Innovating and Advocating for Community Cancer Care

NJSOM MEETING

From Capitol Hill to Bridgewater…

A Crystal Ball Look at Oncology Policy for 2017 and Beyond

Ted Okon

Bridgewater, New Jersey

1/20/2017

And the Crystal Ball Says…

- Policy environment for community oncology should be more favorable "for now"
- Oncology payment reform a reality, regardless of who is in power in DC
  - Embrace it and make it work in your practice
  - MACRA, OCM
- The drug price issue not going away
  - The incoming President won't let it go away
- 340B in hospitals will be an issue in 2017
  - Big fight brewing!
- PBMs will fight hard to control and dispense more oral cancer drugs
- Obamacare will be repealed and replaced; just a very cloudy picture of what "Trumpcare" will look like

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Why An Improved Political Environment?

- Obama Administration gave us the Part B “experiment”
  - Very unlikely the Trump Administration will follow
  - GOP very supportive in stopping it
- HHS/CMS have not been very supportive of community oncology
  - Obama Administration pressed for consolidation
- Republicans in Congress have been more supportive of our issues
  - Application of the sequester cut to Part B drug payment
  - Medicare Part B experiment
  - General consolidation of cancer care across the country
- HHS Secretary nominee Dr. Tom Price very supportive of physicians and our issues

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Oncology Payment Reform

- Private insurers have already started years ago
  - United, Aetna, Anthem, Priority, etc.
- Medicare COME HOME project already done
- Oncology Care Model (OCM) is now rolling
  - 196 practices implementing it (or trying!)
  - Payers at all different levels of readiness
- MACRA final rule out and the implementation clock is ticking
  - Need to make choices now
- Both sides of the political aisle want "value" in payment for medical services and drugs
- *Community oncology needs to be even more agressive in moving on payment reform, especially with the change in DC!!!*

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COA Oncology Care Model (OCM) Strategy

- Help practices make the OCM really work
  - Have close to 80% of the practices networked
- Provide materials to help facilitate implementation
- Created peer-to-peer information exchange
  - Dedicated listserv
  - Affinity groups
  - Meetings and calls
- Brought on very experienced experts (Kavita Patel, MD, Basit Chaudhry, MD, Laura Long, MD)
- Proactive outreach to CMMI on implementation issues and now big concerns
- Evolve the model as needed so it actually works and can be used elsewhere

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OCM Evolution to OCM 2.0

- OCM is a good start but has a ton of issues/problems
  - Trying to make it as “good” as possible in working through the deficiencies
- What would the perfect OCM-type model look like?
- OCM 2.0 is attempt to make the OCM better and to serve as a universal oncology payment reform model
  - Smooths the “rough edges” of the OCM 1.0
  - Takes a more global look at cancer treatment, not just the chemotherapy episode
  - Two variations:
    - Single sided (no practice risk)
    - Double sided (practice at risk but with a floor)

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My Thoughts on MACRA – MIPS and AAPMs

- MIPS is going to be a real crapshoot in terms of where you land
  - Can't just ignore it because a severe downside penalty (9%!) is out there in later years
  - Make a wise decision for 2017 because that's the baseline measurement year for 2019
  - Get your house (practice) in order NOW!
    - Understand what you will be measured on and put new procedures in place as needed
  - Putting your head in the sand is the worse thing you can do!
- Future of community oncology <u>may be</u> in advanced alternative payment models (AAPMs)
  - Good news is they offer 5% bonuses plus upside of the model savings
  - Bad news is you are going at risk
  - Need to incorporate actuarial expertise into your thinking
  - Can't put your head in the sand on this one either!
- MACRA may be simplified but not sure it is going away

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Drug Price Issue Front and Center

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

by Peter B. Bach, MD   SEPTEMBER 17, 2015

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Christine Rushton

Mylan CEO to Def
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By ALANA ABRAMSON
Sep 20, 2016, 6:01 PM ET

THE WALL STREET JOURNAL.

