BIO Policy Briefing: The Medicare Part B Drug Payment Model

April 4, 2016
10:00 AM – 11:30 AM, EST

Panelists:

Kevin M. Kirby, Partner, The Moran Company

Ted Okon, Executive Director, Community Oncology Alliance

Sandie Preiss, National Vice President, Department of Advocacy and Access, Arthritis Foundation

Laurel Todd, Vice President, Healthcare Policy and Research, BIO

Bio Biotechnology Innovation Organization

Summary of the Provisions of the Medicare Part B Payment Demonstration

BIO Briefing of the Medicare Part B Drug Payment Proposed Rule

Kevin Kirby

April 4, 2016

Introduction to the Demonstration

- On March 8, the Center for Medicare and Medicaid Innovation (CMMI) within the Centers for Medicare and Medicaid Services (CMS) published a Proposed Rule to exercise its waiver authority to model changes to the way in which Medicare pays for prescription drugs covered under Part B.
  - CMMI was established by section 3021 of the Affordable Care Act "to test innovative payment and service delivery models to reduce program expenditures…while preserving or enhancing the quality of care furnished to individuals under such titles."
  - CMMI has broad authority to waive Medicare program requirements (as well as more limited authority to waive certain Medicaid program requirements).
- CMS noted that the goal of the Proposed Rule is to "test whether the alternative drug payment designs in this proposed rule will lead to spending our dollars wisely for drugs paid under Part B."
- Comments on the Proposed Rule are due May 9, 2016.

General Structure of the Demonstration

- 5-year demonstration
- Almost all Part B providers furnishing prescription drugs covered under Part B are required to participate
  - CMS plans to include providers who are already participating in other CMMI demonstrations (e.g., the Oncology Care Model) in the Proposed Model, with the exception of providers in the state of Maryland, who are already billing under a Medicare waiver through CMMI's Maryland All-Payer Model.
- All drugs and biologicals covered under Part B are included in the demonstration, except:
  - Contractor-priced drugs (i.e., those that are not nationally priced by CMS);
  - Influenza, pneumococcal pneumonia and hepatitis B vaccines;
  - Drugs infused with a covered item of DME (though these drugs are exempt from Phase I only);
  - Drugs that receive bundled reimbursement as part of End-Stage Renal Disease (ESRD) services;
  - Blood and blood products; and
  - Drugs in shortage (defined as "reported by the FDA to be in short supply").

Phase I of the Demonstration

- Proposed Start Date: As early as the late summer of 2016
- Structure: CMS proposes to reduce reimbursement for drugs covered under Part B from Average Sales Price (ASP) + 6% to ASP + 2.5%, plus a flat per-drug per-day furnishing fee of $16.80.
  - ASP + 6% is the statutory reimbursement rate for Part B therapies, established in the Medicare Modernization Act of 2003.
  - The + 6% add-on was established to offset providers' costs to ship, handle, store, and otherwise meet the requirements to ensure that Part B therapies remain safe and efficacious at the point of administration (these special requirements are most often associated with biological therapies).
  - CMS proposes to update the flat add-on fee annually to account for changes in the Consumer Price Index for Medical Care (CPI-MC).
- Impact of Sequestration: When applied, sequestration will reduce reimbursement under the demonstration to an effective rate of ASP + 0.86% plus $16.53.
- Proposed Budget Impact: CMS designed Phase I to be budget neutral. However, CMS expects (but has not modeled) savings as a result of changes in prescriber behavior.

Phase 2 of the Demonstration

- Proposed Start Date: As early as January 1, 2017
- Proposed Structure: CMS identifies 4 strategies that the Agency is interested in exploring for specific therapies or groups of therapies:

  (1) **Referencing pricing**: CMS would set a benchmark reimbursement rate based on: the payment rate for the average price for drugs in a group of therapeutically similar drug products, the most clinically effective drug in the group, or based on some other threshold specifically developed for such drugs.

  (2) **Indication-based pricing**: CMS would set different prices for a drug based on the clinical effectiveness of the indication for which it is being prescribed (e.g., in a case in which a drug is indicated for two types of cancer, CMS would reimburse at a higher rate for the indication for which the drug is most effective).

  (3) **Risk-sharing arrangements based on outcomes**: CMS would enter into voluntary agreements with manufacturers to link reimbursement with the achievement of certain, pre-specified healthcare outcomes (e.g., improvement in symptoms).

