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Submitted electronically via Regulations.gov

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1670-P
PO Box 8016
Baltimore, MD 21244-8016

**Re: CMS-1670-P—Medicare Program; Part B Drug Payment Model; Proposed Rule**

To Whom It May Concern:

The Pew Charitable Trusts is pleased to offer comments to the Centers for Medicare and Medicaid Services (CMS) on the proposed rule to test new payment strategies for Medicare Part B drugs. Pew is an independent, nonpartisan research and public policy organization dedicated to serving the public. The work in our specialty drugs research initiative is focused on identifying policies that would allow public programs to better manage the cost of pharmaceuticals while ensuring that patients maintain access to the drugs that they need.

These comments are informed by our own analysis and by an April 11 public stakeholder convening that Pew hosted on this topic, which included pharmaceutical companies, provider organizations, and patient groups, to discuss the policies included in the demonstration as well as its study design.[1] While Pew takes no position on the proposed Part B experiment, we offer a number of observations for consideration.

Drug spending in Medicare Part B reached $22 billion in 2015, and Part B drug costs have increased by an average of 8.6 percent annually since 2007.[2] CMS, through the Center for Medicare and Medicaid Innovation (CMMI) and other mechanisms, has numerous initiatives to test and advance innovative payment and delivery models with the potential to improve the quality and efficiency of care provided to Medicare beneficiaries. While some of these have the potential to indirectly influence drug spending, standalone reimbursement for drugs remains a major expenditure for the foreseeable future, and there is merit in efforts to better align incentives with value.

Through the Medicare Part B Drug Payment Model, CMS has proposed to evaluate a number of drug payment strategies, many of which are already used in the private sector by health plans, insurers, and

[1] The Pew Charitable Trusts, "Public Forum on the Medicare Part B Drug Payment Model," Recording available at: http://www.pewtrusts.org/en/about/events/2016/public-forum-on-the-medicare-part-b-drug-payment-model
[2] Medicare Program; Part B Drug Payment Model; Proposed Rule, 81 Fed Reg. 13230 (Proposed March 11, 2016) (to be codified at 42 CFR 511).

pharmacy benefit managers. Limited evidence exists on how these payment policies would affect Medicare beneficiaries' access to drugs, health outcomes, and overall costs; new research that is well-designed could help answer these questions. We offer comments in three main areas:

- Patient protections needed to monitor access to appropriate drug therapies;
- Giving the public ample time to weigh in; and
- Further refinement of the study design.

**Patient protections needed to monitor access to appropriate drug therapies**

At the Pew-hosted public forum on April 11, there was agreement among panelists that CMS should take steps to ensure that patients maintain access to the drug therapies that they need.

Today, there is limited evidence on the consequences of using new payment policies for Part B drugs, and the existing evidence does not provide clear direction on how providers would respond to new payment models. For example, one study by the Office of the Inspector General (OIG) found that utilization of certain prostate cancer drugs increased in response to an increase in payment.[3] In a separate study, researchers concluded that providers increased utilization of lung cancer drugs, though in response to a decrease in payment.[4]

However, there were differing beliefs among panelists on whether Phase I of the demonstration, which would reduce provider payment for high-cost drugs, would adversely affect patient access. There was concern from some that reducing provider payment for high-cost drugs would result in an increased number of providers for whom Medicare payment for some drugs would be less than their acquisition cost. This could lead to limited patient access and worse health outcomes if these providers choose to stop offering these drug therapies to Medicare beneficiaries because they are "underwater".

There was also concern that the demonstration could accelerate the trend of patient care shifting from the physician office setting to the hospital outpatient setting, particularly in oncology. This is an important consideration since the care provided in the hospital outpatient department (HOPD) can be more expensive than that in the physician office. For example, Medicare patients with cancer who receive chemotherapy infusions in a hospital outpatient setting had 34 percent higher costs than patients with cancer who received treatment in a physician's office in 2014.[5]

At the same time, other panelists expressed concern for high drug costs in Medicare Part B, and applauded CMS efforts to test new payment policies that would have the potential to reduce drug spending. These same panelists were also skeptical that the proposed model would limit beneficiary access, noting that the high cost of some drugs today already creates an access barrier.

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[3] Department of Health and Human Services, Office of the Inspector General. "Least Costly Alternative Policies: Impact on Prostate Cancer Drugs Covered Under Medicare Part B." OEI-12-12-00210. November 2012. Available at: http://oig.hhs.gov/oei/reports/oei-12-12-00210.pdf

[4] Jacobson M, Earle CC, Price M, Newhouse JP. How Medicare's Payment Cuts for Cancer Chemotherapy Drugs Changed Patterns of Treatment. *Health Affairs* 2010; 29(7): 1391-1399.

