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”.

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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
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

<table>
<thead>
<tr>
<th>Oncology Care Model</th>
<th>Part B Drug Payment Model</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Developed over a 3-year period</td>
<td>• Appeared out of thin air</td>
</tr>
<tr>
<td>• Extensive expert input</td>
<td>▸ No notice except for error in contractor posting</td>
</tr>
<tr>
<td>▶ MITRE &amp; Brookings</td>
<td>• No expert input</td>
</tr>
<tr>
<td>• Provider &amp; patient input</td>
<td>• No provider or patient input</td>
</tr>
<tr>
<td>• Voluntary</td>
<td>• Mandatory</td>
</tr>
<tr>
<td>• Limited in scope (100 practices)</td>
<td>• National</td>
</tr>
<tr>
<td>• Extensive quality measures</td>
<td>• Secretive</td>
</tr>
<tr>
<td>• Cooperative, transparent process</td>
<td></td>
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<tr>
<td>• Thoughtful &amp; thorough</td>
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</table>
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?
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
March 9, 2016
Mrs. Sylvia Burwell
Secretary
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Burwell:

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 doing so, we believe the CMS Medicare Part B Drug Payment Model is an inappropriate, dangerous, and pernicious 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 CMMI [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 CMMI shall consult representatives of relevant Federal agencies, and clinical and analytical experts with expertise in medicine and health care management. The CMMI shall not operate under any authority to:

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). Its stated mission is to develop a model that is comprehensive, thoughtful, and impactful. It is not a model to test the impact of a new payment model on seniors who are covered by Medicare.

COA Position

- 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
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.
We Need Advocates Engaged NOW!!!

STOP THE MEDICARE EXPERIMENT ON CANCER CARE!

Let’s deliver a simple message to Congress: HELP STOP THE MEDICARE EXPERIMENT ON CANCER CARE!

At the request of cancer care patients, survivors, advocates, providers and practices, we are offering these resources to make getting involved in stopping this misguided Medicare experiment as easy as possible.

If you are a PATIENT or ADVOCATE, Click HERE for Resources.

If you are a CANCER CARE PROVIDER, Click HERE for Resources.

Latest Coverage

The Daily Riser: CMS Medicare Part B Drug Payment Model: What Does It Mean for Seniors?

300+ National & State Organizations Ask Congress: Stop the CMS Drug Payment Proposal!

Drug Channels: Why CMS’s Crazy Plan to Remake Medicare Part B Won’t Work

PhRMA: The Catalyst: 3 things to know about the government’s Medicare payment change

COA Letter on Medicare Part B Drug Payment Model

Innovating and Advocating for Community Cancer Care
Drug Price Issue Front and Center

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

by Peter B. Bach, MD

SEPT 17, 2015, 8:42 PM EDT

AVERAGE COST TO DELIVER A MEDICATION (IN 2013 DOLLARS)

$250,000
$200,000
$150,000
$100,000
$50,000
$25,000
$20,000
$15,000
$10,000
$5,000
$2,500
$1,000
$250
$0

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 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

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

Christine Rushlow, USA TODAY

SEP 16, 2015

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.

Enough Is Enough

The Time Has Come to Address Sky-High Drug Prices

The Opinion Pages

Use Medicare’s Muscle to Lower Drug Prices

By THE EDITORIAL BOARD

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.
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
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.
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

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% \((16.4\% \text{ increase})\) and spending \(6.5\% \text{ increase}\) in the Medicare population
- Prevalence 0.7% to 0.9% \((28.6\% \text{ increase})\) and spending \(13.8\% \text{ increase}\) in the commercially insured population

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

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

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### Cost Drivers Vary Over Study Period

<table>
<thead>
<tr>
<th>Service Category</th>
<th>2004-2014 PPPY Cost Trends</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Medicare</td>
</tr>
<tr>
<td>Hospital Inpatient Admissions</td>
<td>22%</td>
</tr>
<tr>
<td>Cancer Surgeries (inpatient and outpatient)</td>
<td>0%*</td>
</tr>
<tr>
<td>Sub-Acute Services</td>
<td>51%</td>
</tr>
<tr>
<td>Emergency Room</td>
<td>132%</td>
</tr>
<tr>
<td>Radiology – Other</td>
<td>24%</td>
</tr>
<tr>
<td>Radiation Oncology</td>
<td>204%</td>
</tr>
<tr>
<td>Other Outpatient Services</td>
<td>48%</td>
</tr>
<tr>
<td>Professional Services</td>
<td>40%</td>
</tr>
<tr>
<td>Biologic Chemotherapy</td>
<td>335%</td>
</tr>
<tr>
<td>Cytotoxic Chemotherapy</td>
<td>14%</td>
</tr>
<tr>
<td>Other Chemo and Cancer Drugs</td>
<td>-9%</td>
</tr>
<tr>
<td><strong>Total PPPY Cost Trend</strong></td>
<td><strong>36%</strong></td>
</tr>
</tbody>
</table>
## Cost Varies by Cancer Type

<table>
<thead>
<tr>
<th>Cancer Type</th>
<th>2004-2014 PPPY Cost Trends</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Medicare</td>
</tr>
<tr>
<td>Blood</td>
<td>53%</td>
</tr>
<tr>
<td>Breast</td>
<td>36%</td>
</tr>
<tr>
<td>Colon</td>
<td>28%</td>
</tr>
<tr>
<td>Lung</td>
<td>21%</td>
</tr>
<tr>
<td>Non-Hodgkin’s Lymphoma</td>
<td>34%</td>
</tr>
<tr>
<td>Pancreatic</td>
<td>25%</td>
</tr>
<tr>
<td>Prostate</td>
<td>39%</td>
</tr>
<tr>
<td>Other</td>
<td>22%</td>
</tr>
<tr>
<td><strong>Total: All Cancers</strong></td>
<td><strong>36%</strong></td>
</tr>
</tbody>
</table>
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

Innovating and Advocating for Community Cancer Care
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, February 2016.
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
Thank You!

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