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BUSINESS | HEALTH CARE | HEALTH

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*

PROGRESSIVE IDEAS
DONATE

Drug Prices

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Act, which created Medicare's prescription drug program.

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Breaking Down the Drug Price Issue

- 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
  - Community oncology
  - Hospitals, including 340B and cancer hospitals with special Medicare exemption

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Where is Drug Price Debate Likely Heading?

- Direct or overt price controls unlikely – regardless of Trump's tweets
- Tough to imagine "negotiations" between Medicare and pharmaceutical companies on drug prices
  - Pits the Trump Administration against the GOP Congress
  - Sounds good on paper; unworkable in cancer treatment
- Possible greater regulation like the insurance industry
  - Price increases regulated and have to be approved; or are at least transparent
- Tools available to "control" prices include CMMI, IPAB, and importing from Canada (all on the books now)
- "The Art of the Deal" opening salvo just like to Carrier, Boeing, Ford, etc.

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Study on the Cost Drivers of Cancer Care

- Conducted by the actuarial firm Milliman
- Analyzed Medicare and commercial data from 2004 through 2014 to:
  - Identify trends in the overall costs of cancer care
  - Identify trends in the component costs of cancer care
  - Create comparisons between trends in costs for actively treated cancer patients and general population
  - Examine site of care cost differences
- Commissioned by COA
  - Sponsors: Bayer, Bristol-Myers Squibb, Eli Lilly and Company, Janssen Pharmaceuticals, Merck, Pfizer, PhRMA, and Takeda.

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Key Findings

- Total cancer care costs not increasing any faster than overall medical costs
  - Both for Medicare and commercial populations
- Drugs are the fastest growing component of cancer care costs but increases offset by <u>lower</u> increases in inpatient hospitalizations and cancer surgeries
  - Drug cost increases fueled by biologics
- Site of care – where cancer care delivered – shifts dramatic and also fueling increased costs of cancer care
  - $2 billion higher spending to Medicare alone in 2014

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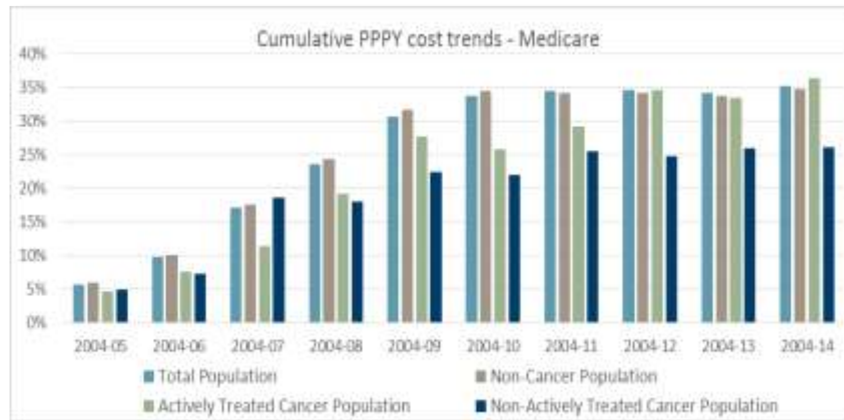
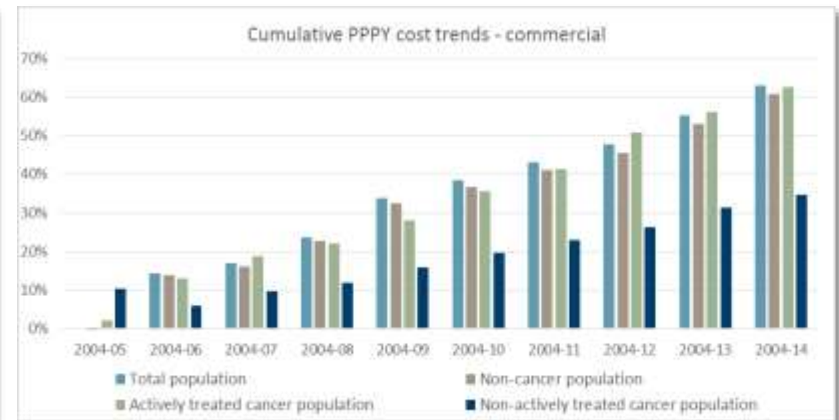
Cancer & Overall Costs Increasing at Similar Rates