[5] Fitch K, Pelizzari PM, Pyenson B. "Cost Drivers of Cancer Care: A Retrospective Analysis of Medicare and Commercially Insured Population Claims Data 2004-2014." Milliman (April 2016), Available at: http://www.communityoncology.org/pdfs/Trends-in-Cancer-Costs-White-Paper-FINAL-20160403.pdf

Providers and patients today are constantly exposed to changes in drug costs and payer reimbursement in both the public and private sectors. For example, if a drug's average sales price (ASP) increases, it is possible that providers would be "underwater" due to the 2-month lag that it takes CMS to update its ASP-based payment rate for Part B drugs. It was noted that these constant changes generally go unnoticed and, therefore, likely have a minimal impact on patient access.

However, CMS has not presented a monitoring plan to address potential risks to beneficiary access in the demonstration. Panelists at the Pew event recognized the need for a robust process to monitor and assess the effects of the new payment policies on patient access during both phases of the model.

It was also suggested that CMS develop a formal mechanism to engage patients, providers, and other stakeholders while the demonstration is underway. Through this process, CMS could actively engage the public on a continual basis in order to monitor the experience of patients and providers in real-time. Leaders at CMS have expressed the importance of such ongoing engagement.

**Giving the public ample time to weigh in.**

CMS has asked for public input on how it should proceed with various aspects of its study design and choice of policy tools in both Phase I and Phase II of the Part B Drug Payment Model. Given the complexity of the demonstration, its development should be transparent, and CMS should continue to seek input from policy experts and stakeholders throughout its development, implementation, and analysis of results. External input is needed to ensure that the proposed demonstration will produce scientifically valid conclusions that will be informative to policymakers.

At Pew's April 11 forum, panelists identified two areas of concern related to how expert and stakeholder input should be solicited in order to constructively inform the design and implementation of the demonstration. The first is related to the general approach being used by CMS to obtain public input on the design of the demonstration. The second is related to the process for determining when to apply the different value-based pricing (VBP) tools to drugs.

*Process for obtaining constructive public input on the design of the demonstration*

CMS has released a proposed rule via the Federal Register and seeks public input through a 60-day comment period. However, concern was raised by panelists that obtaining public input on the development of a demonstration of this complexity requires a much more iterative and engaged process than the federal rule-making process allows.

Panelists suggested that CMS continuously and actively seek the public's input as it develops its research plan, including its research methodology and analytic approach. Even if experts agree today with the general approach described in the proposed rule, they may have concerns with its design in the future as important details of the demonstration are specified. An ongoing, collaborative process would be needed to engage the public, including experts and various stakeholder groups, in a meaningful way.

*Determining the Value of Drugs in Phase II*

In Phase II of the model, CMS has proposed to incorporate a range of VBP tools for a limited number of Part B drugs. As described by CMS, the VBP tools would link "payment for a medicine to patient outcomes and cost-effectiveness."[6] A critical step in developing a VBP policy is the assessment of the effectiveness and cost-effectiveness of pharmaceuticals to determine their value.

Panelists at the Pew meeting were generally supportive of CMS efforts to incorporate value into how it pays for healthcare, and they highlighted two important strategies for CMS to consider in Phase II. First, panelists commented that it would be important for CMS to avoid a "one-size-fits-all" approach in its application of the value-based pricing tools and that VBP strategies should not be applied broadly across pharmaceuticals. They commented that the decision to use a specific VBP tool should be made drug-by-drug and be informed by a critical appraisal of high-quality evidence on the benefits and harms of a drug therapy.

CMS has identified one source for information on the effectiveness and value of drugs—the Institute for Clinical and Economic Review (ICER). However, CMS should also consider other information sources to inform its understanding of the benefits and risks of pharmaceuticals, such as evidence reports produced through the Evidence-based Practice Centers (EPCs) funded by the Agency for Healthcare Research and Quality (AHRQ) as well as published, peer-reviewed literature.

Second, panelists argued that a transparent process that allows for public engagement is needed to determine which drugs are appropriate for the different VBP tools. CMS proposes to allow 30 days for public comment and to provide a minimum of 45 days public notice before implementation of specific value-based pricing tools in Phase II of the demonstration. However, panelists noted that the process of determining the value of drugs would likely require a more iterative and engaged approach involving both clinical and policy experts as well as a diverse group of stakeholders. They suggested that CMS take steps to create a transparent process that would rely on high-quality evidence as well as incorporate input from the public.

