

May 16, 2016

Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
200 Independence Ave SW
Washington, DC 20201

Dear Acting Administrator Slavitt:

The Centers for Medicare & Medicaid Services (CMS) has proposed a new Part B Drug Payment model through the Center for Medicare and Medicaid Innovation (CMMI). We support the Administration's goal to reform the health care delivery system by rewarding high value patient care and innovative approaches to meet this goal. However, we have concerns about the proposed payment model and its potential for unintended effects on beneficiaries and the physician community. We have important questions that CMS should resolve before finalizing the parameters of this demonstration.

We strongly urge the Administration to address these concerns before moving forward with the Part B model. We request that you to closely consider the following issues, and we seek answers to all of our questions relating to the model:

1. Beneficiary Impact: Improved payment accuracy for prescription drugs may reduce beneficiary out-of-pocket costs, and we applaud efforts to address issues related to affordability for beneficiaries. However, reduced costs must be balanced with patient access, and we would like to ensure that beneficiaries' access to vital medications is maintained. While the demonstration is in Phase I, how do you plan to monitor access to care for patients? What analysis has been done to ensure the proposed model will not have a deleterious effect on patient care? Please outline your plan to monitor patient access and quality of care in real time to ensure beneficiaries are not adversely affected by this demonstration.
2. Stakeholder Input: We believe that this demonstration needs a formal mechanism that allows for direct stakeholder input throughout the duration of the project. Patients need to have a voice in the choice of policies, just as they need to be at the center of treatment decisions. Input from patients and their providers can help ensure that this demonstration does not limit access or reduce quality of care. We understand that there will be an appeals process, but we request that CMS include further opportunities for stakeholder involvement and feedback. Does CMS agree that a model-specific stakeholder feedback mechanism should be operationalized throughout the duration of the demonstration?
3. Model Scope: We have concerns about the nationwide scope of this demonstration. Why did CMS propose a nationwide effort, rather than targeting discrete areas in order to appropriately monitor quality outcomes and access? Could CMS modify and narrow the scope of the model and yield sufficiently reliable results to evaluate with respect to model goals?

4. Physician Impact: We are concerned that such rapid and expansive changes as are proposed under this model may have concentrated negative effects on certain physician communities.

- *Small, Independent, and Rural Providers*: The model may have a disproportionate effect on smaller providers, as they may have less purchasing power to exact discounts on prescription drugs and may have to buy them at or above ASP. Physicians located in rural areas and those operating in underserved regions face additional challenges, and may be the only provider available in a local community. Does CMS plan to conduct analysis on how the proposed model may affect small and rural providers? Could CMS consider differential add-on amounts to account for differing purchasing power?
- *Large Impacts in Certain Medical Specialties*: It appears that certain physician specialties, like oncologists, will see a larger payment differential than other specialties. What will CMS do to ensure that beneficiaries are not adversely impacted by these effects? For example, how will CMS monitor that cancer patients will still have access to the most appropriate drug treatment in the most appropriate setting for their conditions if physician payments for oncology drugs are steeply reduced?
- *Physician Acquisition of Drugs*: Given the wide variation in price of drugs paid for under Part B (and accordingly the absolute value of the +6 percent add on payment intended to cover storage and physician work), what analysis has CMS conducted on individual drugs paid under this methodology and how particular medicines that are more commonly used for certain conditions may be affected?
- *Situations where only one therapy is available*: We recognize that CMS is trying to balance incentives where substitutable therapies at different price points are available. However, substitutable therapies are not available in all clinical situations. How will this model account for occasions where the practice of medicine dictates that there is only one therapeutic option available?

5. Interactions with Other Models: CMS has exceeded expectations with regard to delivery system reform efforts and expanding new models of patient care and quality around the nation. We ask that you provide us with more information about how this model would interact with other ongoing demonstrations, such as the Oncology Care Model. We also anticipate that this demonstration will interact with Merit-Based Incentive Payment System and Alternative Payment Models established under the Medicare Access and CHIP Reauthorization Act of 2015. Did CMS consider these interactions carefully from both a beneficiary and provider perspective? How does CMS plan to tease out the impact of this model compared to other models that CMS is concurrently testing?

6. Potential Shifts in Site of Service: We recognize that acquisition costs for physician administered drugs vary, with large institutions able to negotiate lower prices than small, independent physician practices or small rural hospitals. Has CMS considered whether or how this model might affect where patients receive care, at a hospital or independent physician practice?

7. Phase II Comment Period: Phase II includes various innovative approaches for applying value-based purchasing tools. However, the proposed rule does not detail how these tools would be utilized

in the model. We urge CMS to provide more granularity on these approaches so that stakeholders can more thoroughly understand and comment on them. CMS should offer an formal comment period once the details of Phase II are specified. In advance of notice-and-comment rulemaking, we strongly urge the agency to solicit stakeholder input by issuing a Request for Information. We ask that you make your engagement process for Phase II clear and transparent as you consider moving forward.

Value-based purchasing may be a more appropriate model for some therapies, such as for innovative new drugs and those without clinical substitutes. Has CMS considered interactions between the two phases of the demonstrations and whether certain therapies might be better suited to Phase II than Phase I efforts?

CMS is proposing significant and complex changes to an integral part of the Part B program and did so with no input from the Congress. We expect that CMS will make changes to any finalized Part B Drug Payment model that reflect our input, and that of the larger stakeholder community, so that the scale and scope of each test is appropriately sized. We further expect that CMS will work with Congress and other stakeholders to ensure that this model does not undermine the quality of and access to care that Medicare beneficiaries expect and deserve.

In closing, we emphasize that these questions require careful and detailed resolution before CMS moves forward with either phase of the demonstration.

Sincerely,

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