- Per-patient costs increasing at similar rates throughout the study period for 3 populations:
  - Total population
  - Actively treated cancer population
  - Non-cancer population
- For Medicare, these 3 populations trended at 35.2% versus 36.4% and 34.8% respectively
- For commercial, these 3 populations trended at 62.9% versus 62.5% and 60.8%
- The 95% confidence intervals for each cohort's trend line overlap and by this measure the 10-year cost trends between these 3 populations are not statistically different.

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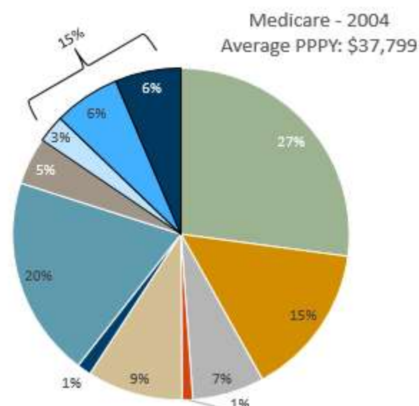
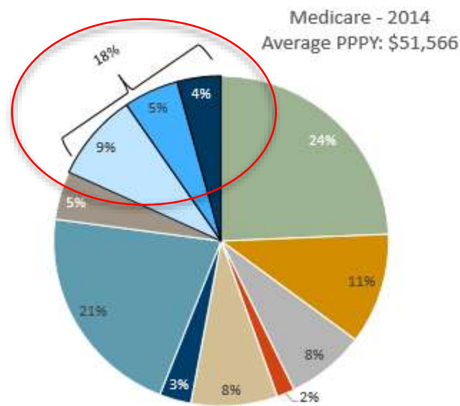
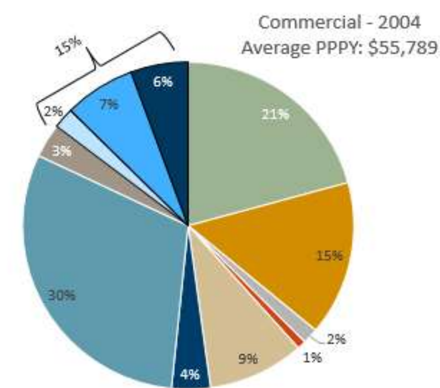
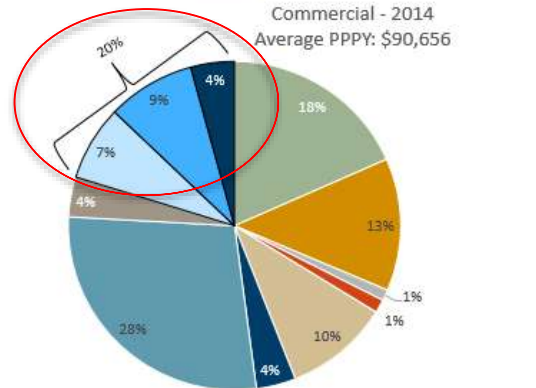
Component Cost Drivers Present a More Complex Picture Than Just Drugs









- Hospital Inpatient Admissions
- Emergency Room
- Other Outpatient Services
- Cytotoxic Chemotherapy
- Cancer Surgeries (IP and OP)
- Radiology - Other
- Professional Services
- Other Chemo and Cancer Drugs
- Sub-Acute Services
- Radiation Oncology
- Biologic Chemotherapy

- Increases in spending:
  - Chemotherapy
    - 15% to 18% in Medicare and 15% to 20% in commercial
  - Biologics
    - 3% to 9% in Medicare and 2% to 7% in commercial
- Lower rate in increased spending:
  - Hospital inpatient admissions
    - 27% to 24% in Medicare and 21% to 18% in commercial
  - Cancer surgeries
    - 15% to 11% in Medicare and 15% to 13% in commercial

