Innovating and Advocating for Community Cancer Care

CHOP BUSINESS SUMMIT

From Capitol Hill to Dallas

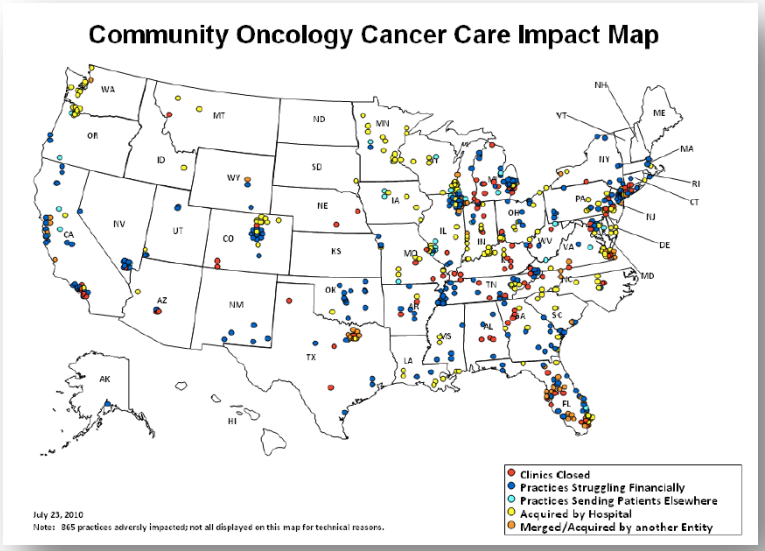
Washington DC Update

Ted Okon
Dallas, Texas
2/12/16

One Slide Summary

- Cancer care landscape is consolidating — *as if you didn't know!*
  - Movement from MD-run community practices to hospitals
    - Continuing trend or reversal?
  - Consolidation has hit the congressional radar screen
  - Community oncologists rallying, fighting, and innovating
    - Real payment reform innovation being pioneered by community oncology
- Good News: SGR fixed, but paying for quality and value is the replacement
  - Oncology payment reform is a fact/reality and it will change cancer care
  - Practices need to be involved in alternative payment models, like the Oncology Medical Home
- ACA/Obamacare future is a great unknown — Clash of progress vs. politics
- Cancer drug pricing is a hot issue in DC right now
  - Easy media and political target
  - All the players — FDA, pharma/bio, insurers (Medicare and privates), community oncology, and general and specialized hospitals (especially 340B and cancer hospitals) — are part of the problem and need to be part of the solution
- *More issues but not enough time to cover them!*

Consolidation of Cancer Care



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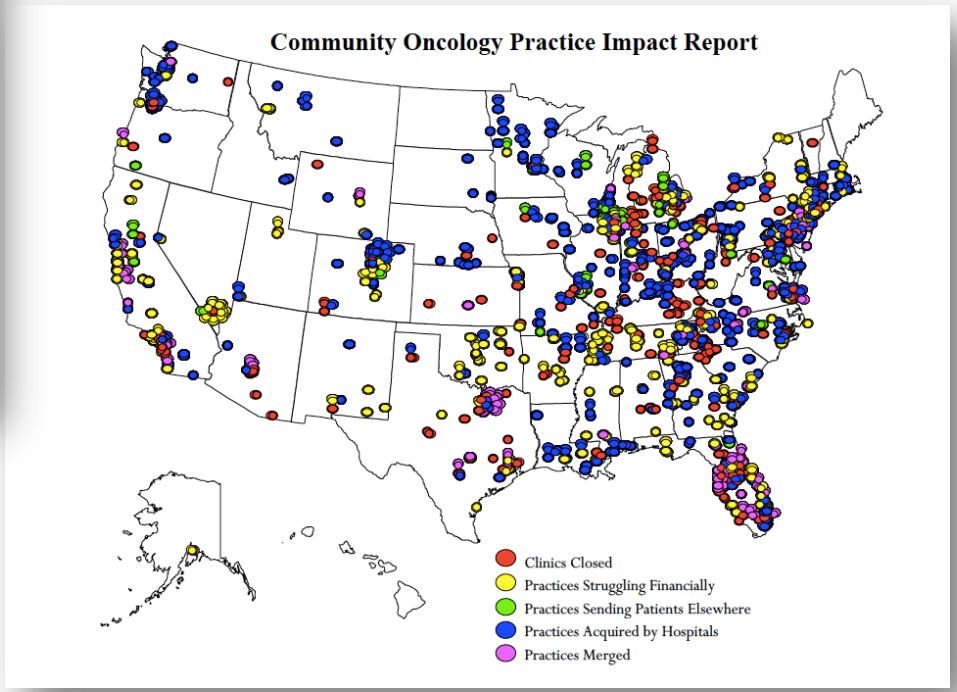

2014

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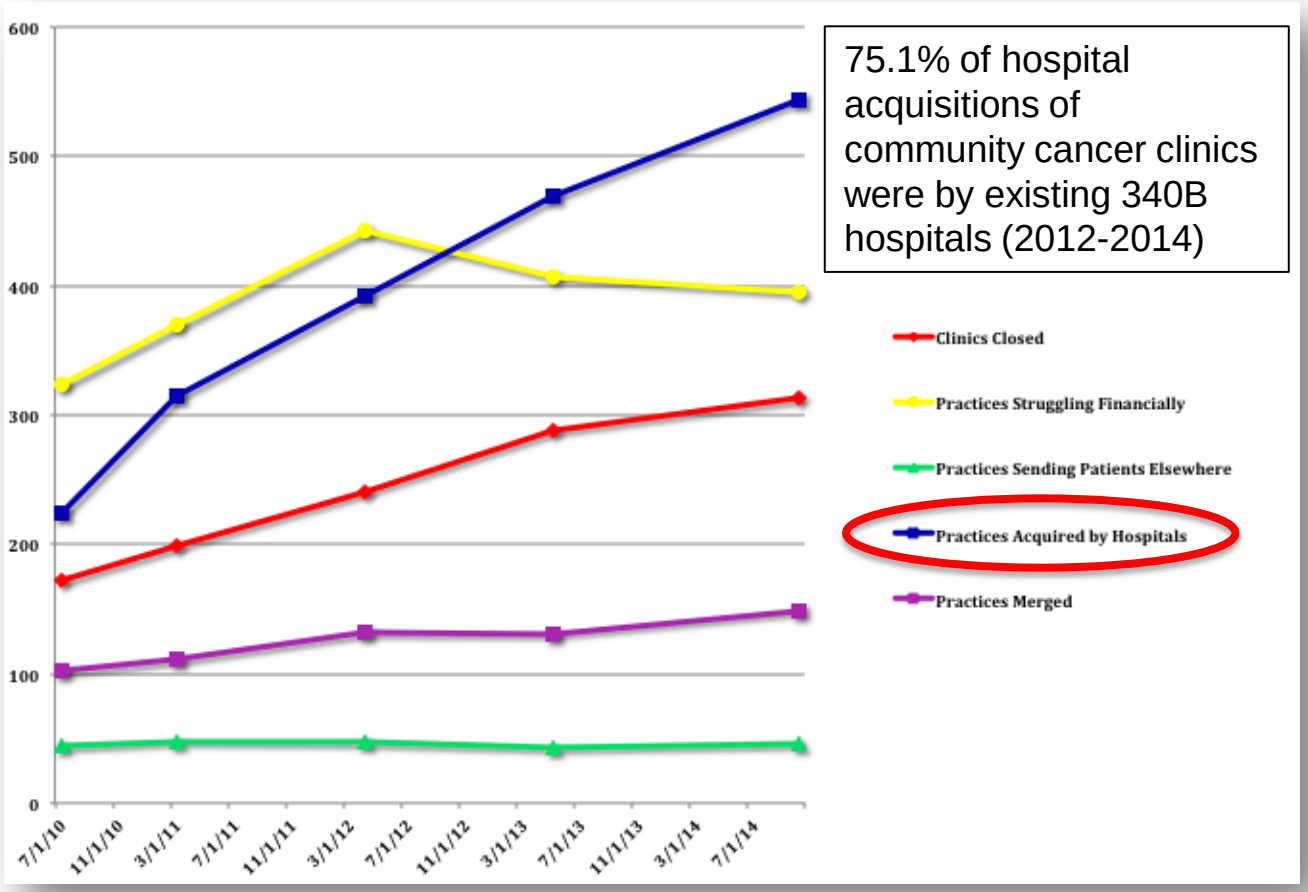
Consolidation Trends



