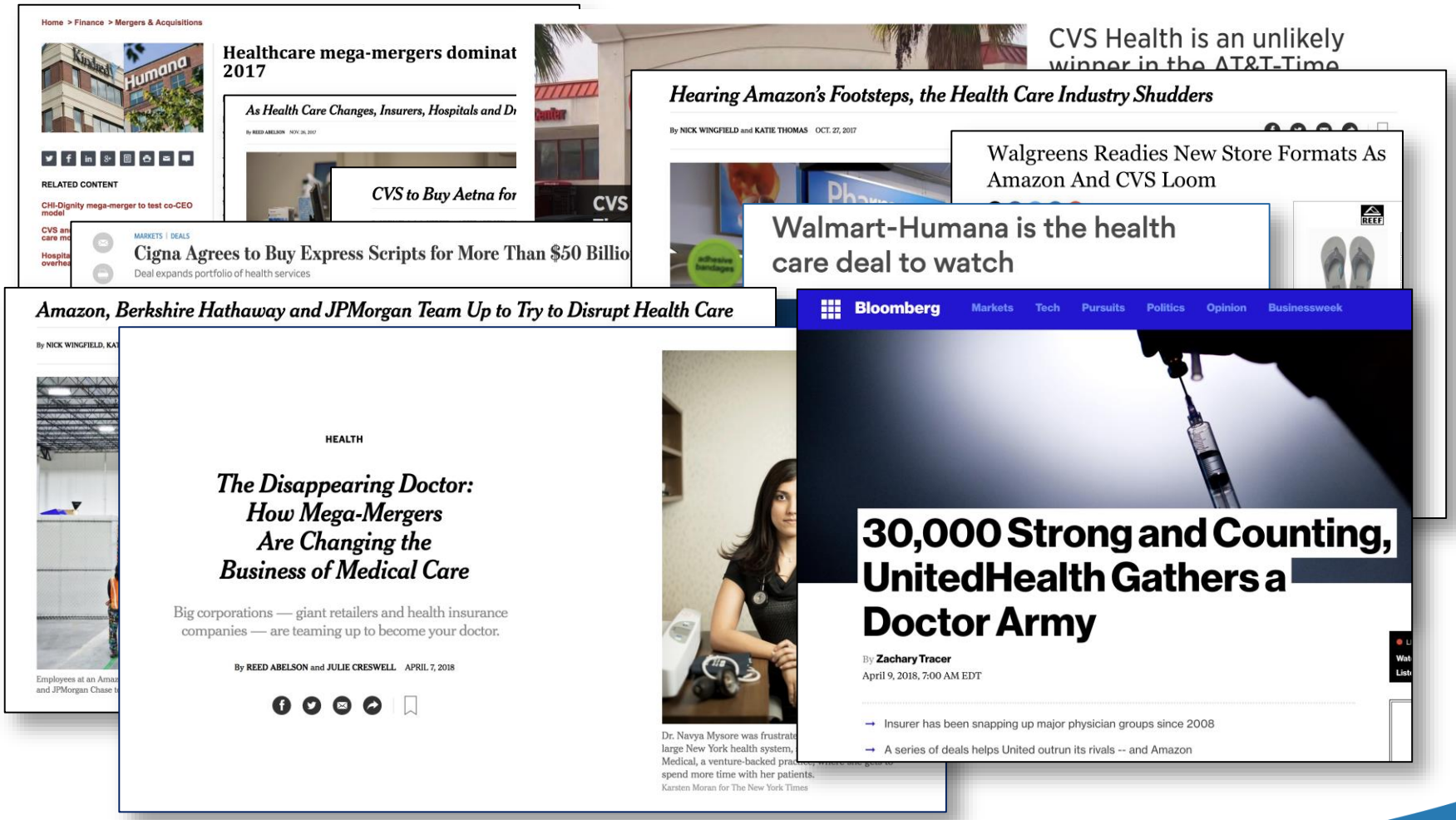
Ted Okon
Executive Director

2018 GASCO Practice Management & Business of Oncology Meeting
Atlanta, Georgia
June 15, 2018

Presentation in One Slide

- The world of healthcare is consolidating and fundamentally changing
  - Top 3 pharmacy benefit managers (PBMs) controlling 80-85% of prescription drugs will control or be controlled by #1, 3 & 4 health insurers
- Drug price issue is not going away
- President's blueprint to lower drug prices contains proposals to move Medicare Part B to D and to bring back from the dead the Competitive Acquisition Program (CAP)
- PBMs are under attack – and rightfully so!
- Real battle of fixing (or not) 340B in hospitals
- Will the OCM make it???