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Cost Drivers Vary Over Study Period

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%**

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Substantial Shift in the Site of Care

Medicare - percent of chemotherapy infusions by site of service

84%

54%

100% 90% 80% 70% 60% 50% 40% 30% 20% 10% 0%

2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014

Physician Office | Non-340B hospital outpatient facility | 340B hospital outpatient facility

- Percent of chemotherapy administered in community oncology practices decreased from 84.2% to 54.1%
  - Cost Medicare $2 billion more in 2014 alone
- 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

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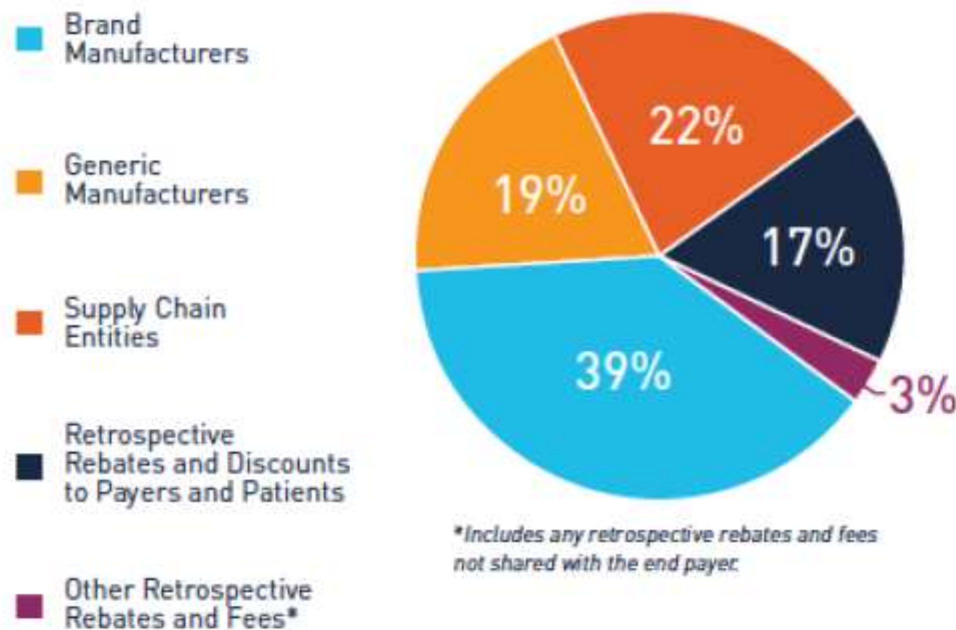
Pricing Not a Clean PIcture



Source: *The Pharmaceutical Supply Chain: Gross Drug Expenditures Realized By Stakeholders*, Berkley Research Group, January 2017