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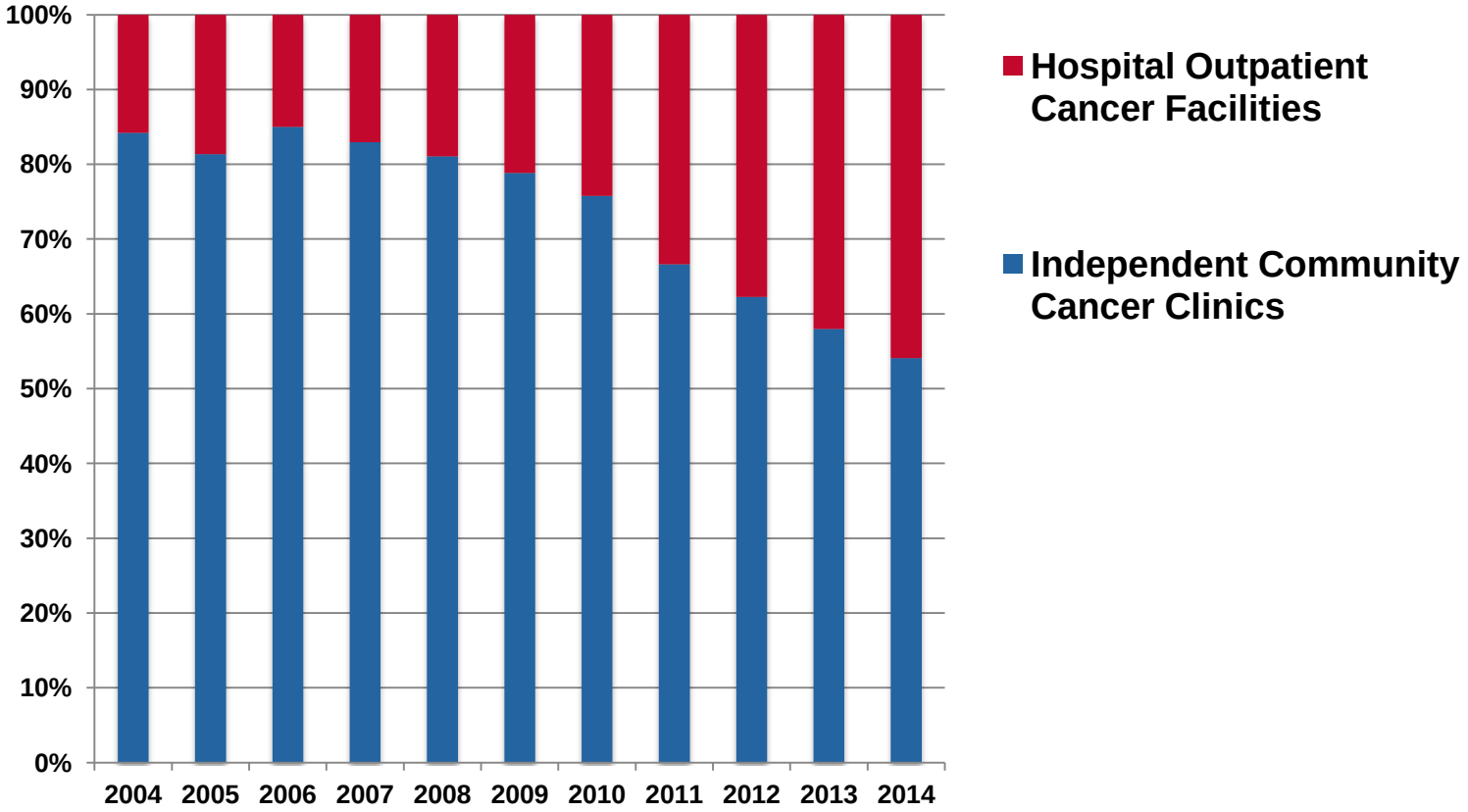
Medicare Spending on Cancer Care: Shift of Spending by Site Dramatic & Increasing



Source*: Medicare Data; Study in Progress,* November 2015

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“Push” and “Pull” Causing Consolidation

Push

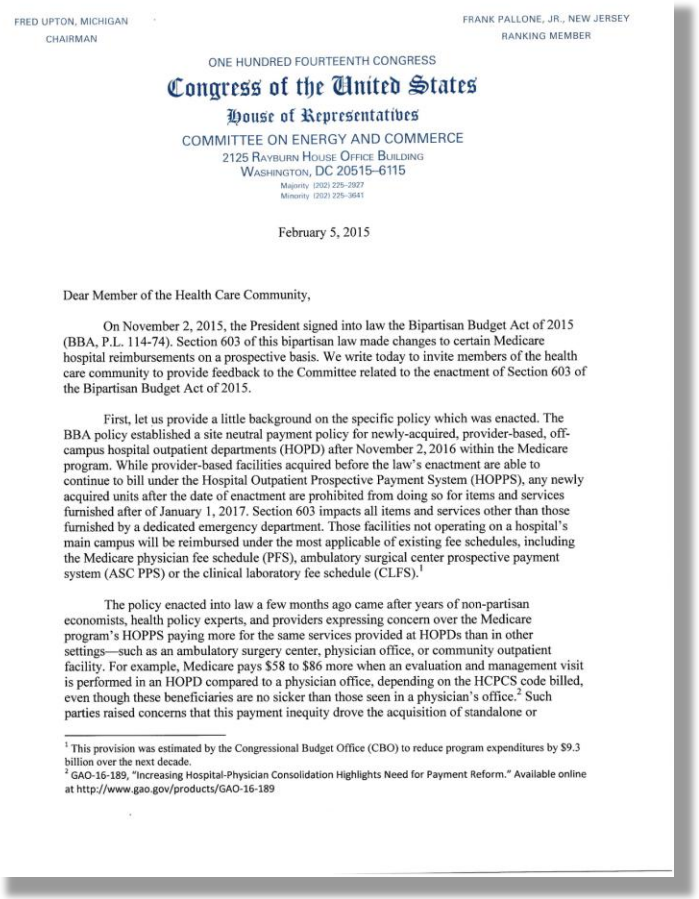
- Declining Payment for Cancer Care
- Administrative Burdens: Physicians forced to do more paperwork than treat patients
- Obstacles to Patient Care: Medicare and insurance company requirements

