United States Senate

WASHINGTON, DC 20510

November 6, 2015

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

Dear Acting Administrator Slavitt:

We are writing to express serious concern regarding the CY2016 preliminary payment determinations issued by CMS for a group of existing Advanced Diagnostic Laboratory Tests (ADLTs), as well as the proposed rule to implement payment reforms for diagnostic laboratory tests. On September 25th, CMS proposed payment determinations that would lead to draconian cuts as high as 90% for these diagnostics, and at the same time, proposed a regulation that further threatens the investment in research and development of these precision medicine tests.

The proposed advanced diagnostic cuts are to a series of new codes for existing tests called Multi-analyte Assays with Algorithmic Analysis (MAAAs)[1]. These innovative tests provide physicians with specific information for managing the care of patients with complex conditions, like cancer, heart transplants, cardiovascular disease and rheumatoid arthritis. And, all have previously gone through a rigorous local coverage and pricing process by CMS's own Medicare Administrative Contractors (MACs).

We understand that the CMS preliminary payment determinations are counter to the agency's own regulations and precedents. The agency has determined in prior years that of the two available payment methodologies, the "gapfill" methodology is the most consistent with regulations and the most accurate way to price new MAAA codes. The prior CMS rationale for gapfilling MAAA codes stated that no comparable existing tests are available to "crosswalk" payment and their own MACs are best suited to provide pricing. Additionally, a Congressional mandated Advisory Panel was convened by CMS in August to provide guidance to the agency on the pricing of these new codes; the panel recommended the gapfill methodology for each. CMS, however, ignored their own expert Panel's recommendations and instead proposed "crosswalks" resulting in drastic cuts.

In the Protecting Access to Medicare Act of 2014 (PAMA), Congress sought to ensure continued beneficiary access to existing laboratory tests by establishing a transition period that would limit pricing reductions to 10% in the first year. These new cuts, proposed on the same day as a delayed rule to implement PAMA do not embrace the spirit of the law. Further, Congress recognized the uniqueness of advanced diagnostic laboratory tests and established a new category for these tests containing multiple biomarkers of "DNA, RNA, or proteins." Unfortunately, in addition to the preliminary determination cuts, CMS's proposed regulation ignored the statute and simply eliminated protein-based MAAA tests from the definition of an advanced diagnostic laboratory test. It is troubling that CMS would disregard Congressional intent as it relates to Advanced Diagnostic Laboratory Tests prior to the start of the PAMA market-based system.

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[1] MAAA CPT codes for CY2016 CLFS consideration include 81490, 81525, 81535 + 81536, 81538, 81540, 81545, 81493, 81595

As you know, Congress and the Administration are working jointly on new initiatives to advance precision medicine and accelerate scientific discovery. Enacting these draconian cuts and ignoring the statutory definition for ADLTs will undoubtedly have a negative impact on patient care and stifle the very innovation that is seeking to deliver on the promise of precision medicine.

We urge CMS to recognize the importance of these precision medicine tests and immediately reverse the proposed cuts and recognize proteins.

Sincerely,

Michael F. Bennet
United States Senator

Rob Portman
United States Senator

Thomas R. Carper
United States Senator

Pat Roberts
United States Senator

Robert P. Casey, Jr
United States Senator

Richard Burr
United States Senator

Charles E. Schumer
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Johnny Isakson
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