NATIONAL VENTURE CAPITAL ASSOCIATION
Funding innovation. Empowering entrepreneurs.

October 20, 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

Re: 2016 CLFS Preliminary Determinations for Multiple-analyte Assays with Algorithmic Analysis (MAAAs)

Dear Administrator Slavitt:

I am writing on behalf of the National Venture Capital Association (NVCA) to provide our perspective on a recent CMS payment policy proposal that would have a significant negative impact on innovation in precision medicine and patient care. On September 25th, CMS released the 2016 CLFS Preliminary Determinations which proposes drastic cuts of up to 90% for these innovative tests. These unique tests provide physicians with specific information for managing the care of patients with complex conditions, including cancer, heart transplants, cardiovascular disease and rheumatoid arthritis. We urge the agency not to finalize this proposal.

NVCA is the voice of the U.S. venture capital community, empowering its members and the entrepreneurs they fund by advocating for policies that encourage innovation and reward long-term investment. As the venture community's preeminent trade association, NVCA serves as the definitive resource for venture capital data and unites its nearly 400 members through a full range of professional services. Our members are keenly aware of the critical connection between CMS policies on reimbursement and the biotechnology innovation ecosystem.

VC Investment in Precision Medicine Companies Has Severely Declined

President Obama called for increased investment in "precision medicine" in his State of the Union address, and the Congress is working on a bipartisan basis to develop legislation to promote "21st century medicine." However, the United States is at a crossroads in the ongoing revolution to leverage advances in genomics into next generation genetic testing and treatment selection for new breakthrough therapies.

As the voice of the VC community, NVCA is uniquely positioned to comment on the investment environment in the life sciences industry and the field of molecular diagnostics in particular. Over the last several years there has been a healthy uptick in venture capital investment in life sciences, predominately in biotechnology. In 2014, investment in the Life Sciences (biotechnology and medical devices) rose to the highest level since 2008 with $8.6 billion, a 29 percent increase over 2013.

Unfortunately, investment in molecular diagnostics has seen the opposite trend. Initial financings in molecular diagnostic start-ups has decreased substantially. Initial financings is an important indicator for new innovations, as many of the most innovative advanced diagnostics were started with venture capital investment. The primary reason for this decline is the universal perception of uncertainty and inadequacy of reimbursement for innovative molecular diagnostics. This uncertainty regarding reimbursement continues to hold back investment in breakthrough personalized medicine innovation that could have a major impact on how we diagnose and treat patients with critically important diseases such as Alzheimer's disease, diabetes, and cancer, and also on how we are able to develop new, precision medicine drugs.

CMS Preliminary Payment Determination Threatens Innovation

The proposed Medicare payment cuts are for a series of new codes for existing innovative tests called Multiple-analyte Assays with Algorithmic Analysis (MAAAs). These innovative tests provide physicians with specific information for managing the care of patients with complex conditions, including cancer, heart transplants, cardiovascular disease and rheumatoid arthritis. All of these tests have already gone through a lengthy coverage and pricing process by CMS's own Medicare Administrative Contractors. These tests have been demonstrated to reduce healthcare costs and improve patient management and outcomes.

Moreover, the CMS Preliminary Determinations are counter to the agency's own regulations and precedents. The agency has determined in prior years that of the two available methodologies, the "gapfill" methodology is the most accurate way to price new MAAA codes. The prior CMS rationale for MAAA codes stated that no comparable existing tests are available to "crosswalk" payment and their own Contractors are best suited to provide pricing. Additionally, an expert Advisory Panel convened in August and October to provide guidance to CMS on the pricing of these new codes recommended the gapfill approach.

The magnitude of the cuts is alarming and the impact on the laboratories would be devastating as reported in a recent attached article in the San Francisco Business Times. In some cases, the Medicare proposed price is below the cost to provide the test. This creates a Catch-22 for patients, physicians and the innovative companies that have researched, developed and marketed these tests. In the Protecting Access to Medicare Act of 2014 (PAMA), Congress established a specific payment category for tests like these known as "Existing Advanced Diagnostic Laboratory Tests". Under the PAMA law these existing tests should be paid at their previously established Medicare payment rates in 2016. It is troubling that CMS would disregard Congressional intent as it relates to Advanced Diagnostic Laboratory Tests.

Conclusion

At a time when Congress and the Administration are working jointly on new initiatives to advance precision medicine, these CMS proposals to cut dramatically payments for existing molecular diagnostic tests will have significant negative impact on patient care as well as being a major disincentive to further innovation. We urge CMS to recognize the importance of these tests and follow the expert Panel's recommendation of gapfill.

We appreciate the Administration's leadership on personalized medicine issues, and we look forward to a continued discussion with the Agency on innovation in the molecular diagnostic field.

Please do not hesitate to contact me with any comments or questions regarding this letter.

Sincerely,

Bobby Franklin
President & CEO