Innovating and Advocating for Community Cancer Care

COMMUNITY ONCOLOGY CONFERENCE

From Capitol Hill to Orlando & the Advocates

How National Policy Issues Affect Your Local Cancer Care

Ted Okon
Orlando, Florida
4/14/2016

Medicare Part B Drug Payment ”Model”

- The government agency running Medicare (CMS) proposing a new “model” on how to pay for drugs needing to be administered under close physician supervision
- Government believes it knows better than physicians what drugs should be used to treat cancer and other diseases
- “Model” will carve up the country by zip codes to ”test” the impact of drastically lower payment rates for cancer drugs
- Government using a financial “stick” to push use of lower priced drugs, even in not most appropriate
- Set up as a true experiment on patient care but no patient safeguards or “informed consent”

Step Back – What is the Government Saying?

- Oncologists are not prescribing the “right” treatment for their patients
  - Clear from the aggressive CMS PR campaign backing introduction of the “model”
    - Oncologists are clearly motivated to prescribe the most expensive drug, not the right drug for the right patient
- Government will “fix” this by disincentivizing selection of higher cost therapies
  - It will use a financial ”stick”
- This needs to be a “model” that tests the CMS beliefs
  - Yet, a forced (mandatory) lower payment for 3/4s of the country
  - Yet, no evidence of the CMS beliefs
    - Evidence to the contrary that CMS is in fact incorrect
- CMS says important to “preserve or enhance” quality
  - Yet, no quality measures or patient safeguards in phase 1
- ”Value” best determined by the government
  - Is this the road to UK NICE and restricting patient access to drugs based on government determination of value?

Clear Evidence CMS Beliefs are Wrong

Changing Physician Incentives for Affordable, Quality Cancer Care: Results of an Episode Payment Model

By Lee N. Newcomer, MD, Bruce Gould, MD, Ray D. Page, DO, PhD, Sheila A. Donelan, MS, and Monica Perkins, PhD

UnitedHealthcare, Minnetonka, MN; Northwest Georgia Oncology Centers, Marietta, GA; and Center for Blood and Cancer Disorders, Fort Worth, TX

Abstract

Purpose: This study tested the combination of an episode payment coupled with actionable use and quality data as an incentive to improve quality and reduce costs.

Methods: Medical oncologists were paid a single fee, in lieu of any drug margin, to treat their patients. Chemotherapy medications were reimbursed at the average sales price, a proxy for actual cost.

Results: Five volunteer medical groups were compared with a large national payer registry of fee-for-service patients with cancer to examine the difference in cost before and after the initiation of the payment change. Between October 2009 and December 2012, the five groups treated 810 patients with breast, colon, and lung cancer using the episode payments. The registry-predicted fee-for-service cost of the episodes cohort was $98,121,388, but the actual cost was $64,760,116. The predicted cost of chemotherapy drugs was $7,519,504, but the actual cost was $20,979,417. There was no difference between the groups on multiple quality measures.

Conclusion: Modifying the current fee-for-service payment system for cancer therapy with feedback data and financial incentives that reward outcomes and cost efficiency resulted in a significant total cost reduction. Eliminating existing financial chemotherapy drug incentives paradoxically increased the use of chemotherapy.

Introduction

The cost of health care in the United States is on an unsustainable trajectory. Using current trends, economists predict that in less than 3 years, it will require 50% of the average U.S. household income to pay the costs of out-of-pocket expenses and the health insurance premium for a family.[1] Cancer therapy is a contributor to these rising costs; it accounts for 11% of UnitedHealthcare's commercial health plan budget, and the proportionate share is rising. The existing fee-for-service payment provides theoretical incentives for overuse and the selection of expensive branded drugs rather than lower cost generic medications. New payment models that reward cost-effective and high-quality treatment are needed.

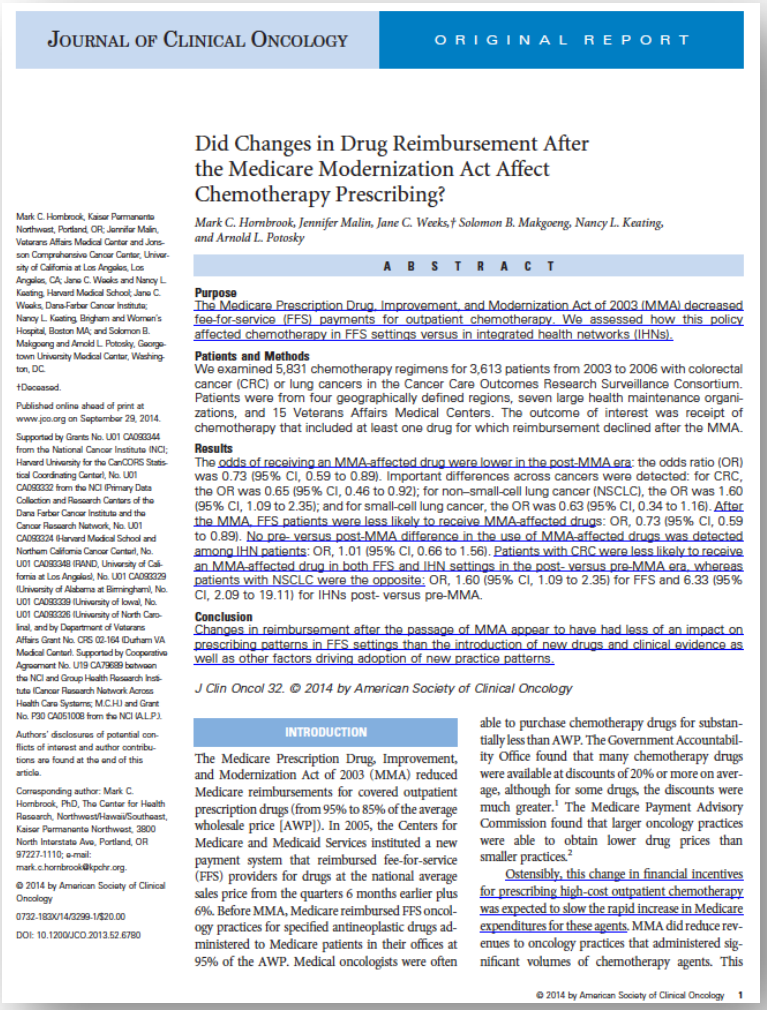
One approach for cost reduction is to reduce the payment amount for each service. After Medicare decreased the reimbursement levels for drugs in 2005, an analysis of patients with lung cancer revealed that oncologists treated more patients with chemotherapy and increased the usage of expensive drugs.[2] The effect on quality was not measured. Medicare continues to experience increases in cancer costs, probably caused by factors like the introduction of new expensive drugs and increased numbers of beneficiaries.