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)
  - Consolidation has not shown to decrease costs
    - Increases costs and causes access problems
  - Example: very clear that costs of cancer care higher in hospitals than independent community cancer clinics and treatment sites have closed

What is CVS?

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

- Specialty Pharmacy
- Drug Store
- Mail Order Pharmacy

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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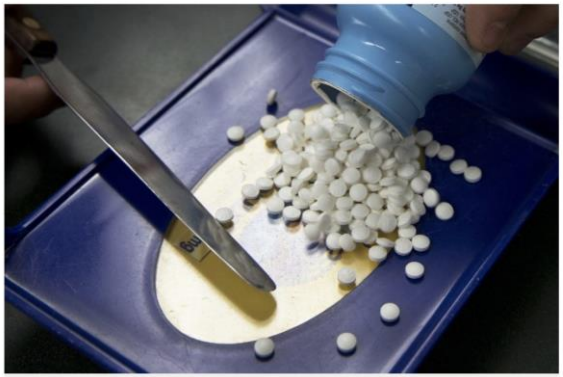
Prescription Congress to

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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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)

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Presidents Blueprint on Drugs

- Commitment to bring down drug "prices"
- Some things the administration can do; others will require Congress
- Good policy proposals:
  - More 340B reform
  - Site payment parity
  - Curtailing PBM rebates to lower "list" prices for patients
- Bad (really bad!!!) proposals:
  - Move Medicare Part B (infusibles) drugs under Part D (orals)
  - Bring back from the dead the Competitive Acquisition Program (CAP)

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

- 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???

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*

Legislative Priorities & Actions

- Stop the application of the sequester cut to Medicare Part B drugs
  - COA Board authorized suing the federal government (OMB & HHS) over Illegal and unconstitutional application of the sequester cut
  - Lawsuit seeking an injunction to stop the cut filed in DC court
- Stop the destructive proposals in the President's blueprint to lower drug prices
  - Moving Medicare Part B under Part D
  - Reviving the fundamentally flawed Competitive Acquisition Program (CAP)
- Fix a broken 340B program (in hospitals)
  - Providing data/analysis telling the true story; generating OpEds to provide balance; and working with Congress on hearings and legislation
    - 4 bills; more possible

Legislative Priorities & Actions

- Stop PBM medication delays/switching, patient trolling, DIR Fees, and excluding community oncology practices from networks
  - Working with Congress on legislation
    - 4 bills; working on 2 others
  - Have more legal action in place than can be reviewed here
- Stop the VA clawbacks
  - Working closely with Congress; talking to the VA

What May Be Added to the List

- Prior authorization delays
  - Opening up discussions with Congress and forming a coalition outside of oncology
- Co-pay accumulators
  - This may become a very big issue for patients and real fast!!!

PBMs Under Increasing Scrutiny

Time To Lift the Curtain On PBM Wheeling and Dealing

They say their deals need to be kept private so they can drive a hard bargain with manufacturers. But employers, consumer groups, and legislators are calling for more PBM transparency.

September 29, 2017

ROBERT CALANDRA

For all the money he spent on his MBA, Ted Okon says the best life lesson he ever received cost him $80. It came from a guy dealing Three Card Monte on a New York City street corner. He was up $40 but in no time lost that $40 plus $40 more. So what lesson did he learn?

"It showed me that you can't win a rigged game," says Okon, executive director of the not-for-profit Community Oncology Alliance. "And right now PBMs have a rigged game akin to that Three Card Monte where they basically control all the terms."

The Community Oncology Alliance is among several groups fed up with the PBM industry's infamously convoluted pricing schedules and contracts. It's time, they say, for the industry to make its murky business practices Windex clear.

When it comes to drug costs, it's a rigged game, says Ted Okon of the Community Oncology Alliance. "Right now PBMs have a rigged game ... [and] basically control all the terms."