Pull

- Hospitals cutting off cancer referrals to oncologists
- Hospitals get higher payments for identical services, such as administering chemotherapy
- 340B Drug Discounts

The "Site Neutral" Medicare Payment Issue

- The issue is hospital outpatient facilities, on and off campus, get higher payments for identical services than provided in physician offices
- Balanced budget bill signed into law 11/2/15 took the first step in "site-neutral" Medicare payments
  - Starting in 2017, new hospital off-campus facilities (as of 11/2/15) will bill the same as independent physician practices
- Last Friday the House Energy & Commerce sent a letter asking for input on this issue
  - Next steps? Stay tuned!



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House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225-2927
Minority (202) 225-3641

February 5, 2015

Dear Member of the Health Care Community,

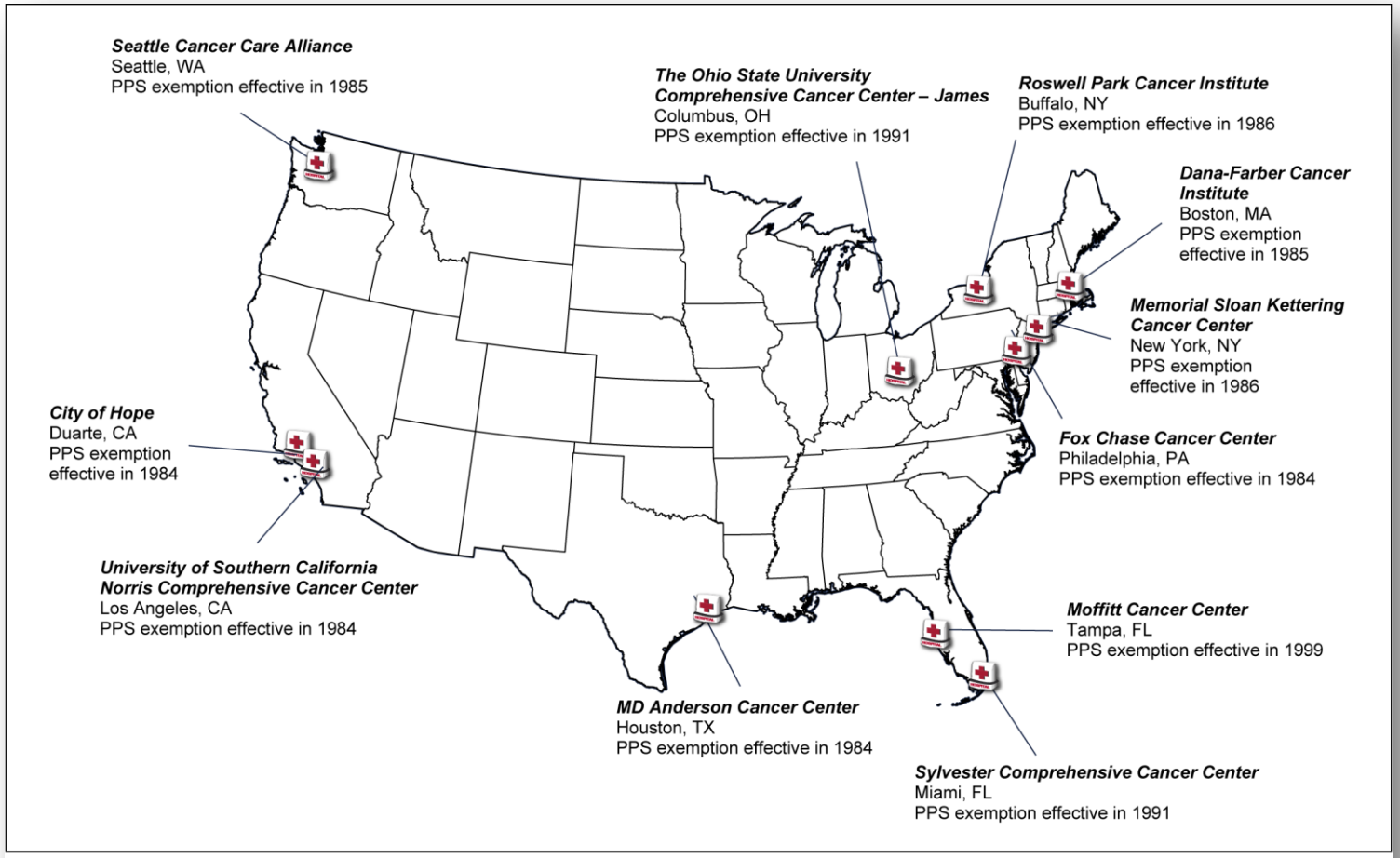
On November 2, 2015, the President signed into law the Bipartisan Budget Act of 2015 (BBA, P.L. 114-74). Section 603 of this bipartisan law made changes to certain Medicare hospital reimbursements on a prospective basis. We write today to invite members of the health care community to provide feedback to the Committee related to the enactment of Section 603 of the Bipartisan Budget Act of 2015.

First, let us provide a little background on the specific policy which was enacted. The BBA policy established a site neutral payment policy for newly-acquired, provider-based, off-campus hospital outpatient departments (HOPD) after November 2, 2016 within the Medicare program. While provider-based facilities acquired before the law's enactment are able to continue to bill under the Hospital Outpatient Prospective Payment System (HOPPS), any newly acquired units after the date of enactment are prohibited from doing so for items and services furnished after of January 1, 2017. Section 603 impacts all items and services other than those furnished by a dedicated emergency department. Those facilities not operating on a hospital's main campus will be reimbursed under the most applicable of existing fee schedules, including the Medicare physician fee schedule (PFS), ambulatory surgical center prospective payment system (ASC PPS) or the clinical laboratory fee schedule (CLFS).[1]

The policy enacted into law a few months ago came after years of non-partisan economists, health policy experts, and providers expressing concern over the Medicare program's HOPPS paying more for the same services provided at HOPDs than in other settings—such as an ambulatory surgery center, physician office, or community outpatient facility. For example, Medicare pays $58 to $86 more when an evaluation and management visit is performed in an HOPD compared to a physician office, depending on the HCPCS code billed, even though these beneficiaries are no sicker than those seen in a physician's office.[2] Such parties raised concerns that this payment inequity drove the acquisition of standalone or

[1] This provision was estimated by the Congressional Budget Office (CBO) to reduce program expenditures by $9.3 billion over the next decade.
[2] GAO-16-189, "Increasing Hospital-Physician Consolidation Highlights Need for Payment Reform." Available online at http://www.gao.gov/products/GAO-16-189

Hospitals with Special Medicare Exemption



Source: Centers for Medicare & Medicaid Services; Map Resources (map). | GAO-15-199

