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United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510–6200

April 28, 2016

Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Mr. Slavitt:

We write to express our strong concern with the policies in the Centers for Medicare & Medicaid Services (CMS) "Part B Drug Payment Model" proposed rule, published in the *Federal Register* on March 11, 2016. We urge you to withdraw the proposed rule immediately as it would severely disrupt care for vulnerable beneficiaries with cancer, macular degeneration, rheumatoid arthritis, neurological disorders, primary immunodeficiency diseases, rare diseases, and other serious medical conditions.

We are perplexed by the scope of the proposed experiment as it would require providers in the vast majority of the country to participate in at least one dramatic payment change. The unprecedented scope is especially troubling considering the policies could decrease the quality of beneficiary care and increase Medicare costs.

We are concerned that the proposed Phase I Average Sales Price (ASP) payment reduction would harm beneficiary access to vital drugs as many providers would face acquisition costs that exceed the Medicare payment amount. This problem would likely be especially acute for small physician practices and practices in rural areas. Physicians who have trouble accessing drugs at the reduced ASP payment would likely refer patients to the hospital outpatient department (HOPD). Driving care to a less-convenient, more costly setting would reduce beneficiary choice, increase costs, and likely further hospital-physician practice consolidation.

We are even more concerned that the Phase II policy ideas are numerous, complex, and not sufficiently vetted. The proposal provides little detail on the ideas and overstates the extent to which they have been tried while asserting that they could all be implemented on January 1, 2017. Stakeholders need to understand these ideas and their implications, which could include denying beneficiaries the drug that best meets their clinical needs.

We are dismayed that the proposal fails to indicate how CMS will assess the impact on the quality of beneficiary care. The proposal states an expectation that Part B drug spending will decrease without harming quality, yet it does not provide the specifics of how access and quality will be assessed during the experiment nor in the evaluation of it. This glaring omission deprives

stakeholders from commenting on how CMS would identify acute problems and determine what constitutes overall success.

We find the process by which CMS developed the proposals as concerning as the policies themselves. CMS failed to consult with outside experts and those with real-world experience. It decided to override the Part B drug payment methodology in statute in nearly all areas of the country on the hunch that it will decrease spending without harming patients. These decisions deeply call into question the ability of CMS to use the Center for Medicare & Medicaid Innovation (CMMI) authority prudently.

In 2014, bipartisan efforts helped prevent CMS from implementing the ill-conceived proposed Part D program changes that would have harmed beneficiaries, especially our seniors. While we were unable to find common ground with our colleagues on the Democratic side of the aisle to join us in this letter, we continue to hold out hope for future bipartisanship since ensuring continued access to life-saving drugs is a shared interest.

Further, we caution against invoking a similar unilateral effort to make changes to the successful Part D program through a flawed and overreaching read of the CMMI's authority. The Senate has already resoundingly rejected in a bipartisan manner many of the policies that the Administration may entertain through the above mentioned 2014 rebuke of the Part D proposed rule. We sincerely hope that you will withdraw this proposed rule and work with the Congress on a bipartisan approach.

Sincerely,

Orrin G. Hatch
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United States Senator

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United States Senator

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United States Senator

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United States Senator

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