  (4) **Discounting or eliminating patient cost-sharing for certain high-value therapies**: CMS would establish lower patient cost-sharing requirements for products determined to be high in value (currently, patients have a 20% coinsurance, though many patients receive benefits through supplemental insurance plans, which cover a significant portion of this coinsurance requirement).

  - In addition to the current comment period, CMS intends to undertake a 30-day notice-and-comment period for each of these strategies, and any others, before they are implemented.
- Proposed Budget Impact: CMS expects Phase II to generate savings, but does not provide an estimate of those savings in the Proposed Rule.

Provider Randomization into Demonstration "Study" or "Control" Arms

- Part B providers will be randomly assigned to one of the three "study arms" or the "control arm," based on their zip code (as aggregated into Primary Care Service Areas (PCSAs)).
  - PCSAs were developed based on primary care referral patterns, and are primarily utilized as the unit of measure for the Dartmouth Medicare Atlas Project.
  - Excluding providers practicing in Maryland, there are 7,048 total PCSAs, so CMS intends to include approximately 1,700 PCSAs per study arm.
  - CMS chose the PCSA unit because it is "sufficiently large to minimize the potential for exposing providers or suppliers to multiple test payment alternatives, while sufficiently small to ensure a sufficient numbers of areas, and to limit cluster effects due to differences that cannot be balanced using stratification, we considered aggregations of contiguous ZIP codes." [Proposed Rule at 32]

Summary of the Structure of the Demonstration

Phase 1 – ASP+X	Phase 2 – VBP
ASP+6% (control arm)	ASP+6% (control)
	ASP+6% with VBP
ASP+2.5% and Flat Fee Drug Payment	ASP+2.5% and Flat Fee Drug Payment
	ASP+2.5% and Flat Fee Drug Payment with VBP Tools

Additional Provisions of the Proposed Rule

- CMS also solicits stakeholder feedback on the following subjects :
  1. Creating Value-Based Purchasing arrangements directly with manufacturers
  2. The Part B Drug Competitive Acquisition Program (CAP)
  3. Episode-based or bundled pricing approach
- CMS solicits input on these three approaches to determine if any or all are appropriate to pursue as part of the Part B Drug Payment Model or in the near future.

Innovating and Advocating for Community Cancer Care

BIO POLICY BRIEFING

Community Oncology Perspective

Part B Drug Payment Model

Ted Okon

4/4/16

Step Back – What is CMS Really Saying?

- Oncologists are not prescribing the “right” treatment for their patients
  - Clear from the aggressive CMS PR campaign in introducing the “model”
    - Oncologists are clearly motivated to prescribe the most expensive drug, not the right drug for the right patient
- CMS 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 hypothesis
  - Yet, a forced (mandatory) reimbursement reduction for 3/4s of the country
  - Yet, no evidence of the CMS hypothesis
    - Evidence to the contrary that CMS hypothesis 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 Hypothesis is 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.

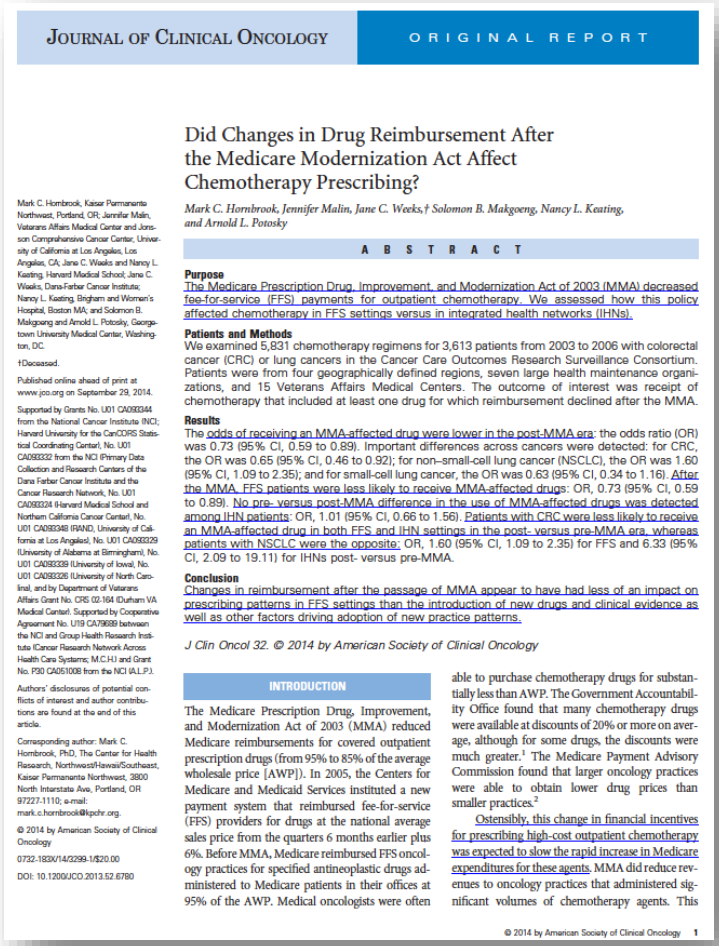
One approach for cost reduction is to reduce the payment amount for each service. After Medicare decreased the reimbursement levels for drugs in 2005, an analysis of patients with lung cancer revealed that oncologists treated more patients with chemotherapy and increased the usage of expensive drugs.[2] 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

