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
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.

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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

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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.
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, S. A. Dave, MS, and Monica Perkman, PhD

UnitedHealthcare, Minneapolis, MN; Northwest Genetics Oncology, Marietta, GA; and Cancer for Blood and Cancer Disorders, Forth Worth, TX

**Abstract**

The study tested the combination of an episode payment coupled with actionable data and quality goals as an incentive to improve quality and reduce costs.

**Methods**

Medical oncologists were paid a single fee, in lieu of any drug margins, to treat their patients. Chemotherapy medications were remunerated at the average sales price, a proxy for gross margin.

**Results**

Over the 18-month study period, the groups were compared with a large national payer registry of fee-for-service patients with cancer to the results of the episode payment model and the impact of the payment change. Comparisons were based on multiple quality measures.

**Conclusion**

The model has the potential for a systemic solution for cancer care with health data and financial information that can be applied to significant total cost reductions. Eliminating the financial system from chemotherapy dramatically increased the value of chemotherapy.

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

Mark C. Fossa, Lisa J. Mendenhall, Barry P. Scheck, Paul A. Hansen, and David M. Schlum

**Purpose**

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) increased drug reimbursement, which affected cancer care. We examined the impact of the MMA on total Medicare payments for drug prescriptions.

**Methods**

We examined drug expenditures for 6.3 million patients from 2002 to 2006 with Medicare (Part D) for services. We analyzed differences in drug utilization and payments before and after the MMA.

**Results**

The MMA led to increased spending for prescription drugs. Overall, total Medicare drug spending increased by $4.3 billion in 2003 and $12.7 billion in 2004. The MMA led to increased spending for prescription drugs by $7.1 billion in 2003 and $13.2 billion in 2004.

**Conclusions**

Changes in chemotherapy prescribing after the passage of the MMA appear to have had little effect on overall Medicare spending but could have implications for future policy decisions.
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
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
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 9, 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, muscular 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 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 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

Innovating and Advocating for Community Cancer Care

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March 9, 2016

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

Mr. Andy Hallett
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 Borelli and Acting Administrator Hallett:

On behalf of the Board of Directors of the Community Oncology Alliance (COA), I am writing to express our concern and objection 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 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 of the Patient Protection and Affordable Care Act (PPACA) 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 (a)(1).”

Furthermore, the ACA states:

“In carrying out the duties under this section, the CMMI shall consult representatives of relevant Federal agencies, and the Centers for Medicaid and Medicare Services, and health care management. The CMMI shall use open door forums.

CMMI has taken well over 2 years, and consulted with various stakeholders, including oncologists, patients, and experts, in developing an oncology payment reform model, the Oncology Care Model (OCM). In fact, members of the COA Board and I participated in the MEDPAC’s Innovation and Breakthrough Innovation technical expert panels 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 CMS.

Therefore, we reiterate our objections to the CMS Medicare Part B Drug Payment Model, which is not a CMS model at all. We urge you to look carefully at the CMS Medicare Part B Drug Payment Model and to support this experiment.

Sincerely yours,

[Signature]

[Title]
Enlist the Help of Congress
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.
BIO’s Primary Concerns with Part B Proposed Rule

- Goals
- Focus
- Approach
- Process
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 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).
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]

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.