VAHO FALL MEETING

Oncology Policy, Pricing, and Payment Reform Issues from DC Down the Road to Richmond

Ted Okon
Richmond, Virginia
10/2/15
Cancer care landscape is consolidating
  • Movement from MD-run community practices to hospitals
    ▶ 3 out of 4 hospital acquisitions tied to 340B pricing
  • Community oncologists rallying, fighting, and innovating
    ▶ Real payment reform innovation being pioneered by community oncology

Alternative payment models are not a fad
  • Oncology payment reform will change cancer care
  • Practices need to be involved in alternative payment models
  • Oncology Medical Home is really gaining traction

Cancer drug pricing is a hot issue in DC right now
  • Being used in part to deflect issues related to preferential reimbursement and 340B
  • Easy media story for 60 Minutes, etc.; even GOP candidates
  • All the players (i.e., pharma/bio, FDA, academics/institutions, community oncologists) are part of the problem
    ▶ All need to be part of the solution

Few other important radar screen issues — biosimilars, incident to, ICD-10, infusion codes
Big News in DC… In Addition to the Pope

John Boehner, House Speaker, Will Resign From Congress

By JENNIFER STEINHAUER  SEP. 25, 2015

Speaker John A. Boehner announced on Friday that he will resign his position and give up his House seat in Ohio.

AP Photo

Resignation triggers all-out leadership scramble

Republican Kevin McCarthy is strongly favored to become speaker, but jockeying is intense for other leadership posts.
What Does It Mean?

- Kept the government open yesterday through early December
  - However, we’re inevitably heading to another budget/debt cliff battle
    ▶ Yesterday announced debt ceiling hit 11/5

- Empowers far right and government “outsiders”
  - Members in the House, and Senate to a degree
  - Presidential candidates

- Most likely gives new “spring in the step” to defunding aspects of ACA/Obamacare
  - ACA/Obamacare becoming entrenched and accepted
  - However, House GOP controls the purse strings for funding
  - Defunding reconciliation bill in the works

- Unclear how it impacts legislation COA has in focus
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 yesterday
    - 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)
"Community oncology practices like mine want to be part of the alternative payment reform path that the Energy and Commerce committee developed in the SGR legislation; however, we need a Medicare alternative payment model in oncology for that to happen. H.R. 1934 is a critical bridge to getting us to that point. I ask Congress to pass this important legislation that will lower the costs of cancer care while enhancing the quality of care for patients.”
Consolidation of Cancer Care

2010

2014

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Consolidation Trends
“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: Insurance company requirements

**Pull**
- Hospital Hardball Tactics: Cut off referrals to oncologists
- 340B Drug Discount Program

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340B Program

- Once obscure government drug discount program intended to cover patients who can’t pay for treatment from falling through the treatment cracks

- Now a HUGE program that more on Capitol Hill are questioning if it is living up to its original intent
  - Recent HRSA guidance touched on some of the hot issues

- Substantial financial benefits to hospitals
  - Up to 100% margins on cancer drugs and other expensive therapies
  - If average oncologist accounts for $4M in drugs, hospital realizes up to $2M per oncologist

- Increasing spotlight on use of 340B discounts in hospitals
  - Federal grantees (AIDS, hemophilia, community health clinics held to higher level of transparency and accountability)
The 340B Program is Primarily a Hospital Outpatient Drug Purchasing Program

- The 340B program has historically been evaluated in the context of total drug sales in the US
  - HRSA, Apexus, AHA and others consistently cite that the 340B program represents only 2% of total US drug sales

- However, the 340B program has evolved into what is currently primarily a discounted hospital outpatient purchasing program and it makes more sense to think about the 340B program in the context of hospital outpatient drug purchases

**Percentage of Total 340B Sales by Entity Type**

- DSH Enrolled Pre 2004: 31%
- DSH Enrolled 2004 or Later: 50%
- HIV: 2%
- CH: 5%
- Other: 2%
60% of Hospital Outpatient Oncology Drugs are Purchased by 340B Hospitals

- When evaluating the 340B program in the context of hospital outpatient services, it is evident that the program is far bigger than commonly understood.
The Trend in 340B Hospital Enrollments…

Cumulative Count of Newly Enrolled 340B DSH and non-DSH Hospitals

<table>
<thead>
<tr>
<th>Year</th>
<th>Newly Enrolled Non-DSH Hospitals</th>
<th>Newly Enrolled 340B DSH Hospitals</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>342</td>
<td>89</td>
</tr>
<tr>
<td>2011</td>
<td>708</td>
<td>145</td>
</tr>
<tr>
<td>2012</td>
<td>897</td>
<td>209</td>
</tr>
<tr>
<td>2013</td>
<td>1068</td>
<td>258</td>
</tr>
<tr>
<td>2014</td>
<td>1222</td>
<td>324</td>
</tr>
</tbody>
</table>
…is Leading to Substantial Incremental Purchases through the 340B Program