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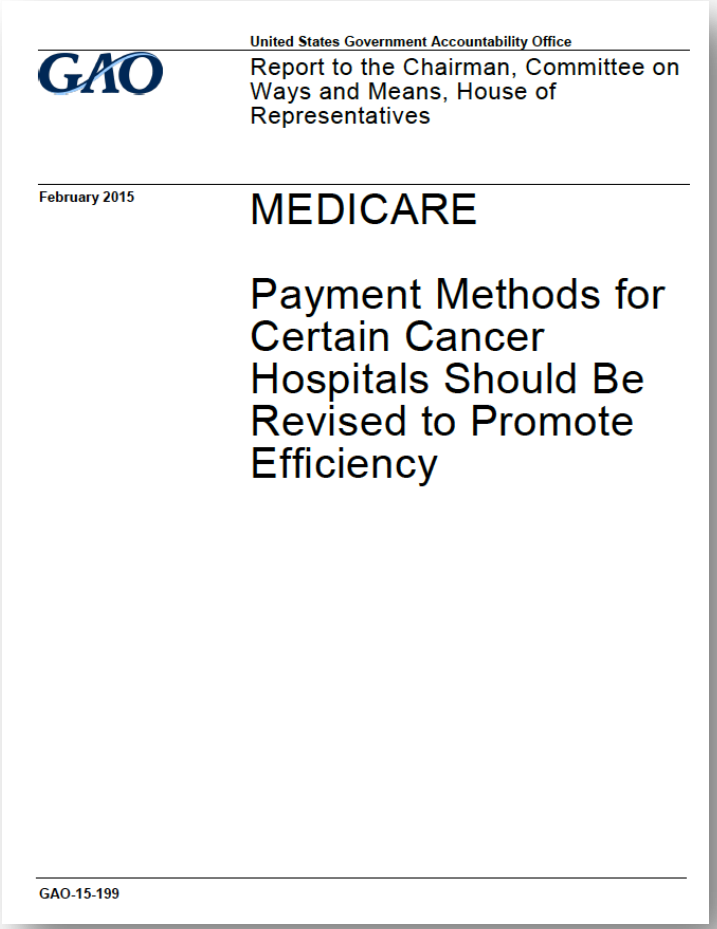
PCHs Cost Medicare $.5 Billion More



United States Government Accountability Office

GAO

Report to the Chairman, Committee on Ways and Means, House of Representatives

February 2015

MEDICARE

Payment Methods for Certain Cancer Hospitals Should Be Revised to Promote Efficiency

GAO-15-199

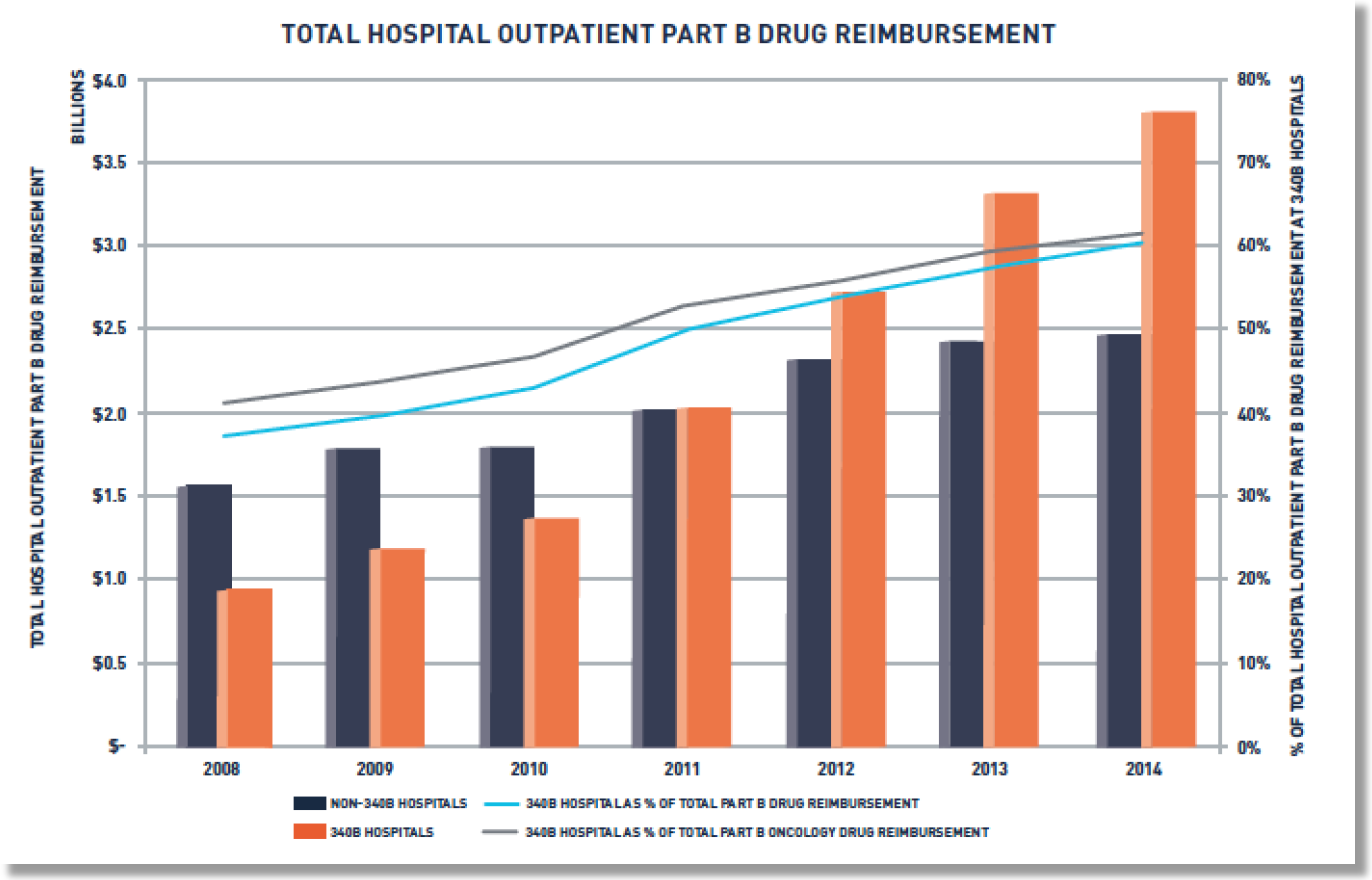
"Because Medicare's payment methodology for PCHs lacks strong incentives for cost containment, it has the potential to result in substantially higher total Medicare expenditures. If, in 2012, PCH beneficiaries had received inpatient and outpatient services at nearby PPS teaching hospitals—and the forgone outpatient adjustments were returned to the Supplementary Medical Insurance Trust Fund—Medicare may have realized annual savings of almost $0.5 billion. **Until Medicare pays PCHs to at least, in part, encourage efficiency, Medicare remains at risk for overspending**."

