

Congress of the United States
Washington, DC 20515

September 9, 2016

The Honorable Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Acting Administrator Slavitt:

Thank you for continuing to engage with Members of Congress regarding the proposed Medicare Part B Payment Model. We share your commitment to delivering better outcomes for Medicare beneficiaries and controlling costs for taxpayers. Several significant concerns remain and we ask that they be fully addressed.

First, like many individuals and organizations that have provided comments on the proposal, we continue to be concerned by the scope of this demonstration. As currently proposed, Phase I would impact fifty percent of providers and Phase II would impact as many as seventy-five percent of providers. This far exceeds the scope of a demonstration and may have negative consequences for Medicare beneficiaries' access to care. Given the current scope of the proposal, it is feasible that patients could face roadblocks in accessing their Part B medications depending on their location. Further, there are no mechanisms in place to provide real-time monitoring to ensure patients are able to access necessary treatments. We remain concerned about the continuity of care, ability to maintain a control cohort, to accurately evaluate outcomes, and to effectively modify the demonstration to deliver better value-driven patient-centered care. We appreciate your acknowledgement of this issue.

Second, we are concerned that a demonstration of this magnitude was developed with little input from the large range of impacted stakeholders. Patient advocates, physicians, researchers, and other involved participants possess valuable insight that can improve the structure and execution of CMS demonstrations. For example, stakeholders played an active and constructive role in the development of the Oncology Care Model, which includes more than 3,200 oncologists and will cover approximately 155,000 Medicare beneficiaries nationwide. While we understand certain limitations now apply because the notice is published, we urge comprehensive and more constructive engagement with affected parties before moving forward with this proposal. Similarly, we are concerned that should the proposal move forward, sixty days may be insufficient time for CMS to effectively execute a successful beneficiary education and outreach program.

Most importantly, we remain concerned for the consequences this demonstration could have on patient health. The purpose of the demonstration is to encourage the use of less costly therapies. This goal is premised on the belief that a less costly substitute exists for conditions treated with Part B drugs or that a substitute will have the same outcomes for these patients. Research has demonstrated that bioequivalence does not necessarily mean therapeutic equivalence. For example, switching bioequivalent behavior health medications, whether branded to generic or generic to generic, can have different and potentially harmful clinical outcomes for patients. In cancer care, there have been significant advancements in the development of targeted therapies aimed at blocking the growth and progression of cancer cells. These therapies hold great promise for cancer patients and are prescribed based on individual criteria and

genetic makeup. We believe that this demonstration should in no way undermine or diminish the health of Medicare beneficiaries or limit the ability of clinicians to appropriately prescribe the best therapies, including personalized medicine, for these patients.

We appreciate that the Secretary of Health and Human Services and the leadership at the Centers for Medicare and Medicaid Services have listened to the myriad concerns raised about this proposed demonstration. We ask that you fully address these concerns. We look forward to working with you to provide better value and healthier outcomes for beneficiaries and taxpayers.

Sincerely,



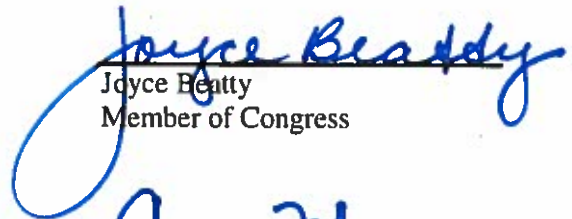
Kyrsten Sinema
Member of Congress



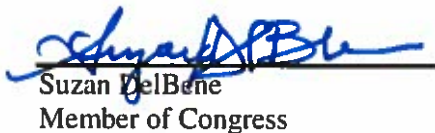
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