Another potential solution to rising costs is paying for care by the episode. Medicare has used this approach for hospital care for more than a decade with the Diagnosis Related Groupers, but the method has not been tested for chronic illness care in an ambulatory setting. Proponents argue that a fixed payment for a defined time period provides the incentive to become more efficient while limiting the provider risk to a manageable sum of money. Bach et al[3] proposed a payment model for cancer therapy that uses the monthly national average chemotherapy cost for each cancer type as the basis for the episode payment. This proposed system would require physicians to use lower cost regimens to remain profitable. Further, it would provide an incentive for pharmaceutical firms to reduce the prices of any medications that exceed the episode payment budget amount.

The Bach proposal attacks drug costs, but it has no effect on other cost categories for cancer care. UnitedHealthcare data suggest that these other categories are significant. For commercially insured patients, chemotherapy drugs represent 24% of total care costs, inpatient and outpatient facility services account for 54%, and physician services constitute the remaining 22%. In a previous article, Newcomer proposed a payment method that removes any adverse incentive to use expensive pharmaceuticals while simultaneously creating an incentive to reduce the total costs of care and improve outcomes.[4] The program included a quality improvement approach that mandated an annual review and discussion of use and quality data. This article reports the results of a 3-year trial of this program.

Methods

UnitedHealthcare collaborated with five volunteer medical oncology groups for the pilot. The program changed four elements of the previous fee-for-service contract relationship. First, the medical groups proactively registered all patients with breast, colon, and lung cancer and provided clinical data to the payer. Second, a single episode payment was made at the initial visit. The method for calculating this payment is described below. Third, all drugs were paid using the average sales price rate



JOURNAL OF CLINICAL ONCOLOGY ORIGINAL REPORT

Did Changes in Drug Reimbursement After the Medicare Modernization Act Affect Chemotherapy Prescribing?

Mark C. Hornbrook, Jennifer Malin, Jane C. Weeks,† Solomon B. Makgoeng, Nancy L. Keating, and Arnold L. Potosky

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Authors' disclosures of potential conflicts of interest and author contributions are found at the end of this article.

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ABSTRACT

Purpose

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) decreased fee-for-service (FFS) payments for outpatient chemotherapy. We assessed how this policy affected chemotherapy in FFS settings versus in integrated health networks (IHNs).

Patients and Methods

We examined 5,831 chemotherapy regimens for 3,613 patients from 2003 to 2006 with colorectal cancer (CRC) or lung cancers in the Cancer Care Outcomes Research Surveillance Consortium. Patients were from four geographically defined regions, seven large health maintenance organizations, and 15 Veterans Affairs Medical Centers. The outcome of interest was receipt of chemotherapy that included at least one drug for which reimbursement declined after the MMA.

Results

The odds of receiving an MMA-affected drug were lower in the post-MMA era: the odds ratio (OR) was 0.73 (95% CI, 0.59 to 0.89). Important differences across cancers were detected: for CRC, the OR was 0.65 (95% CI, 0.46 to 0.92); for non–small-cell lung cancer (NSCLC), the OR was 1.60 (95% CI, 1.09 to 2.35); and for small-cell lung cancer, the OR was 0.63 (95% CI, 0.34 to 1.16). After the MMA, FFS patients were less likely to receive MMA-affected drugs: OR, 0.73 (95% CI, 0.59 to 0.89). No pre- versus post-MMA difference in the use of MMA-affected drugs was detected among IHN patients: OR, 1.01 (95% CI, 0.66 to 1.56). Patients with CRC were less likely to receive an MMA-affected drug in both FFS and IHN settings in the post- versus pre-MMA era, whereas patients with NSCLC were the opposite: OR, 1.60 (95% CI, 1.09 to 2.35) for FFS and 6.33 (95% CI, 2.09 to 19.11) for IHNs post- versus pre-MMA.

Conclusion

Changes in reimbursement after the passage of MMA appear to have had less of an impact on prescribing patterns in FFS settings than the introduction of new drugs and clinical evidence as well as other factors driving adoption of new practice patterns.

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INTRODUCTION

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) reduced Medicare reimbursements for covered outpatient prescription drugs (from 95% to 85% of the average wholesale price [AWP]). In 2005, the Centers for Medicare and Medicaid Services instituted a new payment system that reimbursed fee-for-service (FFS) providers for drugs at the national average sales price from the quarters 6 months earlier plus 6%. Before MMA, Medicare reimbursed FFS oncology practices for specified antineoplastic drugs administered to Medicare patients in their offices at 95% of the AWP. Medical oncologists were often able to purchase chemotherapy drugs for substantially less than AWP. The Government Accountability Office found that many chemotherapy drugs were available at discounts of 20% or more on average, although for some drugs, the discounts were much greater.[1] The Medicare Payment Advisory Commission found that larger oncology practices were able to obtain lower drug prices than smaller practices.[2]

Ostensibly, this change in financial incentives for prescribing high-cost outpatient chemotherapy was expected to slow the rapid increase in Medicare expenditures for these agents. MMA did reduce revenues to oncology practices that administered significant volumes of chemotherapy agents. This

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Likely Impact on Patients & Their Care

- Pressure to get the lower cost therapy, not necessarily the best therapy
- Moving towards one-size therapy fits all; not personalized or precise
- Value for the masses; rather than for the person
- Will likely end up being treated in the outpatient hospital setting
  - Higher cost for patient, Medicare, and taxpayers

Contrast OCM to Part B Payment Model

- Oncology Care Model
  - Developed over a 3-year period
  - Extensive expert input
    - MITRE & Brookings
  - Provider & patient input
  - Voluntary
  - Limited in scope (100 practices)
  - Extensive quality measures
  - Cooperative, transparent process
  - Thoughtful & thorough
- Part B Drug Payment Model
  - Appeared out of thin air
    - No notice except for error in contractor posting
  - No expert input
  - No provider or patient input
  - Mandatory
  - National
  - Secretive