Key Notes on the 340B Program

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

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

62% of Oncology Drugs in 340B Hospitals



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

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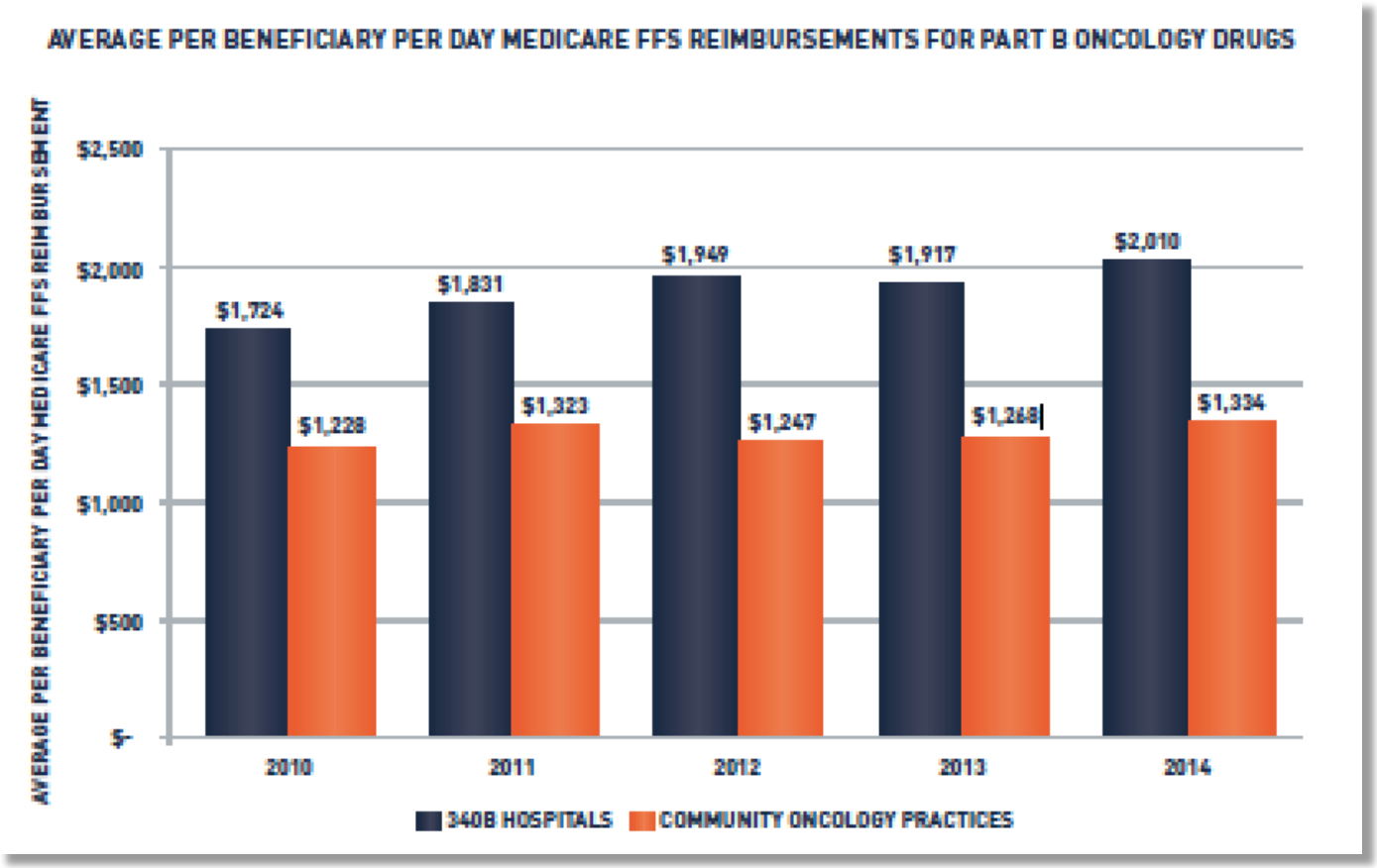
340B Hospitals Cost Medicare 51% More



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

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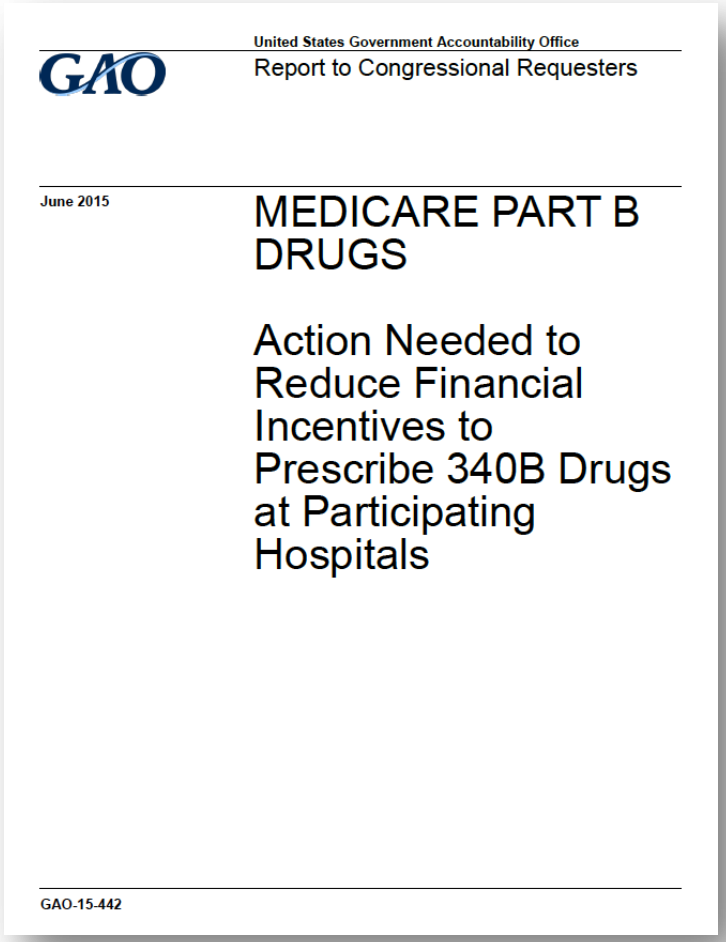
GAO Report on 340B



United States Government Accountability Office

GAO

Report to Congressional Requesters

June 2015

MEDICARE PART B DRUGS

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

GAO-15-442

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

June 2015

340B Expansion Unintended Consequences

- Critical safety net program for patients in need but… expansion of 340B has had unintended consequences
  - Contributing to consolidation of cancer care into the hospital setting
    - Substantial financial incentives for hospitals to purchase cancer clinics
    - Causing higher costs for patients, Medicare, and taxpayers
  - Contributing to consolidating generic marketplace
    - 340B discounts lower marginal profitability of sterile injectable drugs
    - Drug shortages and rising prices of generics without competitors
  - Fueling brand drug prices
    - Increasing magnitude of 340B discounts accounted for in product pricing

