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September 8, 2017

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Verma:

The below signed organizations representing physicians from a number of different specialties thank the Center for Medicare and Medicaid Services (CMS) for its tireless efforts to implement the laboratory provisions of the Protecting Access to Medicare Act of 2014 (PAMA). However, the physician community is becoming increasingly concerned about the potential impacts of PAMA on patient access to critical rapid clinical testing services offered to patients while they are receiving medical care in their physician's office.

Rapid, accurate patient testing in a physician's office is invaluable to early diagnosis of a range of conditions. This type of testing plays a critical role in the treatment of acute illness, as well as in the ongoing management of chronic disease. It can also help avoid emergency care situations resulting in hospitalization. However, if the costs for providing these services at some point exceed the reimbursement for these tests, it will become impossible for these essential services to be provided to patients by their physicians when first presenting with a problem or during regular visits for ongoing management of disease. Initial projections on the impacts of PAMA on patient testing show significant cause for concern that this scenario may become reality when new PAMA payment rates are implemented on January 1, 2018.

Should reimbursement for physician office-based testing services fall below the costs to physicians providing these tests, it will become increasingly difficult for patients to receive timely diagnosis of acute conditions, and ongoing management of chronic conditions will become significantly more burdensome. Prior to PAMA, patients could receive testing results at the time of a first visit to their physician. After PAMA, testing results and diagnosis may require a second follow-up visit—a potentially costly and burdensome task for a number of patients, particularly the vulnerable patients comprising the Medicare and Medicaid populations. Patients in rural areas will also face increasing challenges in accessing testing services, as a significant number of Americans live in areas where the nearest laboratories can be 80 to 100 miles away. Instead of one visit to their local clinic for services such as testing for common illness such as influenza, infectious disease testing, cholesterol screening, pregnancy testing, and rapid cardiac marker diagnostics, patients may be forced to take additional time off work, find child care, find transportation, or travel significant distances in order to receive necessary testing. This raises

issues not only of increased burden, but increased concerns of whether patients will follow-up to receive these critical services at all.

While working to implement PAMA, we recommend that CMS carefully consider congressional intent, as well as the potential impacts of loss of near patient testing services on patients. In order to help mitigate potential negative impacts on patient care and, we urge CMS to:

- 1.) Provide information related to data collected and publish preliminary CY 2018 CLFS rates as soon as possible to allow the physician community adequate time to review and assess the potential impacts on near patient testing services; and
- 2.) Modify the existing PAMA regulations through issuance of an interim final rule that provides for CMS to conduct targeted market segment surveys (reference laboratories, physician office-base laboratories, independent laboratories, and hospital outreach laboratories) to validate and adjust the final amount calculated based on the data collection to ensure congressional intent—payment rates that accurately reflect private market payments across all market segments—is achieved.

Loss of physician office-based laboratories will undoubtedly affect all patients at some point in time, but the impacts will likely be felt by our sickest, elderly, and other vulnerable populations the most. While we thank CMS for its ongoing efforts to implement PAMA, we urge the Agency to consider the potential increased burdens on patients caused by loss of physician office-based testing services as it continues its work in this area. We look forward to continuing to work with the agency to ensure that patient access to critical clinical testing services at the point of care is maintained.

Sincerely,

American Medical Association
American Academy of Family Physicians
American Academy of Home Care Medicine
American Academy of Physical Medicine and Rehabilitation
American Association of Clinical Endocrinologists
American College of Allergy, Asthma & Immunology
American College of Mohs Surgery
American College of Physicians
American Osteopathic Association
American Society of Cataract and Refractive Surgery
American Society of Clinical Oncology
American Urological Association
Infectious Diseases Society of America
Medical Group Management Association

Medical Association of the State of Alabama
Arizona Medical Association

Arkansas Medical Society
California Medical Association
Colorado Medical Society
Connecticut State Medical Society
Medical Society of Delaware
Medical Society of the District of Columbia
Florida Medical Association Inc
Medical Association of Georgia
Hawaii Medical Association
Idaho Medical Association
Illinois State Medical Society
Iowa Medical Society
Kansas Medical Society
Kentucky Medical Association
Louisiana State Medical Society
Maine Medical Association
MedChi, The Maryland State Medical Society
Massachusetts Medical Society
Michigan State Medical Society
Minnesota Medical Association
Mississippi State Medical Association
Missouri State Medical Association
Montana Medical Association
Nebraska Medical Association
Nevada State Medical Association
Medical Society of New Jersey
New Mexico Medical Society
Medical Society of the State of New York
North Carolina Medical Society
North Dakota Medical Association
Ohio State Medical Association
Oregon Medical Association
Rhode Island Medical Society
South Carolina Medical Association
South Dakota State Medical Association
Tennessee Medical Association
Texas Medical Association
Utah Medical Association
Vermont Medical Society
Medical Society of Virginia
Washington State Medical Association
West Virginia State Medical Association
Wyoming Medical Society