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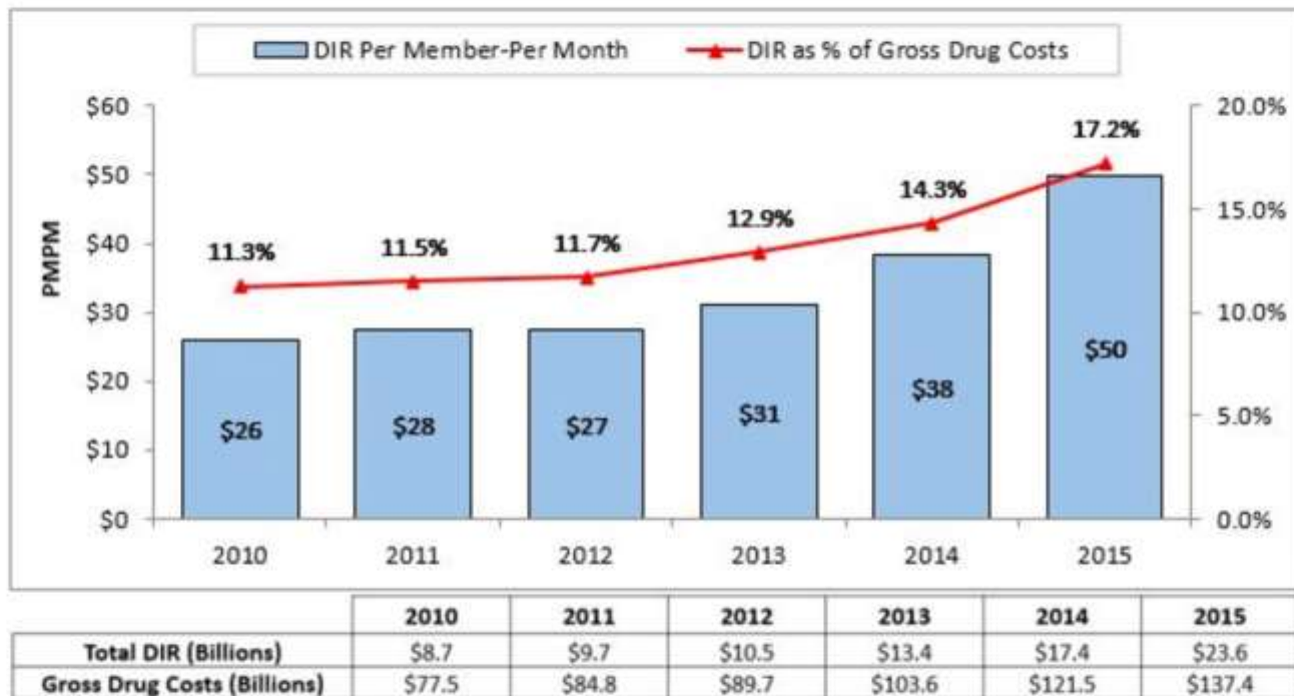
And Even Muddier!



	2010	2011	2012	2013	2014	2015
Total DIR (Billions)	$8.7	$9.7	$10.5	$13.4	$17.4	$23.6
Gross Drug Costs (Billions)	$77.5	$84.8	$89.7	$103.6	$121.5	$137.4

Source: Analysis of DIR and enrollment data from the 2016 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplemental Medical Insurance Trust Funds (CY 2016 Medicare Trustee's Report) and cost data from PDE records.

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The Medicare Part B “Experiment”

- Desperate attempt by the Obama Administration to do something about drug prices
- It’s wasn’t just another reimbursement cut
  - It was truly an experiment on patient care without any of the patient information and safeguards with any clinical research
  - It was the Executive branch stepping over the line in the Constitution that separates Executive and Legislative powers
- And it was government regulators saying they know better than oncologists on how to treat their patients
- Bolder and far worse than any previous reimbursement cut

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COA Position That Stopped the Experiment

COMMUNITY ONCOLOGY ALLIANCE

Filed electronically via http://www.regulations.gov

May 9, 2016

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: *Medicare Program; Part B Drug Payment Model* [CMS-1670-P]

Dear Acting Administrator Slavitt:

On behalf of the Board of Directors of the Community Oncology Alliance ("COA"), I am writing to submit our comments relating to the proposed rule on the *Medicare Program; Part B Drug Payment Model* [CMS-1670-P] (herein referred to as the "Part B Proposal"). For the reasons stated below, we strongly oppose the Part B Proposal and request it be withdrawn.

As COA has publically stated, and as I and other representatives from COA leadership voiced in a meeting with officials from the Centers for Medicare & Medicaid Services ("CMS") and the Center for Medicare & Medicaid Innovation ("CMMI"), we are vehemently opposed to the Part B Proposal. In short, we believe that not only is "Phase 1"[1] of the Part B Proposal (the "Part B Proposal Phase 1") an inappropriate, dangerous and perverse mandatory, national experiment on the cancer care of seniors who are covered by Medicare but also the Part B Proposal raises numerous insurmountable legal issues that have profound consequences.