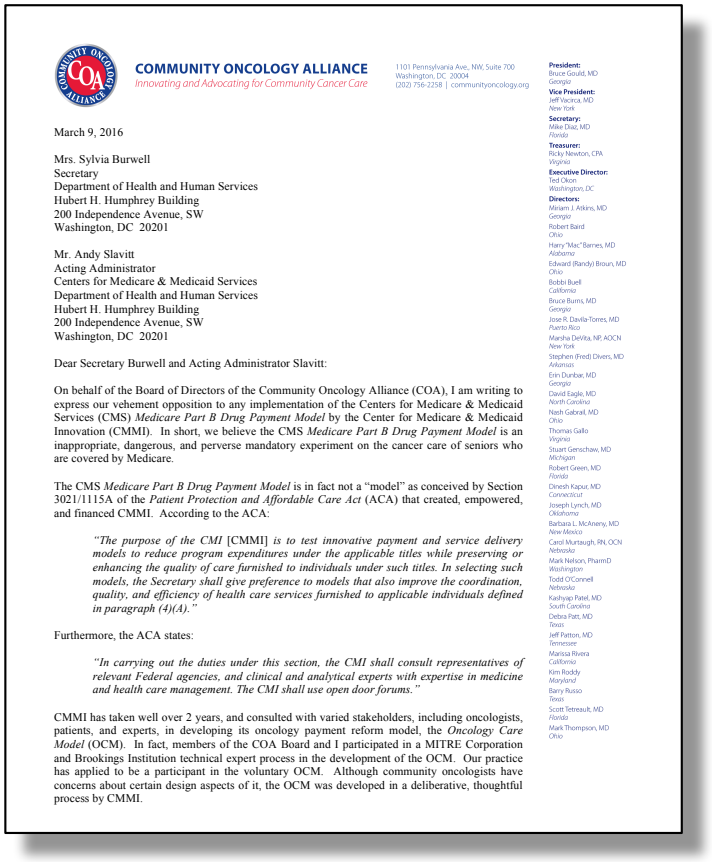
Politics Surrounding the Experiment

- This all comes from the White House
  - Using Executive Branch power to trump (no pun intended) Congress
  - Have told Democrats in Congress to stand down
- Republicans are furious
  - Witness strong Hatch, Upton, and Brady response morning after
  - More executive action over Congress
    - Sets a really bad precedent
  - Another way to attack Obamacare
- There will be a bill to stop this and letter to CMS
  - Question is will it be bipartisan or partisan?

Why Everyone Should Be Very Scared!!!

- This is a nightmare that must be stopped
  - CMS is circumventing law (2003 law establishes Medicare payment for cancer care)
    - If they do it here they can do it with any Medicare law
  - CMS is inserting the government between physician and patient
  - This sets the stage for the government to define value in cancer care
  - We have so much promise with personalized cancer care coming of age but this is cookie-cutter cancer care
  - Who do you want treating you?
    - Your oncologist or the government?
- This is not just about Medicare
  - Insurance companies follow the Medicare lead

COA Position



COMMUNITY ONCOLOGY ALLIANCE
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March 9, 2016

Mrs. Sylvia Burwell
Secretary
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

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

Dear Secretary Burwell and Acting Administrator Slavitt:

On behalf of the Board of Directors of the Community Oncology Alliance (COA), I am writing to express our vehement opposition to any implementation of the Centers for Medicare & Medicaid Services (CMS) *Medicare Part B Drug Payment Model* by the Center for Medicare & Medicaid Innovation (CMMI). In short, we believe the CMS *Medicare Part B Drug Payment Model* is an inappropriate, dangerous, and perverse mandatory experiment on the cancer care of seniors who are covered by Medicare.

The CMS *Medicare Part B Drug Payment Model* is in fact not a "model" as conceived by Section 3021/1115A of the *Patient Protection and Affordable Care Act* (ACA) that created, empowered, and financed CMMI. According to the ACA:

> *"The purpose of the CMI* [CMMI] *is to test innovative payment and service delivery models to reduce program expenditures under the applicable titles while preserving or enhancing the quality of care furnished to individuals under such titles. In selecting such models, the Secretary shall give preference to models that also improve the coordination, quality, and efficiency of health care services furnished to applicable individuals defined in paragraph (4)(A)."*

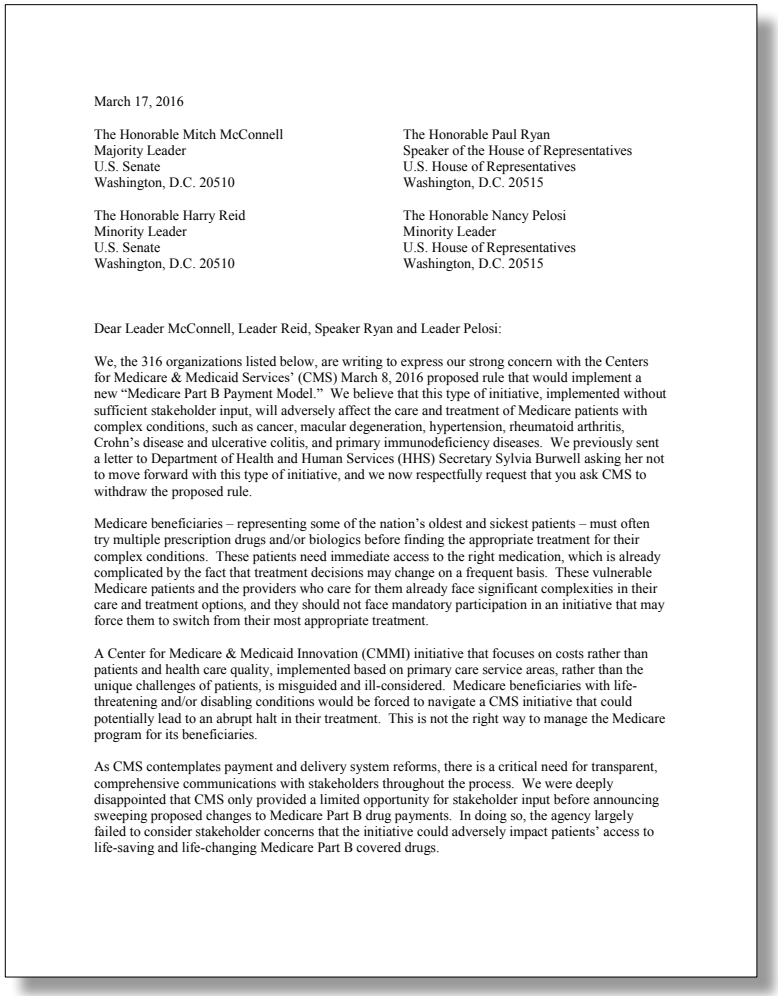
Furthermore, the ACA states:

> *"In carrying out the duties under this section, the CMI shall consult representatives of relevant Federal agencies, and clinical and analytical experts with expertise in medicine and health care management. The CMI shall use open door forums."*

CMMI has taken well over 2 years, and consulted with varied stakeholders, including oncologists, patients, and experts, in developing its oncology payment reform model, the *Oncology Care Model* (OCM). In fact, members of the COA Board and I participated in a MITRE Corporation and Brookings Institution technical expert process in the development of the OCM. Our practice has applied to be a participant in the voluntary OCM. Although community oncologists have concerns about certain design aspects of it, the OCM was developed in a deliberative, thoughtful process by CMMI.