Different frameworks have been developed to assess the value of pharmaceuticals.[7] These are tools that can be helpful to policymakers and guide their decision-making. However, there are also limitations with their use. The frameworks often rely on different methods and are meant to be used in different ways (e.g., informing a patient's choice of treatment vs. the development of payer coverage and payment policies). There is also a lack of consensus on best practices and how to use these tools to inform the development of new payment policies.

Furthermore, as discussed by panelists at the Pew forum, CMS would likely face challenges due to the limited available evidence on the comparative- and cost-effectiveness of drug therapies. For these reasons, it is important that CMS develop a transparent process to assess the value of medicines that draws on the knowledge of experts and stakeholders.

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[6] Medicare Program; Part B Drug Payment Model; Proposed Rule, 81 Fed Reg. 13230, pg. 13243 (Proposed March 11, 2016) (to be codified at 42 CFR 511).

[7] Neumann PJ, Cohen JT. Measuring the Value of Prescription Drugs. *N Engl J Med* 2015; 373(27): 2595-7.

**Further refinement of the study design**

In the proposed rule, CMS has provided an overview of the design of the Part B Drug Payment Model, including information on study participants, the proposed unit of randomization, the policy tools that would be studied, and its proposed evaluation questions. However, a more detailed study plan is needed. We highlight the following considerations:

- *Requiring randomization*. Changes in reimbursement policy are often implemented system-wide without an opportunity to clearly understand the effects of the change. Randomization between a control arm and an intervention offers the opportunity to more carefully evaluate the intervention. Randomization is considered the 'gold standard' for research design because it reduces bias and confounding.

- *Determining the appropriate size of the demonstration.* The appropriate size for any experiment is the minimum size necessary to obtain valid and generalizable study results. CMS has proposed to include "all providers and suppliers furnishing covered and separately paid Part B drugs" on the grounds that such an approach is necessary to ensure that "observed outcomes in each arm of the model do not suffer from selection bias inherent in a voluntary participation model and that observed outcomes can be generalized to all providers and suppliers billing Part B drugs."[8] However, CMS should consider more clearly defining its hypothesis and the scale needed to establish the effect size of interest. Final decisions on the scope of the model—including whether it includes all providers or just providers in select geographic areas—should be based the study design needed to arrive at generalizable conclusions.

- *Requiring mandatory participation*. Allowing for voluntary participation in the demonstration may compromise study results. In a voluntary demonstration, the providers who would choose to participate may not be representative of the overall provider population. In particular, providers who typically administer drugs subject to a payment cut under Phase I—drugs with an ASP above $480[9]—would be less likely to participate than providers who typically administer drugs for which payment would be increased (e.g., drugs with an ASP below $480). Absent mandatory participation, it would be necessary to create a robust process for stratification of participants prior to randomization, though such a step remains susceptible to bias.

- *Unit of randomization.* A number of stakeholders have expressed concern about the Primary Care Service Area (PCSA) as the unit of randomization. Because many provider organizations operate in more than one PCSA, this design could create the potential to direct patients to one practice site or another, depending on the drug to be administered and the assigned reimbursement formula. CMS should carefully evaluate this potential before finalizing the study design.

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[8] Medicare Program; Part B Drug Payment Model; Proposed Rule, 81 Fed Reg. 13230, pg. 13236 (Proposed March 11, 2016) (to be codified at 42 CFR 511).

[9] Hussain F, Borden A. "Proposed Medicare Part B Rule Would Reduce Payments to Hospitals and Some Specialists While Increasing Payments to Primary Care Providers." Avalere (April 2016). Available at: http://avalere.com/expertise/managed-care/insights/proposed-medicare-part-b-rule-would-reduce-payments-to-hospitals-and-some-s

- *Quality measures to evaluate access to and quality of care.* CMS has not identified the measures that would be used to evaluate changes in provider practice patterns or to assess quality of care. CMS has proposed a number of evaluation questions, but has not described how they would be operationalized, such as which quality measures it would use or how it would develop new measures. These are critical steps in the development of the research plan.

Thank you for the opportunity to comment on the proposed rule on the Medicare Part B Drug Payment Model. Should you have any questions, or if we can be of assistance with your work, please contact me by phone at 202-540-6392 or via email at ACoukell@pewtrusts.org.

Sincerely,

Allan Coukell
The Pew Charitable Trusts