Mark C. Hornbrook, Kaiser Permanente Northwest, Portland, OR; Jennifer Malin, Veterans Affairs Medical Center and Jonsson Comprehensive Cancer Center, University of California at Los Angeles, Los Angeles, CA; Jane C. Weeks and Nancy L. Keating, Harvard Medical School; Jane C. Weeks, Dana-Farber Cancer Institute; Nancy L. Keating, Brigham and Women's Hospital, Boston MA; and Solomon B. Makgoeng and Arnold L. Potosky, Georgetown University Medical Center, Washington, DC.

†Deceased.

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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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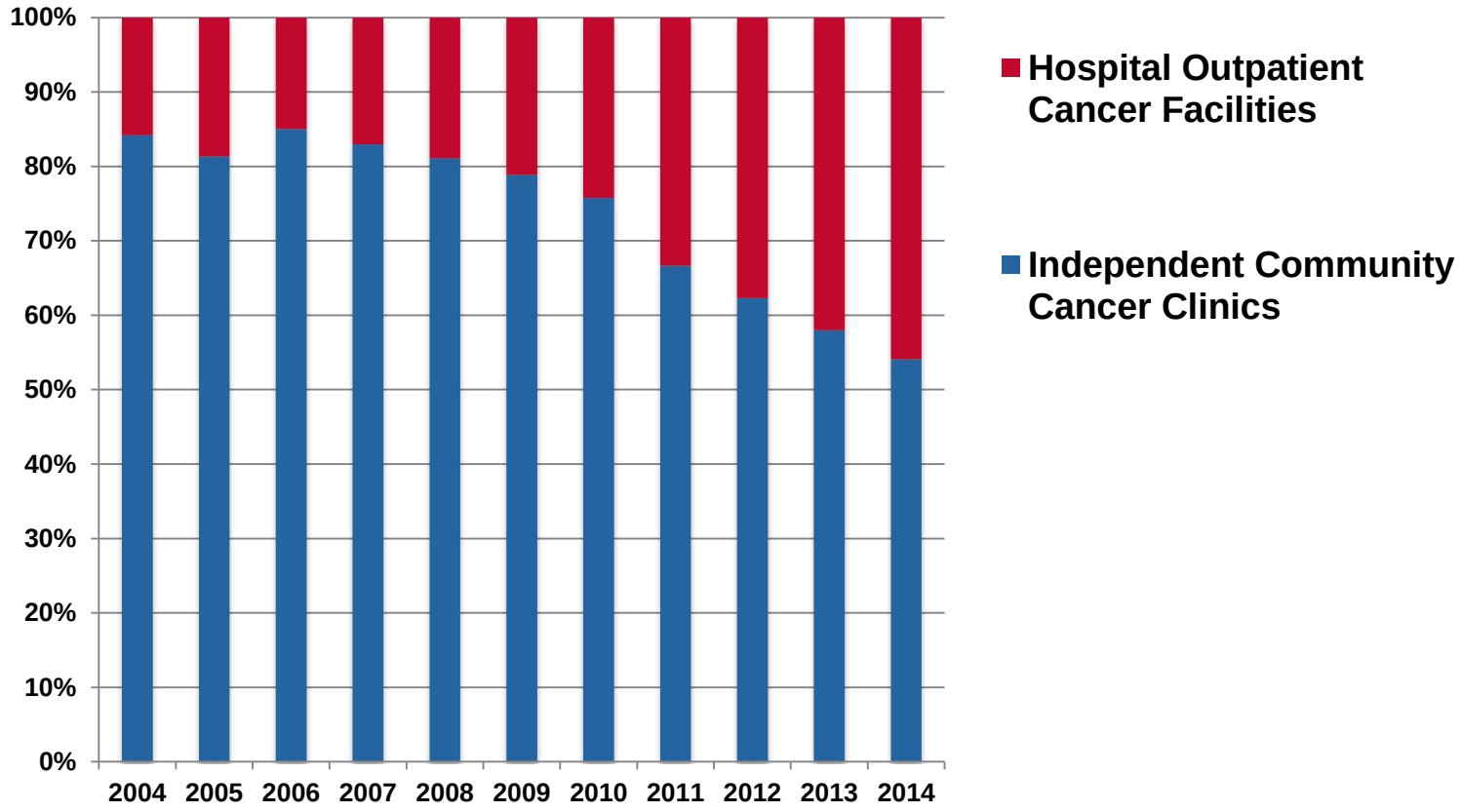
Likely Impact on Patients & Their Care