- Terrible patient care
  - Experiment on cancer care
  - Absolutely no evidence to support this experiment
- Terrible path forward
  - One size fits all medicine
  - Government inserting itself between physician and patient
- Terrible policy precedent
  - CMS can overturn any law by making a CMMI model out of it

Letter to Congress from 316 Organizations



March 17, 2016

The Honorable Mitch McConnell
Majority Leader
U.S. Senate
Washington, D.C. 20510

The Honorable Paul Ryan
Speaker of the House of Representatives
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Harry Reid
Minority Leader
U.S. Senate
Washington, D.C. 20510

The Honorable Nancy Pelosi
Minority Leader
U.S. House of Representatives
Washington, D.C. 20515

Dear Leader McConnell, Leader Reid, Speaker Ryan and Leader Pelosi:

We, the 316 organizations listed below, are writing to express our strong concern with the Centers for Medicare & Medicaid Services' (CMS) March 8, 2016 proposed rule that would implement a new "Medicare Part B Payment Model." We believe that this type of initiative, implemented without sufficient stakeholder input, will adversely affect the care and treatment of Medicare patients with complex conditions, such as cancer, macular degeneration, hypertension, rheumatoid arthritis, Crohn's disease and ulcerative colitis, and primary immunodeficiency diseases. We previously sent a letter to Department of Health and Human Services (HHS) Secretary Sylvia Burwell asking her not to move forward with this type of initiative, and we now respectfully request that you ask CMS to withdraw the proposed rule.

Medicare beneficiaries – representing some of the nation's oldest and sickest patients – must often try multiple prescription drugs and/or biologics before finding the appropriate treatment for their complex conditions. These patients need immediate access to the right medication, which is already complicated by the fact that treatment decisions may change on a frequent basis. These vulnerable Medicare patients and the providers who care for them already face significant complexities in their care and treatment options, and they should not face mandatory participation in an initiative that may force them to switch from their most appropriate treatment.

A Center for Medicare & Medicaid Innovation (CMMI) initiative that focuses on costs rather than patients and health care quality, implemented based on primary care service areas, rather than the unique challenges of patients, is misguided and ill-considered. Medicare beneficiaries with life-threatening and/or disabling conditions would be forced to navigate a CMS initiative that could potentially lead to an abrupt halt in their treatment. This is not the right way to manage the Medicare program for its beneficiaries.

As CMS contemplates payment and delivery system reforms, there is a critical need for transparent, comprehensive communications with stakeholders throughout the process. We were deeply disappointed that CMS only provided a limited opportunity for stakeholder input before announcing sweeping proposed changes to Medicare Part B drug payments. In doing so, the agency largely failed to consider stakeholder concerns that the initiative could adversely impact patients' access to life-saving and life-changing Medicare Part B covered drugs.

- Letter to congressional leadership
- Intent is to show broad support among varied organizations
- Soften up Democrats to break ranks with the White House

We Need Advocates Engaged NOW!!!

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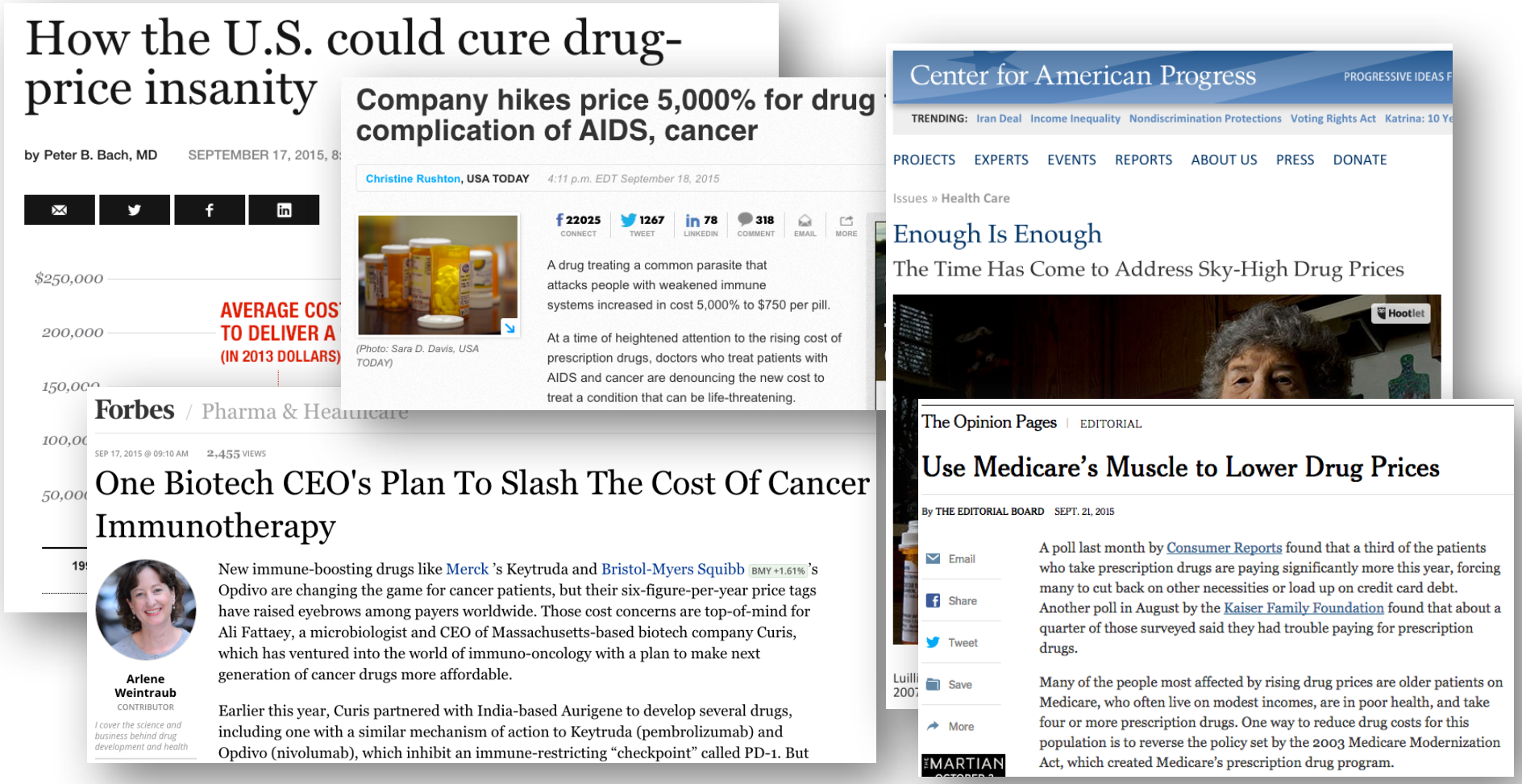
Drug Price Issue Front and Center



