

United States Senate

WASHINGTON, DC 20510

September 15, 2016

Andy Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Acting Administrator Slavitt:

We are writing to express our significant concern regarding the 2016 Preliminary Gapfill Payment Determinations submitted to the Centers for Medicare and Medicaid Services (CMS) by its Medicare Administrative Contractors (MACs) for a group of advanced diagnostic tests. We are concerned that the proposed rates could jeopardize seniors' access to diagnostics that play a critical role in treatment decisions and outcomes.

Earlier this summer, CMS posted preliminary payment determinations that would lead to Medicare reimbursement cuts as high as 90% for certain advanced diagnostics before the market-based payment system takes effect. These cuts come at the same time that the Administration and Congress are working to advance a precision medicine initiative. More specifically, the proposed advanced diagnostic payment cuts are to a series of new codes for existing tests called Multianalyte Assays with Algorithmic Analyses (MAAAs) and a related set of new Genomic Sequencing Procedure (GSP) codes for hereditary cancers. These tests provide physicians with specific information for managing the care of patients with complex and serious conditions, like cancer, heart transplants, cardiovascular disease and rheumatoid arthritis. The use of targeted therapies made possible by these advanced diagnostic tests is integral to the success of precision medicine.

Moreover, we are concerned with the lack of transparency in the process by which these cuts have been proposed and the impact such significant cuts would have on patients' access to these advanced tests. When a gapfill regulatory methodology is used to set pricing, CMS is required to provide a public explanation of how the gapfill criteria was applied; however, CMS has yet to provide an explanation for the recently posted preliminary pricing by the MACs. We strongly urge CMS to provide a public explanation to provide transparency and fulfill Congressional intent.

Also, we are troubled by the wide disparity in the preliminary payment rates, which suggests an inconsistent application of the gapfill criteria. For example, the payment rates submitted by many of the contractors appear to have no relationship to current charges or payment rates by other payers for these tests. In the past, MACs have submitted rates for tests based on how often the tests are run in certain areas of the country. Under the gapfill process, rates are impacted by the lowest prices in various MACs who do not have regular experience with these advanced diagnostic tests. Without any explanation for the preliminary payment rates that have been

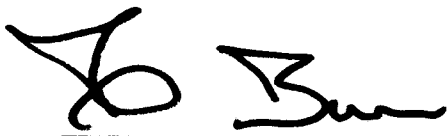
submitted by these contractors, it is unclear how CMS and its MACs have determined payment or applied any specific regulatory criteria.

These proposed cuts are also concerning given CMS' delayed implementation of the Protecting Access to Medicare Act's (PAMA) market-based payment system, which is based on private payment rates. The preliminary contractor pricing does not appear to be based on charges and payment amounts determined by private payers. Under PAMA, Congress sought to ensure continued beneficiary access to existing laboratory tests by establishing a transition period that would limit pricing reductions year-to-year, beginning with a limit of 10% in the first year. These recently proposed cuts would create significant price fluctuations prior to the start of the PAMA market-based system when labs will be reporting private payer data in 2017, which would be contrary to Congressional intent. These proposed cuts may also lead to permanently lower reimbursement across the board as private payers follow rates set by CMS in a manner that is not consistent with PAMA's intent.

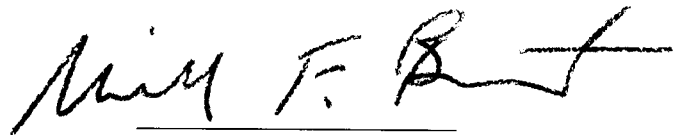
Overall, the proposed payment cuts for advanced diagnostic tests could have a negative and potentially harmful impact on patient care and stifle the very innovation that is necessary to fulfill the promise of precision medicine. Therefore, we urge CMS to instruct the Medicare contractors to adhere to the gapfill regulatory criteria of considering charges and payment rates by other payers when making gapfill payment determinations.

Thank you in advance for your attention to this matter and our concerns. We look forward to working with you to ensure seniors' access to better care through advanced diagnostic testing.

Sincerely,



Richard Burr
United States Senator



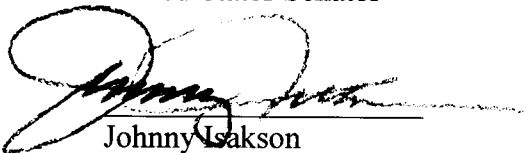
Michael F. Bennet
United States Senator



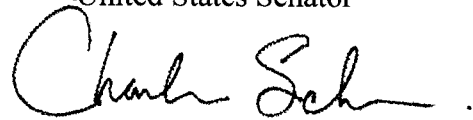
Robert P. Casey, Jr.
United States Senator



Pat Roberts
United States Senator



Johnny Isakson
United States Senator



Charles E. Schumer
United States Senator



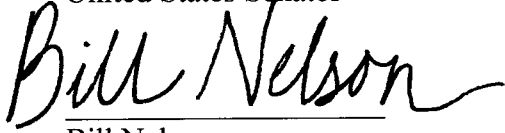
Thomas R. Carper
United States Senator



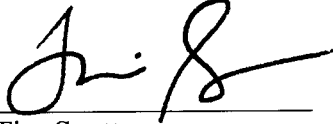
Rob Portman
United States Senator



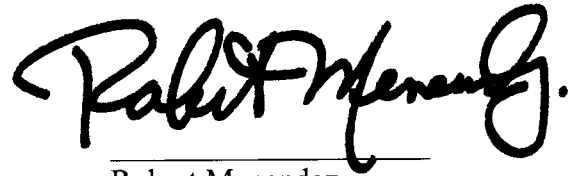
Dan Coats
United States Senator



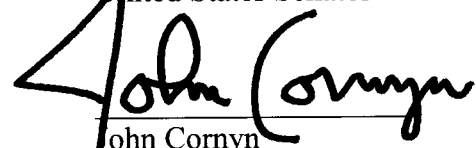
Bill Nelson
United States Senator



Tim Scott
United States Senator



Robert Menendez
United States Senator



John Cornyn
United States Senator