PBM Impact on Patient Care

April 2017

Delay, Waste, and Cancer Treatment Obstacles:

The Real-Life Patient Impact of Pharmacy Benefit M

Over 15 Years of Making a

There is growing awareness of the problems and pitfalls in the United States health care system. Contracted by behalf with pharmaceutical companies, these 'middle mer unavoidable part of our nation's health care system. Contr for over 260 million Americans, PBMs have the power to n included on plan formularies, and how those drugs are dis to receive drugs through PBM-owned specialty pharmacie

However, while the role PBMs play in the U.S. health care by policymakers and the public, with much of the debate takes place of the impact PBMs have on patients.

This paper is the first in a series that will focus on the seri are having on cancer patients today. These are real patie 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

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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

Consolidation: Patients Suffer

HEALTH CARE

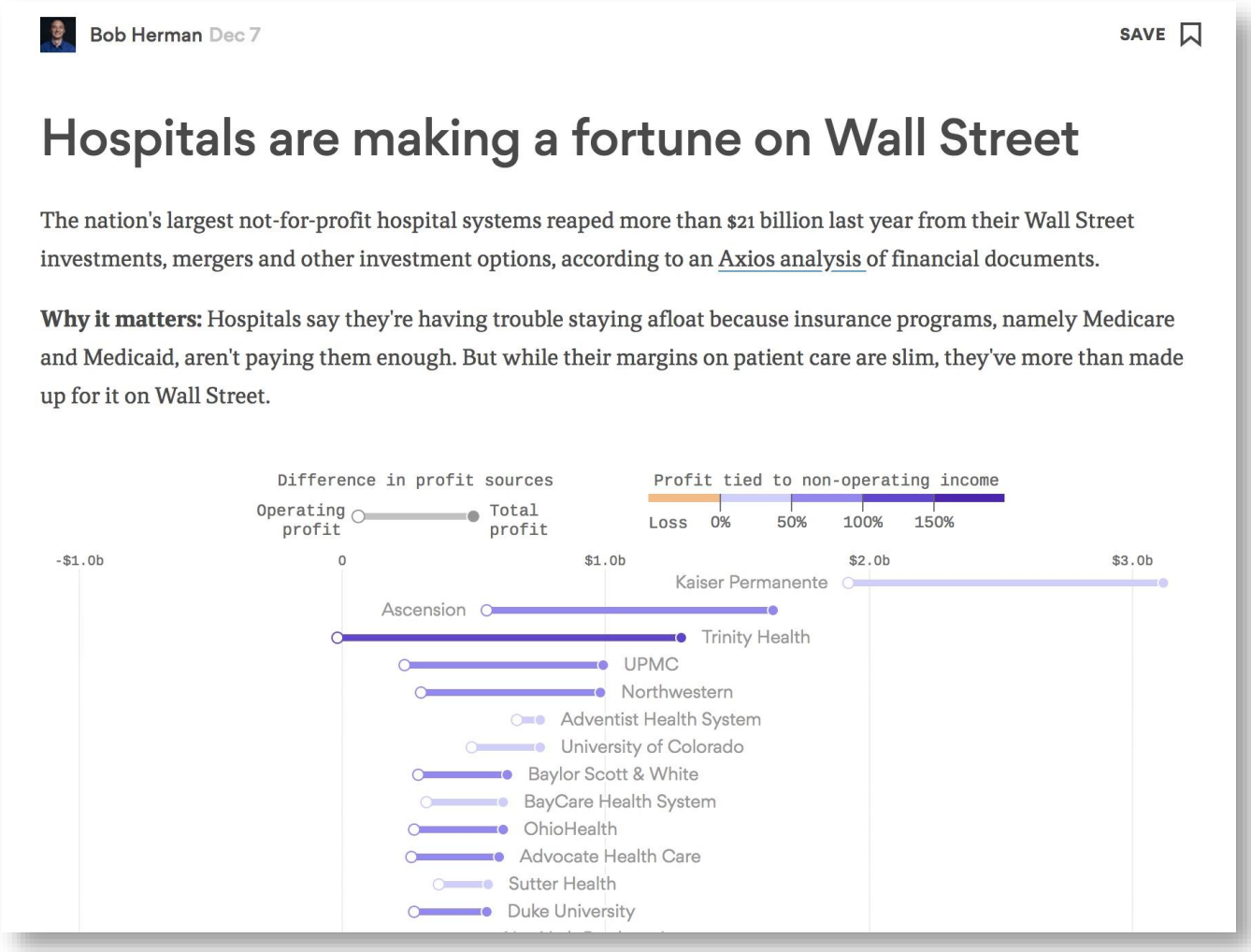
Tax-exempt Mayo Clinic grows, but rural patients pay a price

The famed medical center builds a grand main campus while consolidating services elsewhere.