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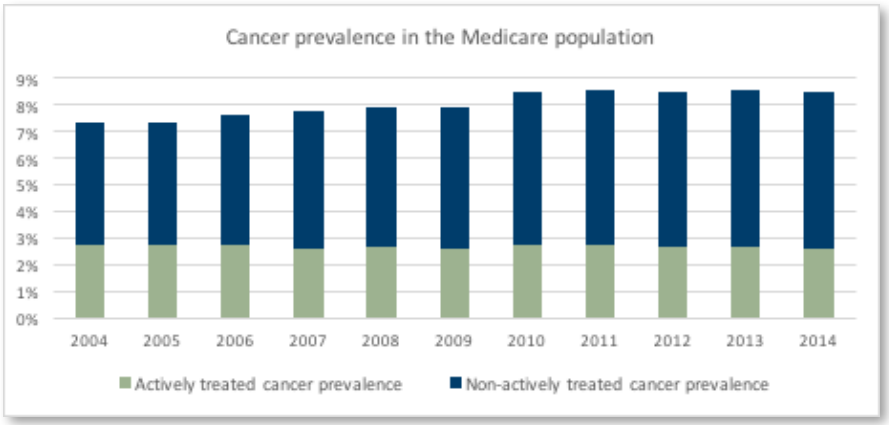
Study on the Cost Drivers of Cancer Care

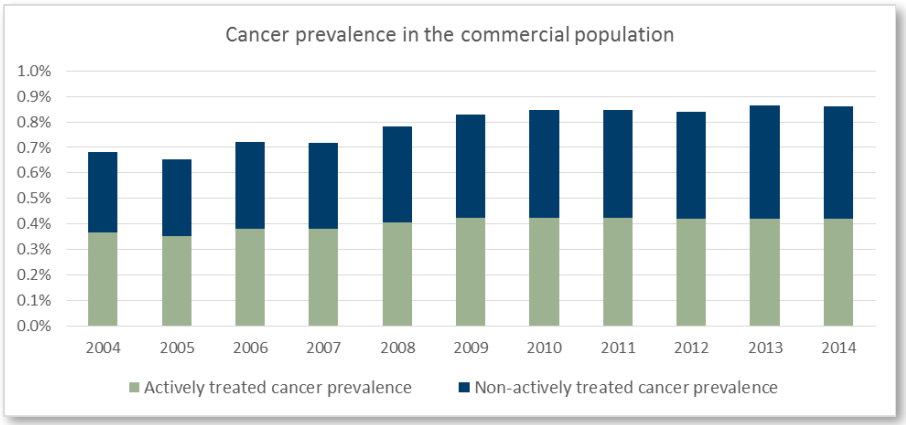
- Conducted by the actuarial firm Milliman
- Analyzed Medicare and commercial data from 2004 through 2014 to:
  - Identify trends in the overall costs of cancer care
  - Identify trends in the component costs of cancer care
  - Create comparisons between trends in costs for actively treated cancer patients 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.

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 decreases in inpatient hospitalizations and cancer surgeries
  - Drug cost increases fueled by biologics
- Site of care – where cancer care delivered – shifts dramatic and fueling increased costs of cancer care
  - $2 billion more in chemotherapy alone to Medicare alone in 2014

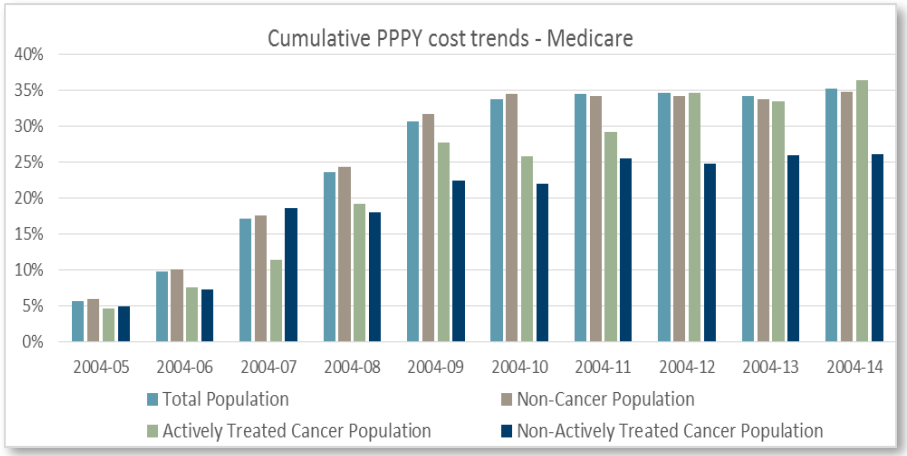
Cancer Prevalence Increasing

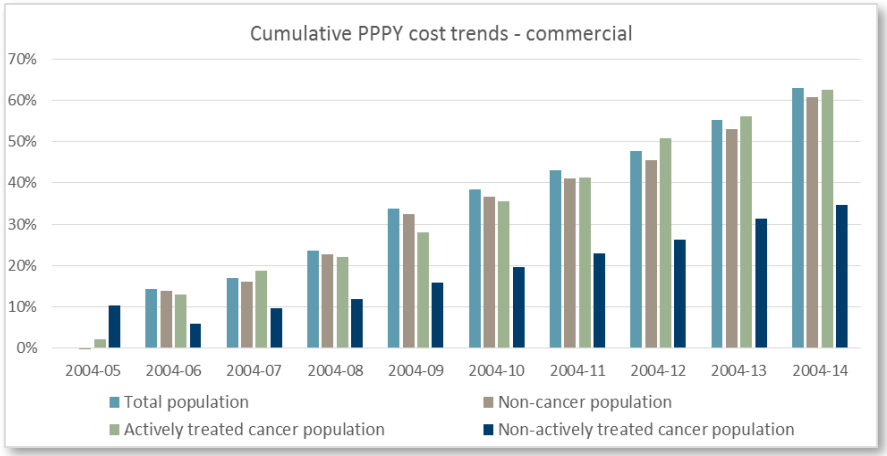




- In the Medicare population, prevalence increased from 7.3% to 8.5% between 2004 and 2014, a 16% increase.
- In the commercial population, prevalence increased from 0.7% to 0.9% between 2004 and 2014, a 26% increase.

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.