PERCENT OF 2013 OUTPATIENT PART B DRUG REIMBURSEMENT TO 340B HOSPITALS BY HOSPITAL TYPE

- PRE-2010 / NON-DSH: 77.4%
- 2010 OR LATER / DSH: 8.4%
- 2010 OR LATER / NON-DSH: 14.2%

Nothing in this document should be construed as tax, legal or regulatory advice.
At the Same Time, Existing 340B Hospitals are Increasing Hospital Outpatient Drug Purchases through Targeted Acquisitions

### Hospital Outpatient Revenue

<table>
<thead>
<tr>
<th>Year</th>
<th>Non-340B Hospitals</th>
<th>340B Hospitals</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>425,723,386,299</td>
<td>304,092,115,596</td>
</tr>
<tr>
<td>2011</td>
<td>470,158,081,696</td>
<td>335,962,571,493</td>
</tr>
<tr>
<td>2012</td>
<td>519,093,607,956</td>
<td>368,865,321,114</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$1,968,707,555,467</strong></td>
<td><strong>$1,411,143,374,508</strong></td>
</tr>
</tbody>
</table>

- **30%**
- **32%**

### Hospital Outpatient Part B Oncology Drug Reimbursement

<table>
<thead>
<tr>
<th>Year</th>
<th>Non-340B Hospitals</th>
<th>340B Hospitals</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>494,857,666</td>
<td>529,523,686</td>
</tr>
<tr>
<td>2011</td>
<td>633,261,549</td>
<td>690,619,055</td>
</tr>
<tr>
<td>2012</td>
<td>761,639,096</td>
<td>861,242,864</td>
</tr>
<tr>
<td>2013</td>
<td>781,957,318</td>
<td>982,641,086</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$2,671,715,630</strong></td>
<td><strong>$3,064,026,692</strong></td>
</tr>
</tbody>
</table>

- **58%**
- **86%**
The Shift in Site of Oncology Care has a Significant Impact on Overall Utilization

Oncology claims are being shifted to...

...a less efficient site of care.

Percentage of Medicare FFS Oncology Claims by Site of Care

Average Medicare Part B Oncology Drug Reimbursement Per Beneficiary Per Day

Nothing in this document should be construed as tax, legal or regulatory advice.
“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.”
340B Impact & Prognosis

- Critical safety net program for patients in need but expansion has had unintended consequences
  - Contributing to consolidation of cancer care into the hospital setting
    - Leads to higher costs for payers and patients
  - Contributing to consolidating generic marketplace
    - Drug shortages
  - Fueling brand drug prices

- Expect more attention on 340B on Capitol Hill and legislation
  - Likely more transparency and accountability for hospitals to justify 340B discounts are serving patients in need
Incentives squarely in the direction of participating in Medicare oncology payment reform

CMMI Oncology Care Model (OCM) a reality
  • First alternative payment model for Medicare

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

Eliminates the SGR
.5% Increases from 2015 - 2019

Merit-Based Incentive Payment System — 2019
Increases or Decreases Based on Composite 0-100 Score of Quality (PQRS), Resource Use (VBM), EHR MU & Clinical Practice Improvement

Alternative Payment Model Participation 2019
5% Bonus Payment 2019-2024
Plus APM Payment

Additional Payment Care Management Payment for Chronic Care Management

2026 & After
.75% APM Increase
.25% Increase Non-APM

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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
Drug Price Issue Front and Center

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

by Peter B. Bach, MD
SEPTEMBER 17, 2015, 8:00 AM EDT

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

AVERAGE COST OF CANCER DRUGS TO DELIVER A “LIFE YEAR” (IN 2013 DOLLARS)

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

New immune-boosting drugs like Merck’s Keytruda and Bristol-Myers Squibb’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 immunoncology 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

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

The Time Has Come to Address Sky-High Drug Prices

Forbes / Pharma & Healthcare

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... And Spotlight Won’t Stop!

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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 (20-30%) of the problem of increasing cancer care costs
• Pharma/bio an easy target for the media, academics, politicians
• Technology advances and demographics large part of the problem
  ▶ Better diagnosis and treatment keeping people alive
  ▶ Shifting demographics and health behaviors increasing cancer cases

Health systems are part of the problem
• 11 cancer hospitals with special exemptions cost Medicare close to $.5 billion more than teaching hospitals in 2012
• 340B hospitals 52% more expensive than community cancer clinics
Hospitals with Special Medicare Exemption
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."
# PCHs Cost Medicare $.5 Billion More

## Table 7: Estimated Additional Medicare Fee-for-Service Outpatient Payment at Prospective Payment System (PPS)-Exempt Cancer Hospitals (PCH) After Application of Payment Adjustment for Selected Service Categories, 2012