- 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

Site of Cancer Care Shifting Dramatically



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

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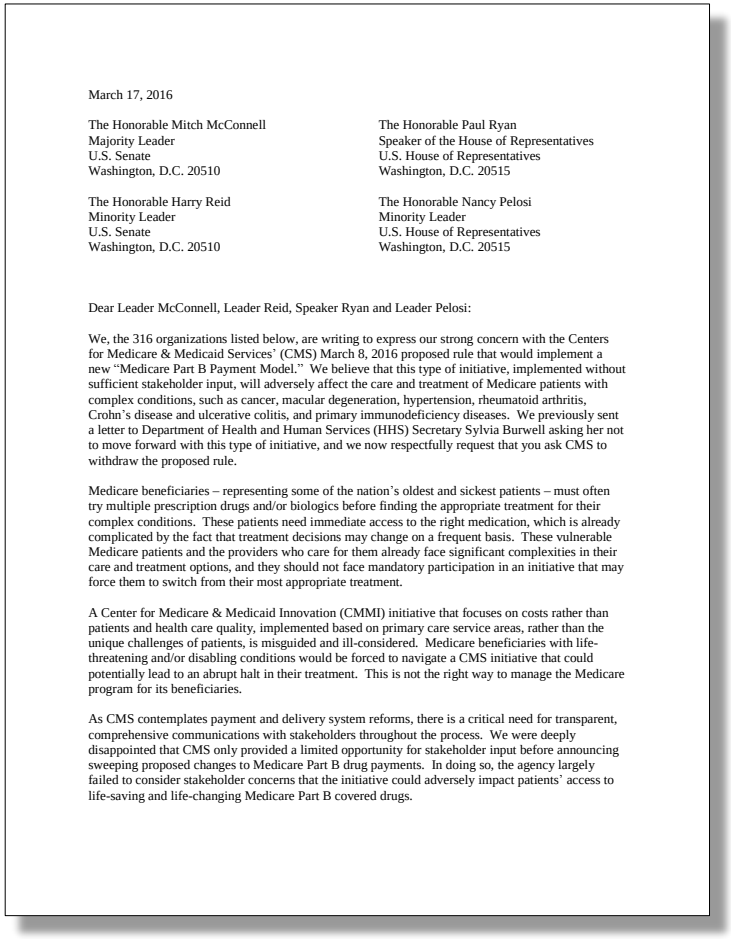
Contrast OCM to Part B Payment Model

- 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

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.

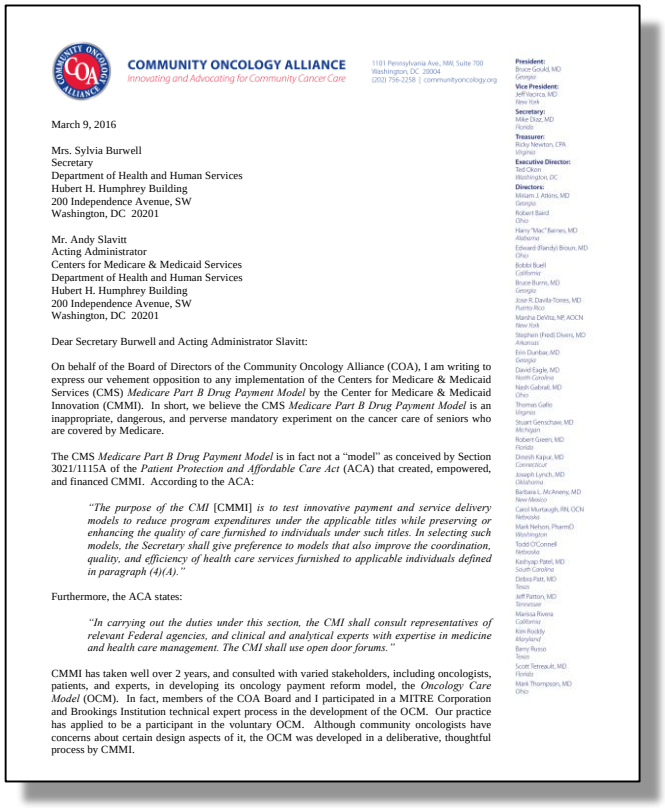
Medicare beneficiaries – representing some of the nation's oldest and sickest patients – must often try multiple prescription drugs and/or biologics before finding the appropriate treatment for their complex conditions. These patients need immediate access to the right medication, which is already complicated 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