Total Spending for Cancer Patients Has Increased Less Than Prevalence

Medicare FFS Population	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Non-cancer	80.5%	80.7%	80.5%	80.5%	80.4%	80.6%	80.0%	79.4%	79.2%	79.3%	79.2%
Cancer	19.5%	19.3%	19.5%	19.5%	19.6%	19.4%	20.0%	20.6%	20.8%	20.7%	20.8%
Actively treated	*11.6%*	*11.3%*	*11.3%*	*10.4%*	*10.9%*	*10.7%*	*11.0%*	*11.3%*	*11.4%*	*11.1%*	*11.2%*
Non-actively treated	*7.9%*	*7.9%*	*8.2%*	*9.1%*	*8.7%*	*8.7%*	*9.1%*	*9.4%*	*9.3%*	*9.6%*	*9.5%*

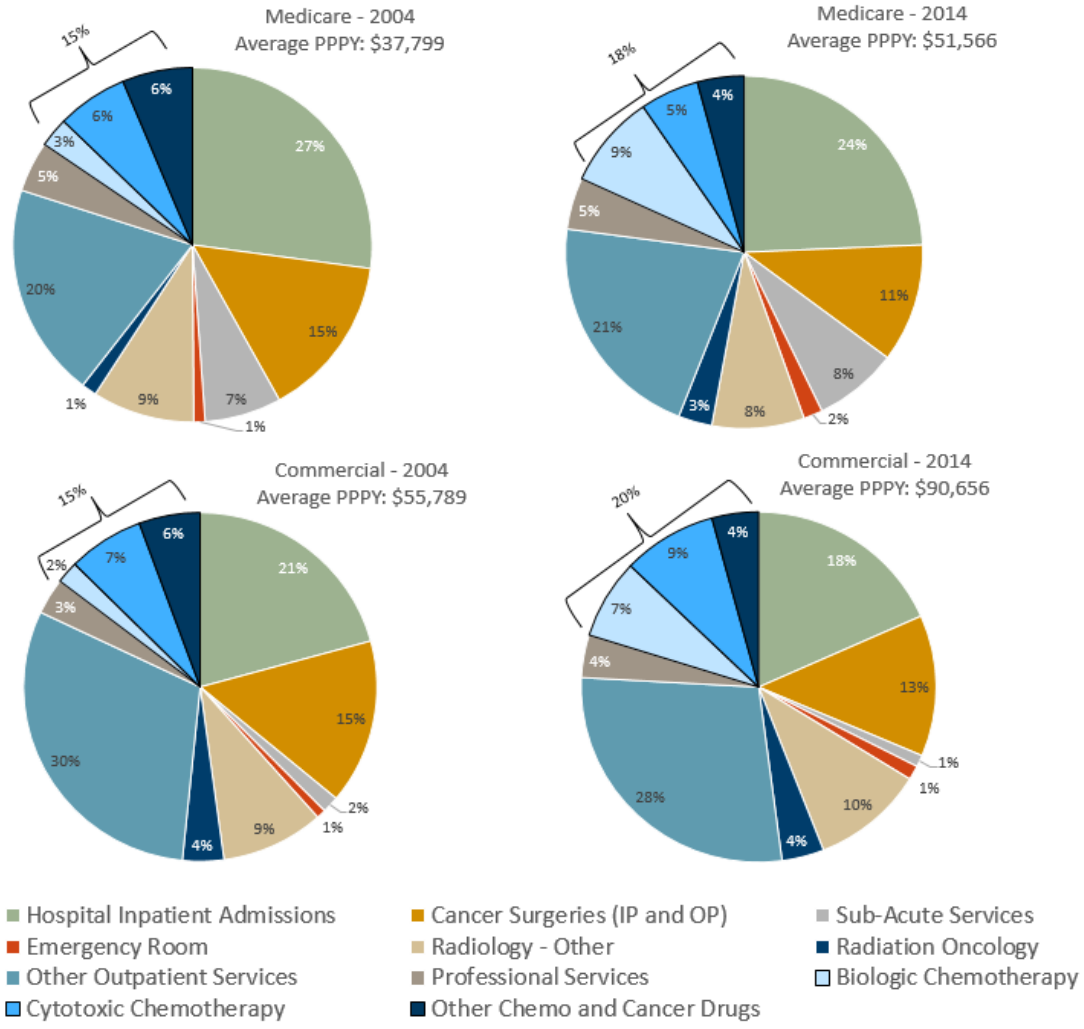
Source: Based on Milliman analysis of the 2004-2014 Medicare 5% sample data

Commercially Insured Population	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Non-cancer	90.6%	90.5%	90.3%	90.0%	89.7%	89.7%	89.4%	89.3%	89.2%	89.1%	89.3%
Cancer	9.4%	9.5%	9.7%	10.0%	10.3%	10.3%	10.6%	10.7%	10.8%	10.9%	10.7%
Actively treated	*7.4%*	*7.3%*	*7.7%*	*7.9%*	*8.1%*	*8.1%*	*8.3%*	*8.4%*	*8.5%*	*8.5%*	*8.4%*
Non-actively treated	*2.0%*	*2.1%*	*2.0%*	*2.0%*	*2.2%*	*2.2%*	*2.3%*	*2.3%*	*2.3%*	*2.4%*	*2.3%*

Source: Based on Milliman analysis of the 2004-2014 Truven MarketScan data

- Over the same period, the prevalence of cancer (actively treated and non-actively treated) increased at a higher rate than the increase in the spending contribution
  - Prevalence from 7.3% to 8.5% (**16.4% increase**) and spending **6.5% increase** in the Medicare population
  - Prevalence 0.7% to 0.9% (**28.6% increase**) and spending **13.8% increase** in the commercially insured population

Component Cost Drivers Present a More Complex Picture Than Just Drugs



- 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
- Decreases in 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

