Asthma and Allergy Foundation of America

May 9, 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:

On behalf of the Asthma and Allergy Foundation of America (AAFA), I write to express our strong concern about the Centers for Medicare and Medicaid Services' (CMS) Center for Medicare and Medicaid Innovation (CMMI) March 8, 2016 proposed rule that would implement substantial changes to the Medicare Part B Payment program. We believe that implementation of this Proposed Rule is misguided and would negatively impact the quality and accessibility of care that patients with complex and/or chronic conditions currently receive.

AAFA, a not-for-profit organization founded in 1953, is the leading patient organization for people with asthma and allergies, and the oldest asthma and allergy patient group in the world. AAFA is dedicated to improving the quality of life for people with asthma and allergic diseases through education, advocacy, and research. We urge you to withdraw the proposed rule immediately as it would have potential negative unintended consequences for people with asthma and allergies, and other serious and chronic conditions.

We are deeply concerned with the lack of stakeholder engagement by CMMI in the development of this proposal. We believe that it is in the best interest of patients that CMS withdraw this rule and, moving forward, implement a process that allows for those who will be most significantly impacted by a payment or delivery system change – patients– to actively engage with CMMI and offer input throughout the development of any future proposed reforms. We are bewildered by the scope of the proposal as it would likely 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 significant 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). Forcing beneficiaries to seek care at a less-convenient, more costly setting such as the HOPD, would reduce beneficiary choice, hamper quality of care, increase costs, and likely result in further hospital-physician practice consolidation. It is critically important that patients have access to the drugs that they need, and are not subjected to random programs that could threaten that access. Patients and providers already face considerable hurdles securing timely care; they should not also be

faced with a mandate to participate in an initiative that could force a physician to alter his or her clinical decision making authority based solely on an economic model and not what is in the best interest of the patient.

We are even more concerned that the Phase II proposals are numerous, complex, vague, and were not sufficiently vetted. The proposal provides little detail on the ideas and overstates the extent to which they have been tested while asserting that they could all be implemented on January 1, 2017. CMS needs to provide additional clarification for all stakeholders and better explain their implications, which could include denying beneficiaries the drug(s) that best meets their clinical needs. We are concerned that the proposal as written would result in major unintended consequences that would hinder patient access to care.

We are dismayed that the proposal fails to indicate how CMS will assess the impact on the availability of and access to quality 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 demonstration nor in the evaluation of it. This glaring omission deprives stakeholders from commenting on how CMS would identify any challenges and problems and determine what constitutes overall success.

Additionally, any time CMS considers payment and delivery system reforms, the agency must communicate with stakeholders through a transparent process that allows for engagement in the development of such a reform. We find the opaque process that CMS used to develop the proposal even more alarming than the proposal itself. CMS failed to consult with outside experts and those with real-world experience. CMS neglected to obtain input from stakeholders including beneficiaries and patient advocacy organizations.

We stand ready and are willing to work with CMS to ensure that our nation's beneficiaries can access the treatments that work best for them. Thank you for the opportunity to provide comments on this proposed rule. Please do not hesitate to contact me at csennett@aafa.org or Meryl Bloomrosen, AAFA's Senior Vice President of Policy, Advocacy, and Research at mbloomrosen@aafa.org for further information.

Sincerely,

Cary Sennett

Cary Sennett, MD, PhD
President and CEO
Asthma and Allergy Foundation of America