We are appalled that CMS has marketed an ill-conceived attempt to control Part B drug prices by aggressively mounting a public relations campaign calling into question the motivations of oncologists. In the process, CMS has implied without basis that community oncologists are not providing their patients with the most appropriate, highest quality cancer care. CMS' questioning of the motivations of community oncologists is not productive in achieving constructive oncology payment reform.

Aside from the implications of the baseless statements by CMS, it is alarming that CMS is proposing to experiment on the cancer care provided to the nation's most vulnerable cancer patients—seniors and those individuals with disabilities covered under Medicare. Our first and foremost concern with this Part B Proposal is for our patients dealing with a terrible disease. Because of that, we intend to fight as hard for our patients to stop the Part B Proposal as we do every day for them in providing the highest quality, and most affordable, cancer care. For the sake of all of our patients—*and generations of cancer patients to come*—CMS must not proceed with

[1] Section 1115A of the Patient Protection and Affordable Care Act is divided into two parts or phases: (1) a phase 1 testing of models (referred to as phase 1); and (2) upon the completion of phase 1, an optional phase for the expansion of the duration and scope of a model being tested (referred to as phase 2). However, for the reasons discussed in this letter, the phase 1 of the Part B Proposal is not a phase 1 test as contemplated by Section 1115A.

- **Bad Medicine**
  - Few truly interchangeable drugs in oncology
  - Experiment on cancer care
  - Absolutely <u>no</u> evidence to support this experiment
- **Flawed Economics**
  - 10-year CMS experiment has consolidated care and led to higher drug prices
  - CMS adding more fuel to the fire
- **Destructive Policy**
  - CMS can overturn any law by making a CMMI model out of it
  - Unconstitutional

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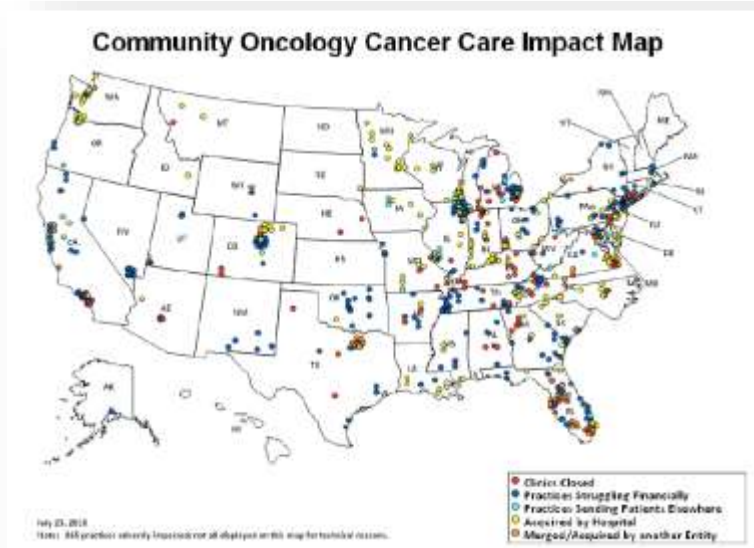
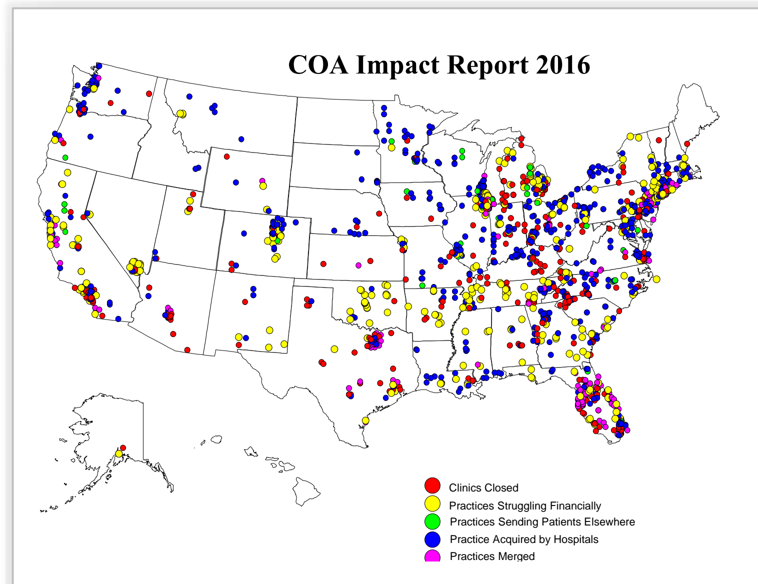
Consolidation of Cancer Care



