April 30, 2013

Marilyn B. Tavenner
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

Dear Administrator Tavenner:

We are a coalition of patients, providers, clinical laboratories, diagnostic test manufacturers, pharmaceutical companies, and venture capital investors unified in our concern over interim 2013 Medicare Administrative Contractor (MAC) reimbursement rates for molecular diagnostic testing. This development could set back dramatic advancements made in cancer care and treatment of other diseases that have extended and enhanced the quality of life for thousands of patients. A troublesome factor adding to the urgency of the issue is that these rates, while not final, are in effect today retroactive to January 1, 2013. This is causing laboratories to make tough choices about the type of testing they can afford to offer Medicare beneficiaries, as for many laboratories many of these rates are below the cost of performing the test.

Advances in molecular diagnostics are enabling personalized medicine. They allow physicians to better characterize a patient's cancer or disease and guide them toward precise care, often a highly targeted therapy, and to better predict patient outcomes and drug response based on uniqueness of the individual. Knowing how a patient might respond at a molecular level to a particular treatment allows a physician to determine the best course of care at given points in time, preventing trial and error treatments, saving healthcare dollars and delivering better care faster.

The Centers for Medicare and Medicaid Services (CMS) must also take into consideration that many new therapies depend on companion diagnostics to determine which patients qualify for a particular drug. As the MACs determine reimbursement rates for the new molecular diagnostic codes for 2013 and as CMS considers rates for 2014 and beyond, the costs of providing these tests as well as the totality of the clinical value these tests offer must be considered and included in the reimbursement.

Failure to consider the total costs of providing these critical tests means limiting access to molecular diagnostics and denying patients the highest level of diagnostic certainty. The promising future for patients whose lives may be transformed as a result of molecular diagnostics is dependent upon uninterrupted access to this revolutionary technology.

We request that CMS address these unsustainable reimbursement rates immediately and work within its authority to ensure that the process for setting the reimbursement rates is transparent, and fully considers all the costs of providing high quality molecular diagnostics so that cancer patients and those suffering from other diseases are ensured access to these services in 2013 and in the future.

Sincerely,


ACLA
American
Clinical Laboratory
Association


CALIFORNIA
CLINICAL
LABORATORY
ASSOCIATION


LUNG CANCER ALLIANCE


ARUP LABORATORIES


CLARIENT
A GE Healthcare Company


Machaon Diagnostics
specialized coagulation testing


ASCEND
GENOMICS


COLON
CANCER
ALLIANCE


natural molecular
TESTING CORPORATION


NeoGenomics
Laboratories


AURORA
DIAGNOSTICS


FOUNDATION
MEDICINE


NOVARTIS


Bio
Biotechnology
Industry
Organization


GenMark DX


NATIONAL
VENTURE CAPITAL
ASSOCIATION
Funding innovation. Empowering entrepreneurs.


BIOMÉRIEUX


GENOMAS


KNIGHT
CANCER INSTITUTE
Oregon Health & Science University
OHSU


BR
BioReference
LABORATORIES


gsk
GlaxoSmithKline


PGxL
laboratories


BIO
THERANOSTICS
A BIOMÉRIEUX COMPANY
SOLUTIONS FOR METASTATIC CANCER


HOLOGIC™


Predictive
BIOSCIENCES


CARIS
LIFE SCIENCES


ican international cancer advocacy network
the virtual lifeline for proactive cancer patients


SIEMENS


CBLPATH


Luminex®


youScript
Personalized Prescribing System