<table>
<thead>
<tr>
<th>PCH</th>
<th>Level 2 hospital clinic visits</th>
<th>Level V drug administration</th>
<th>Intensity-modulated radiation therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>City of Hope</td>
<td>$10</td>
<td>$30</td>
<td>$68</td>
</tr>
<tr>
<td>Dana-Farber Cancer Institute</td>
<td>37</td>
<td>106</td>
<td>233</td>
</tr>
<tr>
<td>Fox Chase Cancer Center</td>
<td>16</td>
<td>45</td>
<td>100</td>
</tr>
<tr>
<td>MD Anderson Cancer Center</td>
<td>37</td>
<td>106</td>
<td>233</td>
</tr>
<tr>
<td><strong>Memorial Sloan Kettering Cancer Center</strong></td>
<td><strong>38</strong></td>
<td><strong>111</strong></td>
<td><strong>244</strong></td>
</tr>
<tr>
<td>Mott Cancer Center</td>
<td>15</td>
<td>44</td>
<td>90</td>
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<tr>
<td>The Ohio State University Comprehensive Cancer Center – James</td>
<td>25</td>
<td>71</td>
<td>156</td>
</tr>
<tr>
<td>Roswell Park Cancer Institute</td>
<td>13</td>
<td>37</td>
<td>82</td>
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<tr>
<td>Seattle Cancer Care Alliance</td>
<td>35</td>
<td>101</td>
<td>223</td>
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<tr>
<td>Sylvester Comprehensive Cancer Center</td>
<td>10</td>
<td>29</td>
<td>64</td>
</tr>
<tr>
<td>University of Southern California Norris Comprehensive Cancer Center</td>
<td>22</td>
<td>64</td>
<td>141</td>
</tr>
</tbody>
</table>

340B Hospitals Cost Medicare 52% More
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
  - Moving from CMMI OCM to bundled payments for episodes of care *with drugs*
  - 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 and NCCN “value” tools
  - Others?
- More media attention fueled by academics

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Solutions?

- Government needs to move into the 21st century to increase competition
  - Streamline the FDA to decrease costs and approval timelines
  - Decrease regulations

- Pharma/bio companies get innovative with pricing that better reflects drug value
  - Tie pricing to effectiveness/outcomes
    - However, structural/policy/legal impediments to making this work
  - Value-based Insurance Design (VBID)
    - Drugs with clearest advantages have least impediments/hurdles

- Academics and institution-based oncologists need to look inward and realize their institutions contribute to the problem

- Community oncology needs to advance solutions in payment reform
  - Private insurers getting behind this effort
COA Oncology Medical Home Solution

- Oncology Medical Home = Community Oncology 2.0 and beyond
  - 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
COA Oncology Medical Home Solution

- Oncology Medical Home accreditation by the Commission on Cancer
  - 7 COME HOME practices + 3 others
    - 9 now accredited

- Identified and standardized 19 quality/value measures
  - Increasingly being used by providers and payers
  - Working with EMR and IT vendors to extract data on measures

- Patient satisfaction survey close to 55,000 completed
  - Modification of CAHPS clinical survey
  - English, Spanish, Chinese, Korean, and Russian versions

- Tools for practices to help in OMH transformation
  - [www.medicalhomeoncology.org](http://www.medicalhomeoncology.org)

- Associated payment reform model
  - Embodied in H.R. 1934
Proposed changes in the Medicare Physician Fee Schedule relating to “incident to” provisions
  • Does the treating physician have to be the supervising physician?
  • COA has commented on this to CMS, informally and formally

Biosimilars
  • They are here and coding issue (i.e., separate codes or bundled code) has reimbursement repercussions
  • COA held panel session at Board meeting and commented to CMS

ICD-10 is here — Day 2!
  • COA will be monitoring this for adverse impact on practices

Noridian medical director proposing to change codes for drug administration
  • Just another way to cut costs
Good Read on Community Oncology

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

Payer Exchange Summit III

October 27, 2015

PAYER EXCHANGE SUMMIT III
ONCOLOGY PAYMENT REFORM

OCTOBER 27, 2015, TYSONS CORNER, VA
Sponsored by the Community Oncology Alliance (COA)

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2016 Community Oncology Conference

- Over 600 people attended last year
  - Including payers
- 3 tracks
  - Clinical
  - Business
  - Patient Advocacy
- Great new venue at Universal

The Community Oncology Conference is going back to Orlando to an exciting new venue at Universal Orlando Resort!

SAVE THE DATE | APRIL 14-15, 2016

The Community Oncology Conference will be held on Thursday and Friday, April 14-15, 2016 at the Loews Royal Pacific Resort (a Universal Orlando resort), 6300 Hollywood Way, Orlando, FL 32819.
Thank You!

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