2010



2016

Source: *Community Oncology Alliance 2016 Practice Impact Report*

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Consolidation of Cancer Care

Clinics Closed: 172, 199, 241, 288, 313, 380

Struggling Financially: 323, 369, 442, 407, 395, 390

Sending Patients Elsewhere: 44, 48, 47, 43, 46, 45

Acquired by Hospital: 224, 315, 392, 469, 544, 609

Merged or Acquired by Corporate Entity: 102, 111, 132, 131, 149, 157

7/1/10 9/1/10 11/1/10 1/1/11 3/1/11 5/1/11 7/1/11 9/1/11 11/1/11 1/1/12 3/1/12 5/1/12 7/1/12 9/1/12 11/1/12 1/1/13 3/1/13 5/1/13 7/1/13 9/1/13 11/1/13 1/1/14 3/1/14 5/1/14 7/1/14 9/1/14 11/1/14 1/1/15 3/1/15 5/1/15 7/1/15 9/1/15 11/1/15 1/1/16 3/1/16 5/1/16 7/1/16

— Clinics Closed — Struggling Financially — Sending Patients Elsewhere — Acquired by Hospital — Merged or Acquired by Corporate Entity

Source: *Community Oncology Alliance 2016 Practice Impact Report*

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What COA Did

- Involved in spearheading multiple letters from Congress to CMS
- Major national radio ad campaign supported by print and digital ads, mailers, SM targeting specific members of Congress
- Developed/hosting 2 dedicated websites for providers & patients
  - www.cancerexperiment.org
  - www.StopCMSCuts.com

- Major OpEd campaign
- Generating national and local media coverage
- Working with congressional committees on several approaches to stopping this experiment on seniors' cancer care
- 4/5 meeting with CMS/CMMI leadership
- Testified at 2 congressional hearings
- Made it an election issue with 3 major Senate campaign ads about it

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340B & Site Neutrality

- 340B in the crosshairs – Question is, “How long does the bubble expand?”
  - There is actually legislative language to increase transparency and accountability
- HOPPS final rule out implementing first step in site neutral payments
  - Result of the Bipartisan Budget Act of 2015
  - CMS held pretty firm in actually operationalizing payment cuts (50% or so)
  - Gave in on existing (grandfathered) facilities expanding services and still billing under hospital fees
  - Hospitals fought to get some relief in the CURES bill passed last Congress
  - More push-back on hospital consolidation of practices and financial impact at federal and state levels

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PBM/Specialty Pharmacy Issues

- CVS Caremark moved to shift all dispensing practices to "out of network" for Medicare Advantage plans effective January 2017
  - Indications were that Express Scripts was ready to follow CVS lead
  - Massive practice, media, and state/federal legislative effort stopped CVS
  - COA not letting up on this and related issues
- Absurd (<u>and I mean ABSURD!</u>) DIR fees
  - Charge what they want, how they want, when they want
- Express Scripts tightening "formulary" access to treatments and steering business to Accredo
- With more oral oncolytics coming out of the pharma R&D pipeline, expect more attempts to capture this business
  - They will go after not only dispensing practices but those with retail pharmacies
  - *Profits before mankind!*

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What is COA Doing?