By **DAN DIAMOND** | 11/16/2017 05:04 AM EST

Retired family physician Bill Buege worked under the Mayo Clinic after it bought Albert Lea's small hospital in 1996 and until he left in 1999. "I didn't think it was gonna work," Buege said. "I told them a tertiary medical center would not work in a small town." | Tom Baker for POLITICO

Hospitals Not Exactly Poor



Bob Herman Dec 7

SAVE

Hospitals are making a fortune on Wall Street

The nation's largest not-for-profit hospital systems reaped more than $21 billion last year from their Wall Street investments, mergers and other investment options, according to an Axios analysis of financial documents.

Why it matters: Hospitals say they're having trouble staying afloat because insurance programs, namely Medicare and Medicaid, aren't paying them enough. But while their margins on patient care are slim, they've more than made up for it on Wall Street.

Revenue Up, Charity Care Down

HEALTH CARE

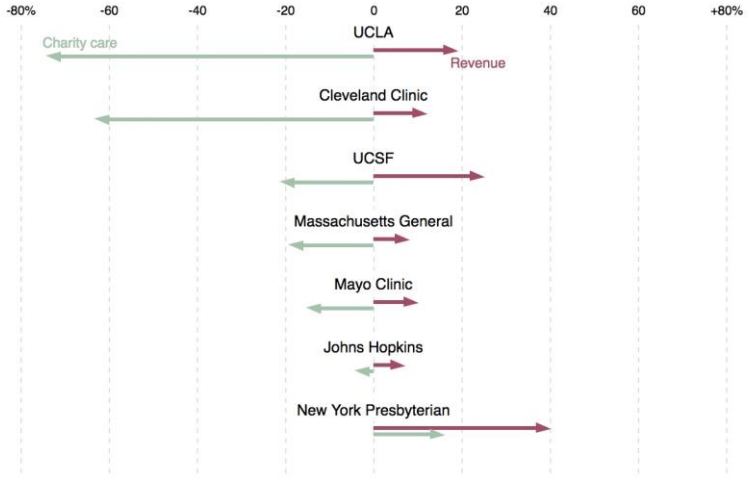
How hospitals got richer off Obamacare

After fending off challenges to their tax-exempt status, the biggest hospitals boosted revenue while cutting charity care.

By **DAN DIAMOND** | 7/17/17 05:00 AM EDT

Revenue up, charity care down

While operating revenue increased under Obamacare for not-for-profit hospitals like the Cleveland Clinic and UCLA Medical Center, the amount of charity health care they provided fell. For example, while UCLA saw operating revenue grow by more than $300 million between 2013 and 2015, charity care fell from almost $20 million to about $5 million.



SOURCE: Figures drawn from hospitals' financial statements. Revenue growth reflects a mix of ACA coverage expansion, acquisitions and other strategic investments.

Site of Care Payment Differences

JAMA Oncology

Home | New Online | Issues | For Authors

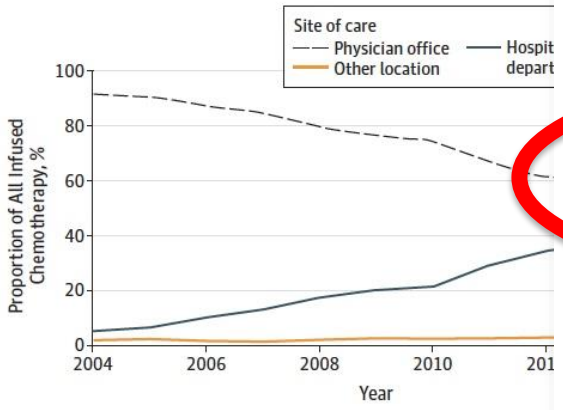
Global Burden of Cancer, 1990-2015

Spending by Commercial Insurers on Chemotherapy Based on Site of Care, 2004-2014

The impact of price variation because of the site of care—receiving treatment in a ph tient department (HOPD)—i spending.[1] While patients r either setting, insurers typic at a higher rate than to phys payment difference becaus and treat more medically c