340B Hospitals Fighting Back

THE ASCO POST

NEWS

The 340B Drug Pricing Program: Backgroun Concerns, and Solutions

By Hagop Kantarjian, MD, and Robert Chapman, MD

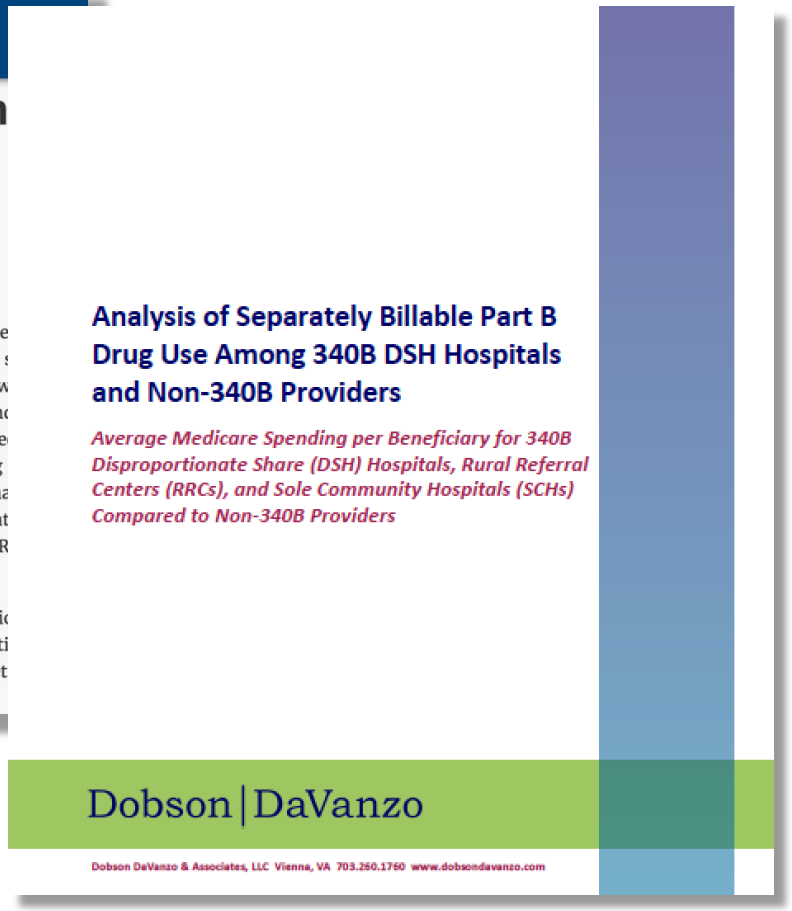
January 25, 2016

Hagop Kantarjian, MD

Robert Chapman, MD

The 340B Drug Pricing Program was created by Congre through the Veterans Health Care Act of 1992 to allow s health-care entities—including safety-net providers w large shares of uninsured and low-income patients and other "covered entities"—to obtain drugs at discounte prices.[1,2] Congress gave these providers access to drug discounts in response to escalating drug prices that ma difficult for them to handle the needs of vulnerable pat The Health Resources and Services Administration (HR administers 340B.[3]

Drug manufacturers participating in Medicaid or Medic Part B programs give 20% to 50% discounts on outpati drugs (based on an average manufacturer price). In ret pharmaceutical companies are able to participate in



Analysis of Separately Billable Part B Drug Use Among 340B DSH Hospitals and Non-340B Providers

Average Medicare Spending per Beneficiary for 340B Disproportionate Share (DSH) Hospitals, Rural Referral Centers (RRCs), and Sole Community Hospitals (SCHs) Compared to Non-340B Providers

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Dobson DaVanzo & Associates, LLC Vienna, VA 703.260.1760 www.dobsondavanzo.com

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Importance of 340B Facts

November 20, 2015, 06:00 am

Ensure 340B program is about patients, not hospital profits

By Ted Okon

106 14

COMME

There is no question the 340B drug discount program provides a critical safety net for Ame
most vulnerable patients; especially those served by disproportionate share hospitals, fede
qualified health centers, and safety net providers, such as Ryan White HIV/AIDS clinics. Bu
started in 1992 as a relatively small prescription drug discount program for qualifying faciliti
has exploded in size due to the participation of hospitals that often deliver relatively little ch
care.

One factor fueling this growth is hospital acquisition of community cancer clinics, which ma
qualify for participation in the program after being acquired by a 340B hospital. This huge
expansion is unsustainable and threatens the 340B program's future. Moreover, it has had
unintended consequence of increasing the costs of cancer care for seniors and taxpayers.

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It's ALWAYS About Patients!!!

Houston mother forced to pay triple price for cancer drug after insurance company denies coverage

Your money or your life -- that's the choice a Houston nurse and mother said she had to make after her health insurance company refused to pay for an expensive, new cancer drug.

Not only would O'Callaghan have to pay for that drug out of her own pocket, the hospital, Baylor College of Medicine, informed her she would have to pay $12,226 for each dose, or a total of more than $61,000 for five doses.

"That's almost three times what the insurance company would have paid for that drug," O'Callaghan said. "How does anybody come up with that kind of money?"

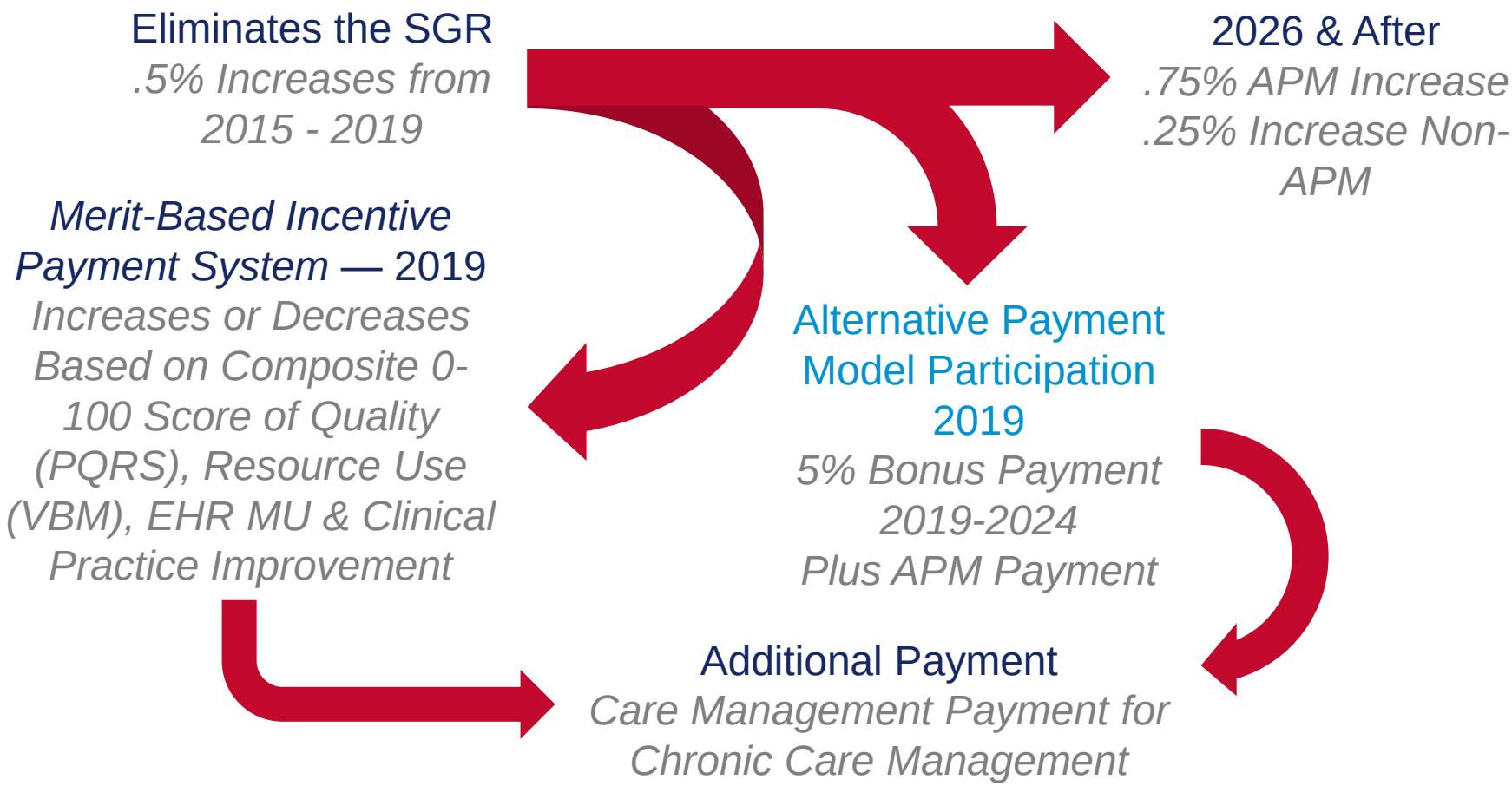
What's Next for 340B?