COA Position



COMMUNITY ONCOLOGY ALLIANCE
Innovating and Advocating for Community Cancer Care

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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.
  - Anti-VBID

Enlist the Help of Congress

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Thank You!

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

www.facebook.com/CommunityOncologyAlliance

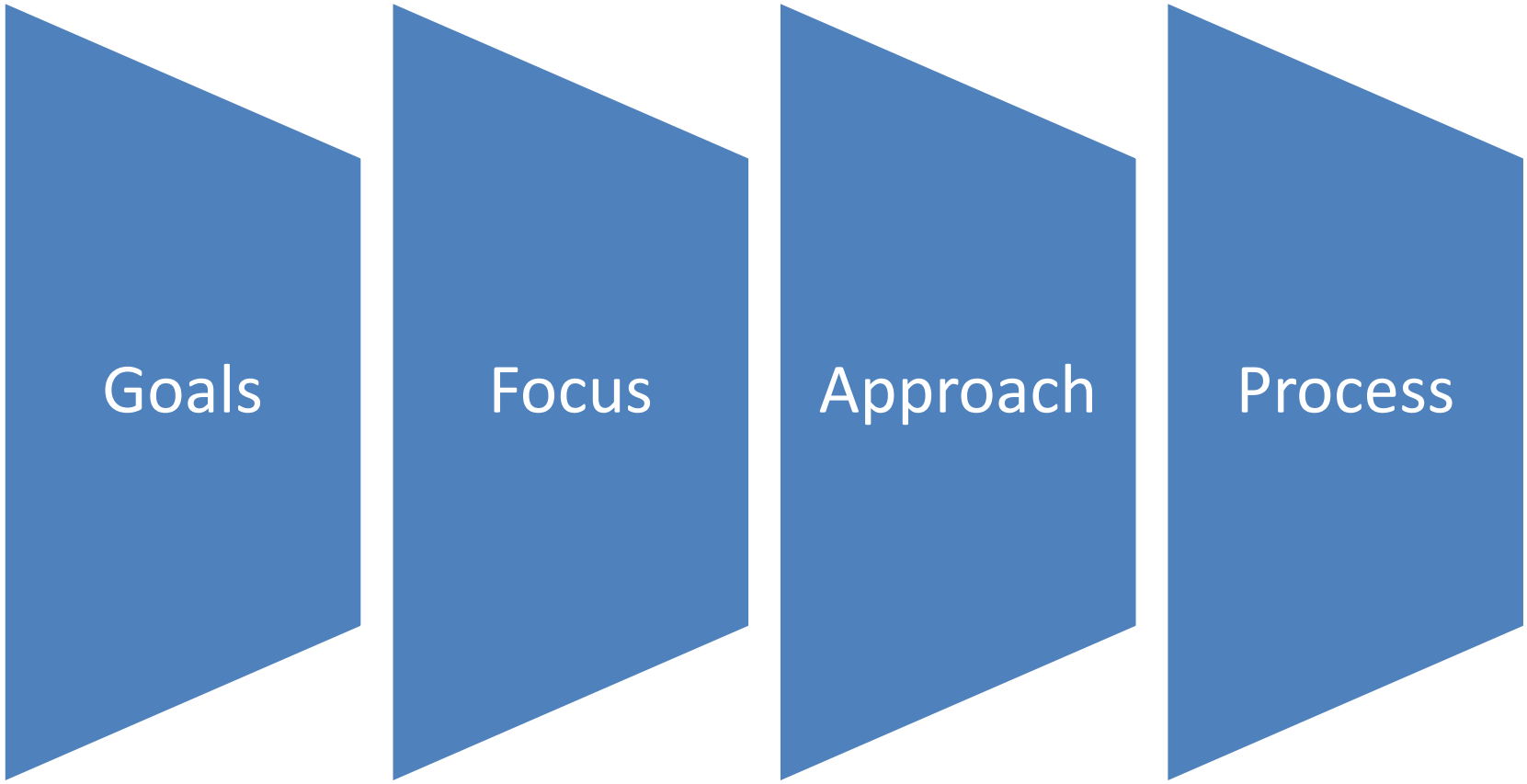
BIO's Initial Perspectives on the Part B Drug Payment Demonstration

Laurel L. Todd
Vice President, Healthcare Policy & Research
Biotechnology Innovation Organization (BIO)

BIO Briefing on the Medicare Part B Drug Payment Proposed Rule
Monday, April 4, 2016
Washington, D.C.

