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April 27, 2016

Mr. Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Mr. Slavitt:

As members of the Senate Finance Committee, we write to express our concerns regarding the Part B Drug Payment Model (the Model) recently proposed by the Centers for Medicare & Medicaid Services (CMS) through the Center for Medicare and Medicaid Innovation (CMMI). We appreciate CMS's interest in testing strategies to improve value in all aspects of our health care system. However, we have heard numerous concerns from patients, providers and other stakeholders about the Model's potential to have unintended consequences on Medicare beneficiaries' access to care and physician-administered drugs. Any proposed changes to the Part B program must be carefully considered to prevent any disruptions in care for Medicare beneficiaries, particularly those with serious and complex conditions.

CMMI plays an important role in driving the health care system toward the delivery of high-value, integrated care. As a general principle, CMMI should initially implement focused demonstrations, which, if successful, can be adopted by the Medicare program. However, the changes that CMS has put forward in the Model are significant and complex. As proposed, the Model tests the impact of mandatory changes to Medicare payments for nearly all Part B medications, with up to 75 percent of providers required to participate in the Phase I change to the statutory Average Sales Price (ASP)-based payment methodology and/or the Phase II value-based purchasing tools.

Given the broad scope, CMS should resolve the following issues before moving forward with the Model:

Beneficiaries' access to Part B medications and quality of care. We have heard concerns from numerous stakeholders that the combined effect of sequestration and the proposed changes to the ASP-based payment methodology may result in some physicians facing acquisition costs that exceed the Medicare payment for certain Part B prescription drugs, potentially limiting beneficiary access to these medications. This is of particular concern for physicians in small, independent practices and those practicing in rural and/or underserved areas, and the patients they serve.

CMS should ensure that adequate real-time monitoring systems are in place to rapidly detect and respond to any negative impact on beneficiaries' access to medications or quality of care. CMS should also establish a formal mechanism that allows for direct patient input throughout the duration of the Model. In addition, we urge CMS to ensure that the scope of each phase of the Model is no larger than necessary to allow for meaningful assessment, paying special attention to the potential impact on Medicare beneficiaries receiving care from physicians in small, independent practices and rural and/or underserved areas.

Potential impact on site of service. We are concerned that the Model may not adequately account for the differentials between care settings. In the event that their acquisition costs exceed the Medicare payment available under the Model, community-based physicians may refer their patients to hospital outpatient departments (HOPDs) to receive Part B medications. Community-based care is an essential part of our health care system, and a shift in site of service from community-based practices to HOPDs would result in higher overall costs for both beneficiaries and the Medicare program. We therefore urge CMS to prevent incentives to shift site of service from community-based practices to HOPDs and take action to ensure appropriate access is maintained.

Interaction with existing delivery and payment reform models. We have also heard concerns about the impact of the Model on physicians' ability to participate in existing delivery and payment reform models, such as the Oncology Care Model (OCM) and alternative payment models incentivized by the bipartisan Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). We urge CMS to ensure that the Model does not unintentionally discourage participation in existing and future initiatives designed to improve value in our health care system.

In addition, greater engagement with the impacted community is needed, and we urge CMS to engage in a meaningful dialogue with stakeholders. As an example, we believe value-based purchasing strategies have the potential to result in both lower costs and improved quality of care for Medicare beneficiaries. However, stakeholder involvement, including direct patient input, is essential to the successful development and application of value-based purchasing tools.

In closing, given the broad scope of the Model and the concerns raised by patients, providers and other stakeholders, it is critical that CMS resolve each of the above-described issues before proceeding.

Sincerely,

Senator Ron Wyden

Senator Charles E. Schumer

Senator Debbie Stabenow	Maria Cantwell
Bill Nelson	Pall Menendez. Senator Robert Menendez.
Senator Thomas R. Carper	Ben Carlin Senator Benjamin L. Cardin
Senator Sherrod Brown	Min F B Senator Michael F. Bennet
Senator Robert P. Casey Jr.	Mork R. Warner Senator Mark R. Warner