May 9, 2016

Mr. Andy Slavitt  
Acting Administrator  
Centers for Medicare and Medicaid Services  
200 Independence Avenue, SW  
Washington, D.C. 20201

Dear Mr. Slavitt:

NAMDRC, the National Association for Medical Direction of Respiratory Care, has as its primary mission “to improve access to quality care for patients with respiratory disease by removing regulatory and legislative barriers to appropriate treatment.” We submit these comments regarding the Centers for Medicare and Medicaid Services (CMS) recent proposal to implement a new Medicare Part B Drug Payment Model. NAMDRC has strong concerns that this initiative, which is mandatory and nationwide in scope, could adversely impact the medical care of seniors who suffer from chronic obstructive pulmonary disease and other related pulmonary diseases. We are also concerned about the precedent this policy sets by using limited demonstration authority to change statutory payment policy nationwide.

While NAMDRC supports the goals of developing new healthcare delivery methods to increase quality and provide more efficient patient care, we are nevertheless troubled by the Part B drug reimbursement policy proposed by CMS as it appears to have been created in a vacuum without any input from stakeholders involved, particularly beneficiaries and their physicians. Forcing vulnerable Medicare beneficiaries, many with potentially life threatening conditions, including COPD, the third leading cause of death in the United States, and asthma, to be exposed to a new mandatory payment initiative that runs the notable risk of impeding access to life-saving therapies runs counter to various initiatives that Congress put forth.
While we understand the need to look seriously at cost issues within our core health programs, we must not subject beneficiaries and their physicians to the problematic choice between practice economics and prescribing the most medically appropriate treatment for each individual patient. As you may know, biologic medications for treatment of asthma are likely to take an important role in treatment protocols in the immediate future. The development of new biologics in the broader pulmonary field is also likely to expand in the foreseeable future; one new biologic for asthma was approved recently, and two new biologics in the pipeline are likely to be approved by the end of the year.

In the proposed approach, CMS expresses concern that the current 6% ASP add-on payment “may encourage the use of more expensive drugs because the 6 percent add-on generates more revenue for more expensive drugs.” In addition to lacking any data to support this premise, the reimbursement changes contemplated under this model may actually increase overall health care spending by causing patients to receive care in more expensive settings.

Most importantly, there is no evidence indicating that the payment changes contemplated by the model will improve quality of care, and may adversely impact those patients that lose access to their most appropriate treatments. Instead, we believe that Medicare beneficiaries would be best served by a more patient-centric approach with appropriate safeguards, while also fostering physician-patient collaboration and ensuring that the unique needs of seniors are met. Therefore, we request that you withdraw the proposed rule and obtain meaningful stakeholder input, including from patients and providers, before proceeding with Phase 2 of the proposed pilot.

Sincerely,

Timothy A. Morris, MD
President