Biotechnology Innovation Organization

BIO's Primary Concerns with Part B Proposed Rule



The Proposed Rule is Misaligned with its Stated Goals

- CMS states that the goal of the Proposed Rule is to "spend[] our dollars more wisely for drugs paid under Part B, that is, a reduction in Medicare expenditures, while preserving or enhancing the quality of care provided to Medicare beneficiaries."

- While BIO agrees with this goal, the provisions of the Proposed Rule will undermine—not facilitate—efforts to achieve it.

  - The Proposed Rule would limit providers' ability to obtain Part B therapies at or below the Medicare reimbursement rate.
    - MedPAC has noted that some providers already have difficulty obtaining therapies at or below ASP + 6%.
    - The Proposed Rule could negatively impact the financial viability of community providers' practices, and thus, exacerbate the trend of hospital/provider consolidation.

  - Limiting provider access to therapies can, in turn:
    - Force patients who are stable on a therapy to switch to different therapy; and/or
    - Force patients to obtain care from a different provider, potentially making them travel farther and incur higher out-of-pocket costs.

The Narrow Focus of the Proposed Rule is At Odds with Comprehensive Reform

- The Proposed Rule has an extremely narrow focus, and thus, suggests a piecemeal approach to Medicare payment and delivery-of-care reform.
  - Payment for Part B drugs and biologicals is less than 3% of total Medicare spending.

- The narrow focus of the Proposed Rule is contrary to the focus of CMMI's other demonstrations, which take into account all aspects of patient care and promote comprehensive practice transformation (e.g., Oncology Care Model, Bundled Payments for Care Improvement Initiative).

- The Proposed Rule ignores the role of, and potential interaction with, existing demonstration programs and MACRA implementation.
  - The Merit-based Incentive Payment System is being developed now, to be implemented in 2019 (in year 3 of the Part B Demo).

CMS's Approach to the Proposed Rule is Inconsistent with the Spirit of its Demonstration Authority

- The Proposed Rule is not consistent with the spirit of the demonstrations that Congress intended CMMI to undertake.
  - The scope (e.g., national roll-out, mandatory participation) is not aligned with the nature of a "demonstration."
  - The narrow focus on short-term costs does not align with the types of models that Congress identified in the ACA (e.g., models that emphasize care coordination, practice transformation, and improvements to the quality of care).
  - CMS has produced no evidence that "that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures," a central tenet of potential demonstrations.
    - In fact, data suggest that the ASP methodology has helped to curb the growth in Part B drug costs (a trend line that has remained flatter than the trend in the growth of the CPI for medical care from 2006-2014)[1] and promoted broader patient access.
    - Evidence suggests that when Part B providers are faced with two therapeutically similar therapies, they tend to choose the one that costs *less*, not more.[2]

[1] Moran Company. 2015. *Trends in Weighted Average Sales Prices for Prescription Drugs in Medicare Part B, 2006-2014*.
[2] Pershing, S., *et. al*. 2015. Treating Age-Related Macular Degeneration: Comparing The Use Of Two Drugs Among Medicare And Veterans Affairs Populations. *Health Affairs* 34(2): 229-238.

CMS's Process for Developing the Proposed Rule was Not Transparent or Collaborative

- CMS has not used a transparent, inclusive, or collaborative process to develop a demonstration program.

- Based on existing rules governing notice-and-comment rulemaking, the Final Rule can only contain variations on the themes of proposals put forward in the Proposed Rule (the "logical outgrowth" standard).
  - Thus, CMS had already narrowed the universe of potential ideas to address quality of care and overall expenditures in Part B before asking for public feedback.

- Moreover, CMS proposed several concepts in Phase II of the Proposed Rule that are not ready for implementation, and did so despite the fact that the Agency is still in the process of collecting information from a diversity of stakeholders on legal, regulatory, and operational impediments to these concepts.