- Hired legal firm specializing in pharmacy issues to fight for community oncology
  - Legal letter to CVS
  - White paper on PBMs featuring CVS decision
  - State and federal congressional outreach on CVS
  - Patient outreach on CVS
  - DIR white paper almost completed
  - Legal letter sent to Express Scripts this week
  - Survey practices on how they are impacted (DIR fees, formularies)
  - More

CMS Report on DIR (Versus DIR Fees)

Medicare Part D – Direct and Indirect Remuneration (DIR)

Date	2017-01-19
Title	Medicare Part D – Direct and Indirect Remuneration (DIR)
Contact	press@cms.hhs.gov

Medicare Part D – Direct and Indirect Remuneration (DIR)

Under Medicare Part D, Medicare makes partially capitated payments to private insurers, also known as Part D sponsors, for delivering prescription drug benefits to Medicare beneficiaries. Medicare relies on transaction data reported by Part D sponsors to make sure these payments are accurate. Often, the Part D sponsor or its pharmacy benefits manager (PBM) receives additional compensation after the point-of-sale that serves to change the final cost of the drug for the payer, or the price paid to the pharmacy for the drug. Examples of such compensation include rebates provided by manufacturers and concessions paid by pharmacies. Under Medicare Part D, this post point-of-sale compensation is called Direct and Indirect Remuneration (DIR) and is factored into CMS's calculation of final Medicare payments to Part D plans.

Total DIR reported by Part D sponsors has been growing significantly in recent years. Part D sponsors and PBMs are engaging to a greater extent in arrangements that feature compensation after the point-of-sale, and the value of such compensation is also generally increasing. As a result, CMS has observed a growing disparity between gross Part D drug costs, calculated based on costs of drugs at the point-of-sale, and net Part D drug costs, which account for all DIR.

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The Obamacare Crisis in 2 Pictures

Obamacare price hikes vary from state to state

How average monthly premiums for a 27-year-old buying the second-lowest cost silver plan will change in 2017 from 2016:

Up to 10% | 10-20% | 20-40% | 40% or more | No data

Data not available for all states. California averages are calculated by region while other states are calculated by county.

Source: Department of Health and Human Services   WASHINGTON POST

Obamacare's marketplaces have become less competitive since 2014

Number of ACA insurers available

no data | 0 | 1 | 2 | 3+

Sources: *Washington Post & Vox.com*

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Dismantling of Obamacare

- GOP majority Congress passed “budget reconciliation” bills (Senate and House) setting up repeal and replace
  - Reconciliation only requires majority vote in the Senate (and House)
  - Ironically, Congress used reconciliation to pass Obamacare
- Unclear as to the timing of repeal
  - Growing calls among the GOP to not repeal until a replacement is ready
  - All variations of “replace” plans but no clear path forward at this time
  - Trump tweets about replace immediately & “universal coverage” muddying the picture
- CBO scored repeal bill as causing 18 million to lose insurance in first year and premiums rising 20-25% in the non-group market
  - Catch is score included no replacement

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Clarification From VP Elect Pence

- "Orderly transition out of Obamacare"
- Pass a replacement bill that will lower cost of health insurance and make it more affordable
- Trump Administration is "very close" to completing a replacement plan with congressional leadership
- Replacement plan passed near simultaneously with repeal
- Stay tuned!

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Trick Repealing/Replacing Obamacare

- Obamacare simply ingrained in the healthcare system
- Aspects of Obamacare are liked
  - Overcoming preexisting conditions, annual/lifetime caps
  - Having children up to 26 on parents' policies
- Big dilemma is how to overcome the mandate
  - Mandating people have insurance OR pay a penalty drives the positive score (economics) on Obamacare
  - One solution is for automatic insurance enrollment
    - Op out if you don't want it
    - What's the difference?
    - Not the Republican way
- Do Republicans take the opportunity to touch Medicare?

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Cancer Moonshot???

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COA 2017 Priorities

- Legislative focus
  - Sequester cut to Part B drug payment
  - Oncology payment reform
  - 340B and site payment parity
  - PBM issues
    - DIR fees
    - Steerage
- Advance oncology payment reform
  - OCM changes
  - OCM 2.0
- Ramp up patient advocacy

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2017 Community Oncology Conference

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GAYLORD NATIONAL RESORT & CONFERENCE CENTER
APRIL 27-28

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Thank You!

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