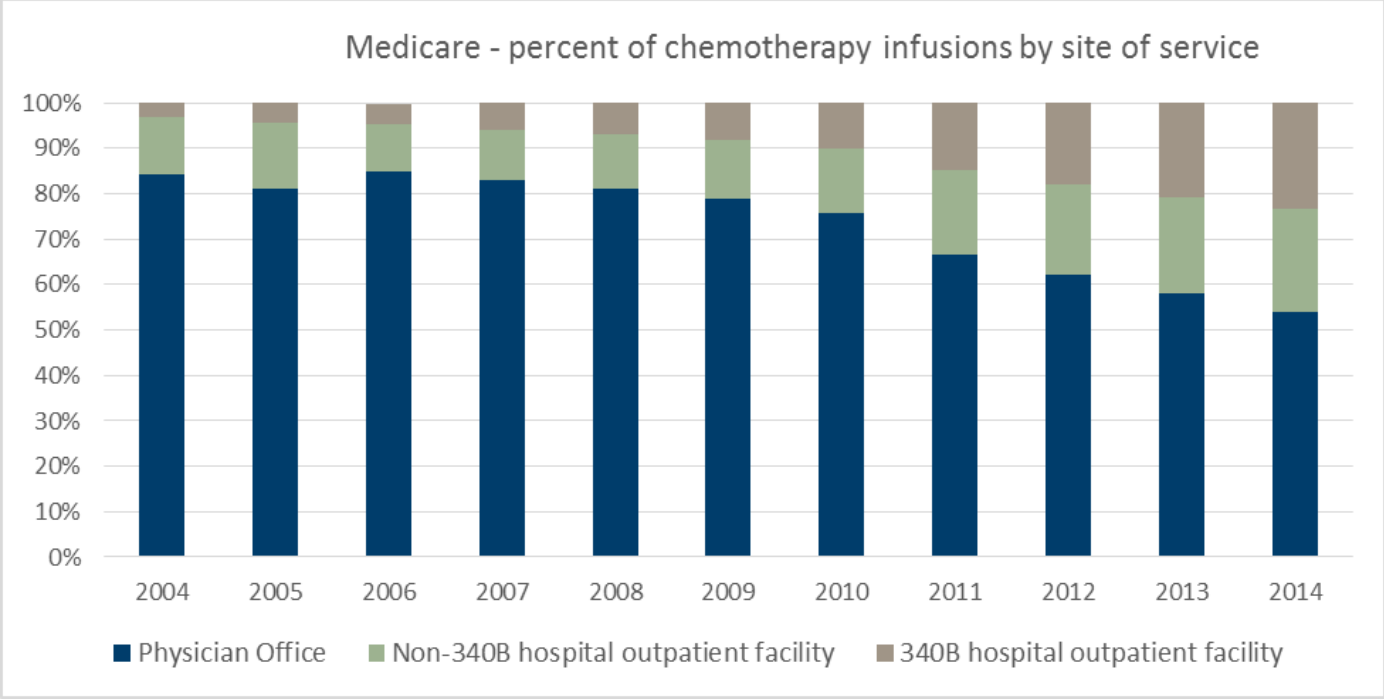
Cost Drivers Vary Over Study Period

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%**

Cost Varies by Cancer Type

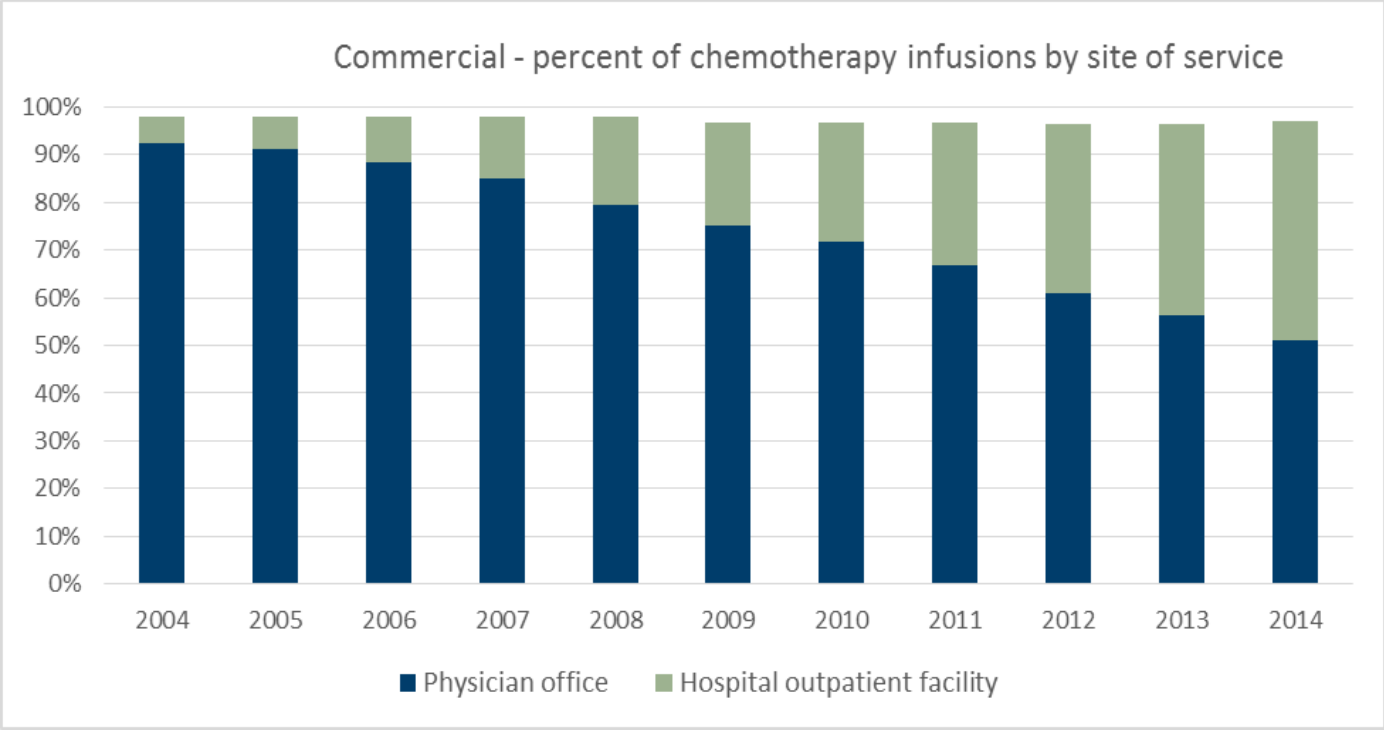
Cancer Type	2004-2014 PPPY Cost Trends	
	Medicare	Commercial
Blood	53%	73%
Breast	36%	71%
Colon	28%	65%
Lung	21%	59%
Non-Hodgkin's Lymphoma	34%	69%
Pancreatic	25%	54%
Prostate	39%	79%
Other	22%	58%
Total: All Cancers	**36%**	**62%**

Substantial Shift in the Site of Care



- Percent of chemotherapy administered in community oncology practices decreased from 84.2% to 44.1%
- 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