Critics argue that the va than overhead expenses, s study, we describe trends i cancer chemotherapy in HO 2004 through 2014 among

Figure 1. Shift in Site of Care for Infused Chemotherapy Among Commercially Insured Patients, 2004-2014

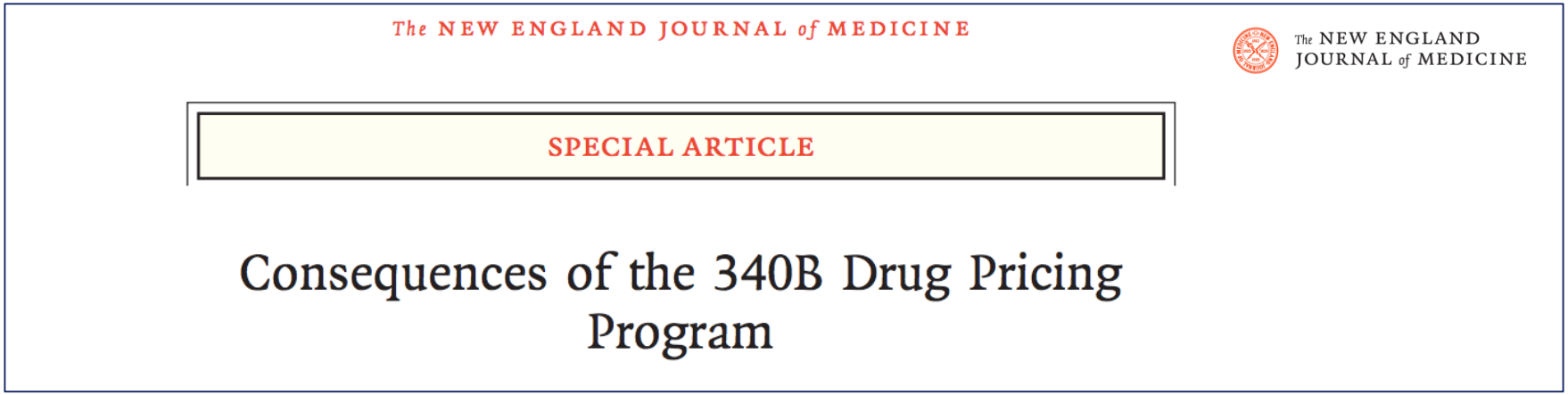


Analysis of the MarketScan Commercial Claims and Encounters D a prevalence cohort of commercially insured individuals who we physician-administered infused chemotherapy.

Results | Of the 283 502 patients initiating treatment with infused chemotherapy between 2004 and 2014, patients receiving care in physician offices were older compared with those receiving care in HOPDs (mean, 54 vs 51 years; $P < .001$) and they had a statistically, but not clinically meaningful, lower comorbidity (comorbidity score of zero: 95% in offices vs 94% in HOPDs; $P < .001$). The rate of commercially insured patients receiving infused chemotherapy in HOPDs increased from 6 % of infusions in 2004 to 43% in 2014 (**Figure 1**).