- Congress has legislative language developed on 340B
  - Waiting for HRSA, government agency that oversees 340B, to provide final guidance on aspects of the 340B program
  - Next step would be a legislative hearing on 340B language
  - Several members of Congress looking to introduce 340B bills
  - MedPAC recommends cutting 340B drug reimbursement by 10%

SGR Fixed!!!

- SGR fixed but the fix ushers in a new world of Medicare paying for quality and value
- CMMI Oncology Care Model (OCM) is close to being reality
  - First alternative payment model for Medicare relating to oncology
- Oncology payment reform bill introduced by Representatives Cathy McMorris Rodgers and Steve Israel as addition to the CMMI OCM
  - Mrs. McMorris Rodgers is 4th highest GOP Representative
  - Mr. Israel is co-chair of the House Cancer Caucus (former DCCC chairman)
- *Medicare moving where the private payers are already!!!*

SGR Payment Reform Overview



CMMI OCM Oncology Payment Reform Pilot

- Care management fee ($160) and performance fee
  - In addition to current FFS payments
  - Structure similar to COA's model
- Must hit specified levels of quality
  - Defined quality measures
- Built around 6-month chemotherapy bundle
  - Services and drugs
- Major structural problems with the model
  - Too prescriptive
  - Performance is "gainsharing" — competing against yourself
  - Have no idea how performance will be measured
  - Setting up drug bundles next
    - Data collected will help that!

McMorris Rodgers & Israel Payment Reform Bill

- *Cancer Care Payment Reform Act of 2015* (H.R. 1934)
- 3 phase demonstration project
  - Attest applying for OMH accreditation
  - Get at least conditional OMH accreditation
  - Implement the OMH
- 2 payment mechanisms
  - Care coordination fee during the first 2 phases
  - Shared savings after achieving OMH accreditation
- Can apply for CMMI project then switch to this demonstration project
- Provides for easy upfront payment to put OMH processes in place
- Very good prospects for getting bill passed
  - Legislative hearing end of 2015 with Dr. Bruce Gould testifying

The Quality and Value Train Has Left the Station

- Policy makers already defining, and measuring, quality and value, often with little patient or provider input
  - PQRS
  - Value-Based Purchasing Modifier
    - Already in hospitals
    - Here now for physicians
- Private payers implementing new payment models with quality measures
  - Aetna set to expand its Oncology Medical Home project
- Quality risks becoming the next drug pathway
  - Everyone has a different set of quality metrics
    - Different quality metrics for different patients

COA Oncology Medical Home Solution

- Oncology Medical Home
  - More concerted effort to control costs while enhancing the quality of care
- Costs that can be controlled more directly than others:
  - Hospitalizations
    - Including hospital readmissions
  - Emergency department utilization
  - Drug utilization
  - Imaging utilization
  - Treatment radiation utilization
- Measure costs and quality, including patient satisfaction

ACA/Obamacare: Progress Versus Politics

- Progress covering preexisting conditions and lifting annual/lifetime insurance caps
- More Americans insured
  - However, insured Americans way under estimates to date
  - Most subsidized or on Medicaid
  - CoOps and more state exchanges in financial difficulty or failing
- Republicans looking for ways to defund
  - 63 attempts so far
  - Last one just passed the Congress but vetoed by the President
- Bottom line: Progress and politics clashing over ACA/Obamacare
  - 2016 elections will determine fate

Drug Price Issue Front and Center

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

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

$250,000
200,000
150,000
100,00
50,00
19

AVERAGE COS
TO DELIVER A
(IN 2013 DOLLARS)

Company hikes price 5,000% for drug complication of AIDS, cancer

Christine Rushton, USA TODAY 4:11 p.m. EDT September 18, 2015

(Photo: Sara D. Davis, USA TODAY)

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A drug treating a common parasite that attacks people with weakened immune systems increased in cost 5,000% to $750 per pill.

At a time of heightened attention to the rising cost of prescription drugs, doctors who treat patients with AIDS and cancer are denouncing the new cost to treat a condition that can be life-threatening.

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Issues » Health Care

Enough Is Enough

The Time Has Come to Address Sky-High Drug Prices

Forbes / Pharma & Healthcare

SEP 17, 2015 @ 09:10 AM 2,455 VIEWS

One Biotech CEO's Plan To Slash The Cost Of Cancer Immunotherapy

Arlene Weintraub
CONTRIBUTOR

I cover the science and business behind drug development and health

New immune-boosting drugs like Merck 's Keytruda and Bristol-Myers Squibb BMY +1.61% 's Opdivo are changing the game for cancer patients, but their six-figure-per-year price tags have raised eyebrows among payers worldwide. Those cost concerns are top-of-mind for Ali Fattaey, a microbiologist and CEO of Massachusetts-based biotech company Curis, which has ventured into the world of immuno-oncology with a plan to make next generation of cancer drugs more affordable.