Same Pattern in Commercial



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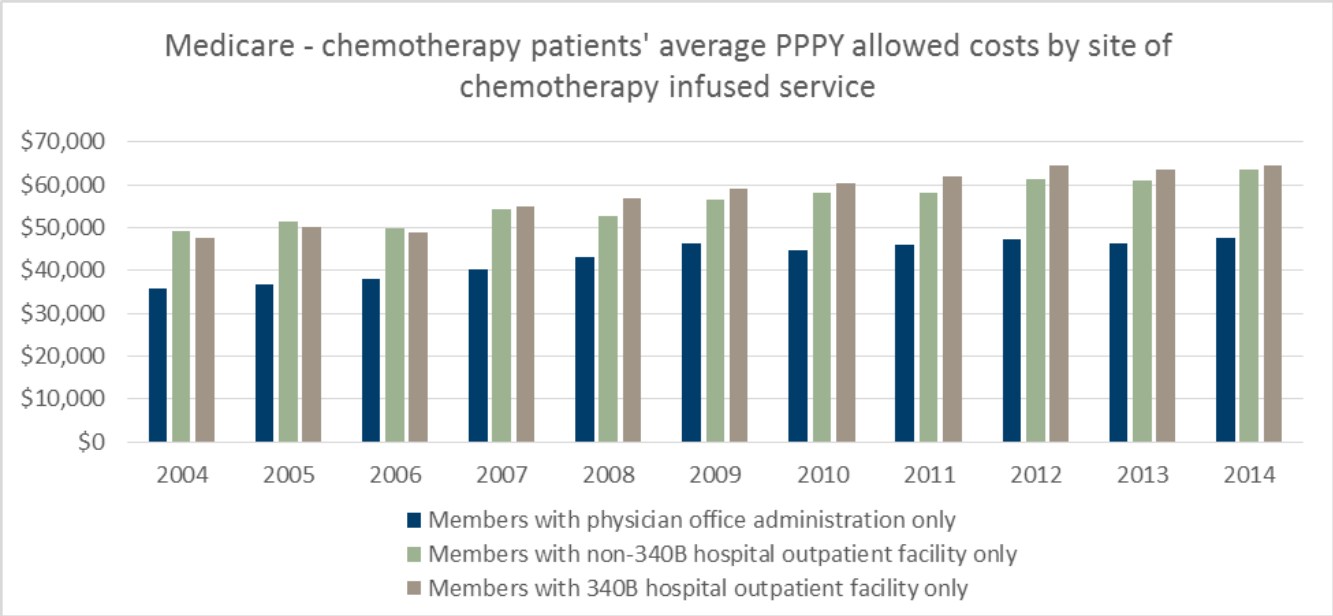
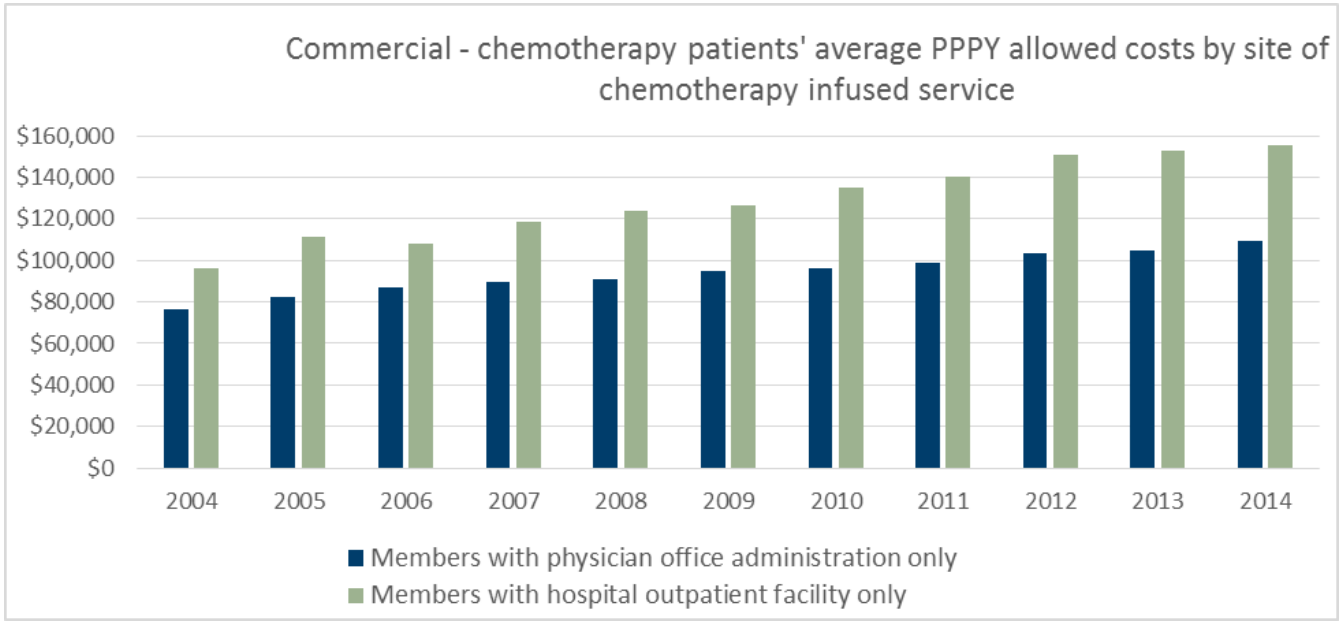
Medicare Costs Significantly Higher in Hospitals



- Compared to patients receiving all chemotherapy in a physician office, those receiving all chemotherapy in a hospital outpatient facility had PPPY costs that were:
  - $13,167 (37%) higher in 2004
  - $16,208 (34%) higher in 2014

Commercial Costs Significantly Higher in Hospitals



- Compared to patients receiving all chemotherapy in a physician office, those receiving all chemotherapy in a hospital outpatient facility had PPPY costs that were:
  - $19,475 (25%) higher in 2004
  - $46,272 (42%) higher in 2014

Cost to Medicare of the Shift in Site of Care

- Medicare spending on chemotherapy alone would have been $2 billion lower if all of the shift had not occurred
  - The total impact of the shift much greater than $2 billion because of other services (e.g., radiation, imaging, E&M) shifting
    - Avalere Study – *"These findings suggest that when care is initiated in the typically higher-paying HOPD setting, the services that follow also result in higher spending relative to when care is initiated in the office setting. Thus, the payment differential that begins with the initial service may extend and amplify throughout the entire episode."*
  - Hospital facility fees further drive up the costs
- Shift greater on the commercial side, and costs even higher in hospitals, so impact greater to private payers

Source*: Medicare Payment Differentials Across Outpatient Settings of Care*, Avalere Health, February2016.

Take Aways from the Cost Drivers Study

- Increasing prices of cancer drugs are a real problem but not focus of all cancer costs as per the media and the academics
  - Cut cancer drug spending in half (totally unrealistic) and spending is only cut by 9-10%
- Medicare is being subsidized by commercial payers
  - Commercial chemotherapy costs 129.2% higher in community oncology practices for commercial than Medicare
  - 145.3% higher in outpatient hospitals
- Site of care shift is a real driver of cancer care costs
  - In fact, is the most important driver

Innovating and Advocating for Community Cancer Care

Thank You!

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