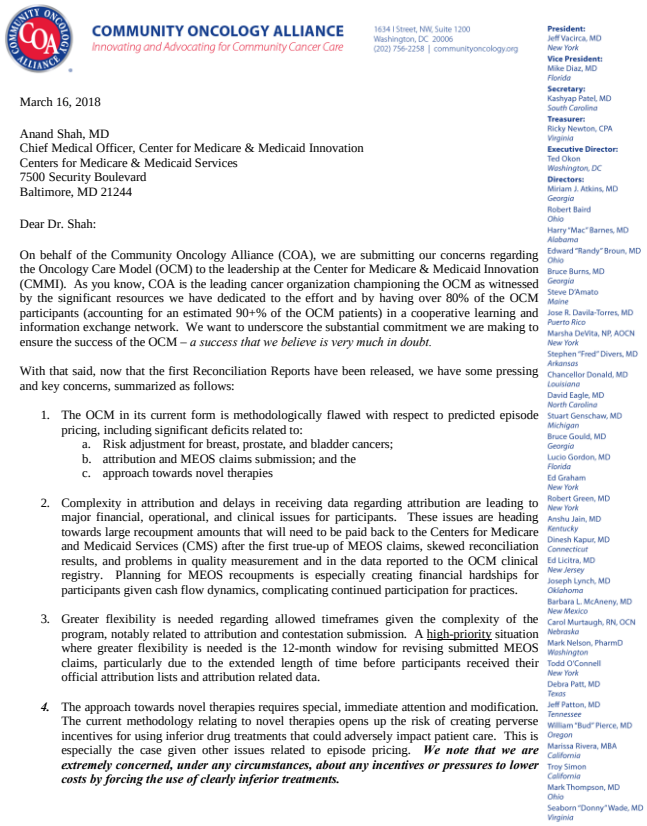
Spending at the drug level was significantly lower in offices vs in HOPDs ($1466; 95% CI, $1457-$1474 vs $3799; 95% CI, $3761-$3836; $P < .001$). Day-level spending was lower for patients treated in offices ($3502; 95% CI, $3490-$ vs $7973; 95% CI, $ Total reimbursement during the 6-month treatment-episode was also lower in offices ($43 700; 95% CI, $42 885-$44 517 vs $84 660; 95% CI, $82 969-$86 352; $P < .001$) (**Figure 2**). Sensitivity analysis on breast cancer patients found similar results.

340B Revelations



- Bombshell 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"***

Viability of the OCM?



COMMUNITY ONCOLOGY ALLIANCE
Innovating and Advocating for Community Cancer Care

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March 16, 2018

Anand Shah, MD
Chief Medical Officer, Center for Medicare & Medicaid Innovation
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Dr. Shah:

On behalf of the Community Oncology Alliance (COA), we are submitting our concerns regarding the Oncology Care Model (OCM) to the leadership at the Center for Medicare & Medicaid Innovation (CMMI). As you know, COA is the leading cancer organization championing the OCM as witnessed by the significant resources we have dedicated to the effort and by having over 80% of the OCM participants (accounting for an estimated 90+% of the OCM patients) in a cooperative learning and information exchange network. We want to underscore the substantial commitment we are making to ensure the success of the OCM – *a success that we believe is very much in doubt.*

With that said, now that the first Reconciliation Reports have been released, we have some pressing and key concerns, summarized as follows:

1. The OCM in its current form is methodologically flawed with respect to predicted episode pricing, including significant deficits related to:
   a. Risk adjustment for breast, prostate, and bladder cancers;
   b. attribution and MEOS claims submission; and the
   c. approach towards novel therapies

2. Complexity in attribution and delays in receiving data regarding attribution are leading to major financial, operational, and clinical issues for participants. These issues are heading towards large recoupment amounts that will need to be paid back to the Centers for Medicare and Medicaid Services (CMS) after the first true-up of MEOS claims, skewed reconciliation results, and problems in quality measurement and in the data reported to the OCM clinical registry. Planning for MEOS recoupments is especially creating financial hardships for participants given cash flow dynamics, complicating continued participation for practices.

3. Greater flexibility is needed regarding allowed timeframes given the complexity of the program, notably related to attribution and contestation submission. A high-priority situation where greater flexibility is needed is the 12-month window for revising submitted MEOS claims, particularly due to the extended length of time before participants received their official attribution lists and attribution related data.

4. The approach towards novel therapies requires special, immediate attention and modification. The current methodology relating to novel therapies opens up the risk of creating perverse incentives for using inferior drug treatments that could adversely impact patient care. This is especially the case given other issues related to episode pricing. ***We note that we are extremely concerned, under any circumstances, about any incentives or pressures to lower costs by forcing the use of clearly inferior treatments.***

- Problems with specific methodology flaws
  - Calculations of base cancer-specific treatment costs
- Problems with attribution and timeliness of reports
- Problems with novel therapy approaches
- Problems in understanding the "grading system"
- Is model viable?

Developing the OCM 2.0

- Evolving the OCM 1.0 and fixing structural problems
- Basic model concept sound – care coordination fee and shared savings – but implementation is flawed
- Starting when the medical oncologist gets the patient, not around some artificial 6-month "bucket"
- Focus needs to be on all cancer care costs, not just "chemotherapy"
- Include value-based models for drugs – e.g., indication and outcomes contracting
- Objective is to develop the template for an adaptable "universal" model for all payers, not just Medicare

2019 COA Conference

Thanks!!!

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