Earlier this year, Curis partnered with India-based Aurigene to develop several drugs, including one with a similar mechanism of action to Keytruda (pembrolizumab) and Opdivo (nivolumab), which inhibit an immune-restricting "checkpoint" called PD-1. But

The Opinion Pages | EDITORIAL

Use Medicare's Muscle to Lower Drug Prices

By THE EDITORIAL BOARD SEPT. 21, 2015

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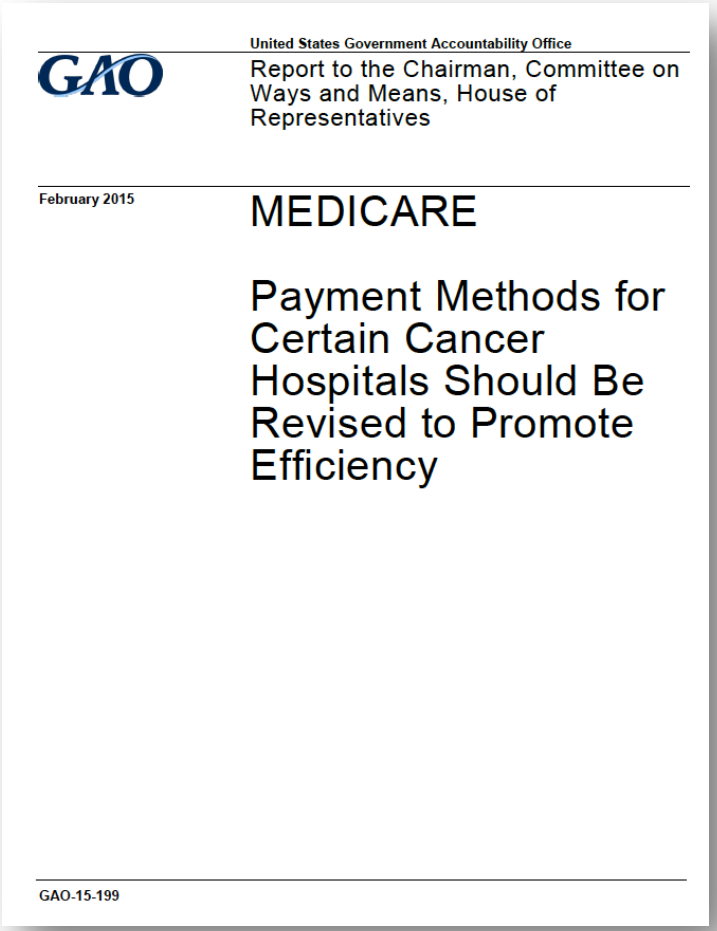
A poll last month by Consumer Reports found that a third of the patients who take prescription drugs are paying significantly more this year, forcing many to cut back on other necessities or load up on credit card debt. Another poll in August by the Kaiser Family Foundation found that about a quarter of those surveyed said they had trouble paying for prescription drugs.

Many of the people most affected by rising drug prices are older patients on Medicare, who often live on modest incomes, are in poor health, and take four or more prescription drugs. One way to reduce drug costs for this population is to reverse the policy set by the 2003 Medicare Modernization Act, which created Medicare's prescription drug program.

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

PCHs Cost Medicare $.5 Billion More



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Where is Drug Price Debate Likely Heading?

- Direct or overt price controls unlikely in current political landscape
- Indirect price controls more likely
  - Modifications to ASP
  - Bundling of drug costs
  - More restrictive exchange formularies
  - Tighter pathways from insurers
- Possible greater regulation like the insurance industry
  - Price and increases regulated and have to be approved
- Greater price attention in ASCO, NCCN, and other “value” tools
- More media attention, especially with bad actors out there such as Turning Pharmaceuticals

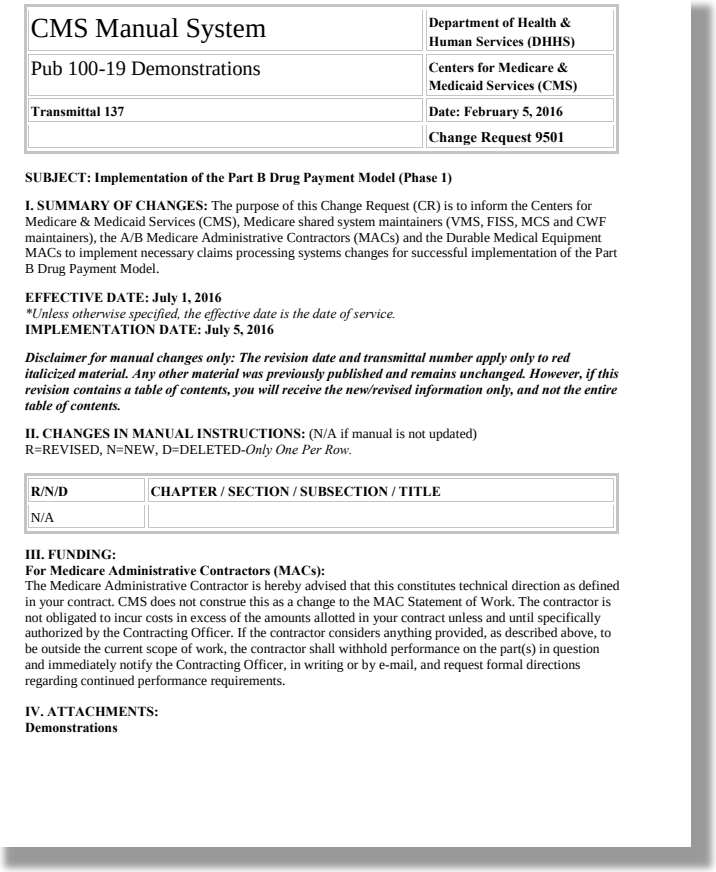
Important Legislation

- Cancer Care Payment Reform Act (H.R. 1934)
  - Creates a national Medicare demonstration project for oncology payment reform based on the Oncology Medical Home
  - Hearing on this bill already
    - COA President Dr. Bruce Gould testified
- Cancer Patient Protection Act (H.R. 1416)
  - Stops CMS from applying the Medicare sequester cut to Part B drugs
- Medicare Patient Access to Treatment Act (H.R 2895)
  - Establishes site payment parity for the delivery of cancer care services (e.g., chemotherapy infusions)

Other Issues

- Biosimilars
  - Approvals
  - Reimbursement
- Medicare carriers moving to lower reimbursement for administration of biologics
- Medicaid expansion
  - Lowering Medicaid portion of reimbursement for Medicare/Medicaid dual eligible patients
- Attempts to lower ASP + 6% drug reimbursement

The CMS ASP Experiment



CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-19 Demonstrations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 137	Date: February 5, 2016
	Change Request 9501

SUBJECT: Implementation of the Part B Drug Payment Model (Phase 1)

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to inform the Centers for Medicare & Medicaid Services (CMS), Medicare shared system maintainers (VMS, FISS, MCS and CWF maintainers), the A/B Medicare Administrative Contractors (MACs) and the Durable Medical Equipment MACs to implement necessary claims processing systems changes for successful implementation of the Part B Drug Payment Model.

EFFECTIVE DATE: July 1, 2016
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: July 5, 2016

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N/A	

III. FUNDING:
For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:
Demonstrations

- CMS let “slip” a transmittal to carriers informing them to prepare for an ASP adjustment
- Idea is to vary ASP plus multiplier based on zip code groupings for all or specific Part B drugs
- COA responded aggressively against this “experiment” on cancer care
- CMS backed down; for now

Good Read on Community Oncology

COA Releases Major White Paper on the State of Integrated Community Oncology

Download your copy on the COA website at www.CommunityOncology.org.

2016 Community Oncology Conference

- Over 600 people attended last year
  - Including payers
- 3 tracks
  - Clinical
  - Business
  - Patient Advocacy
- Great new venue at Loews Royal Pacific Resort in Universal Studios Orlando, Florida

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Thank You!

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www.CommunityOncology.org
www.MedicalHomeOncology.org
www.COAadvocacy.org (CPAN)

www.facebook.com/CommunityOncologyAlliance

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