

August 2, 2018

The Honorable Orrin Hatch  
Chairman  
Senate Committee on Finance  
219 Dirksen Senate Office Building  
Washington, DC 20510

The Honorable Ron Wyden  
Ranking Member  
Senate Committee on Finance  
221 Dirksen Senate Office Building  
Washington, DC 20510

The Honorable Kevin Brady  
Chairman  
House Committee on Ways and Means  
1100 Longworth House Office Building  
Washington, DC 20515

The Honorable Richard Neal  
Ranking Member  
House Committee on Ways and Means  
341 Cannon House Office Building  
Washington, DC 20515

The Honorable Greg Walden  
Chairman  
House Committee on Energy and Commerce  
2125 Rayburn House Office Building  
Washington, DC 20515

The Honorable Frank Pallone  
Ranking Member  
House Committee on Energy and Commerce  
237 Cannon House Office Building  
Washington, DC 20515

Dear Chairmen and Ranking Members:

As organizations representing patients, health care professionals, laboratories, and diagnostic manufacturers, we urge Congress to take immediate action to address the harmful cuts to the Clinical Laboratory Fee Schedule (CLFS) that are now in effect because of the flawed implementation of the Protecting Access to Medicare Act (PAMA). By not collecting reimbursement data from more than 99 percent of laboratories, HHS implemented a CLFS that fails to accurately reflect the clinical laboratory market and ignores Congress' directive, resulting in extreme cuts to vital lab services that will jeopardize care for the most vulnerable Medicare patients.

Reducing access to clinical lab services drives up the cost of care for patients and taxpayers. Millions of Americans who are managing diabetes, heart disease, liver disease, kidney disease, prostate and colon cancers, anemia, infections, opioid dependency, and countless other common diseases and conditions rely heavily on access to these routine lab tests to prevent costly interventions.

Moreover, most laboratories servicing long-term care facilities provide rapid results daily, as many senior patients require close, routine monitoring. This same day turnaround helps identify any critical issues at an early stage, keeping patients healthier and preventing more costly interventions. Patients who are frail or reside in medically underserved communities, including rural areas, are at particular risk. These communities and patients rely on a shrinking number of smaller, local laboratories: laboratories that will face the brunt of these cuts—a nearly 30 percent reduction overall in Medicare reimbursement.

These cuts will force laboratories serving the most vulnerable and homebound patients to shut down operations, eliminate tests, lay off employees, and reduce services for patients. In fact, according to a study by the National Independent Laboratory Association, within the first six months of the new rates going into effect, laboratories have reported cutting staff, limiting—or ending—testing services such as home care visits, and reducing the frequency of services to skilled nursing facilities—leaving no option for the most fragile patient populations.

Without action by Congress, PAMA will create serious health care access and public health issues for Medicare patients. Without ready access to clinical laboratory services, patients risk missed or delayed diagnoses, increased barriers to maintaining their health, and forgoing the opportunity to prevent even worse health outcomes or disease. In a medical age where technology is pushing closer to patients, the bureaucratic policies implemented through PAMA will drive care and the promise of better health further away from patients.

As a stakeholder community, we have been working to address the negative impacts of PAMA through legal, regulatory, and Congressional channels. We stand together in our position that the Congress must advance legislation to:

- Modify PAMA to address data integrity concerns and market exclusion through a statistically valid process that is least burdensome on providers and ensures access for patients;
- Ensure that the private payer data CMS collects accurately represents all segments of the clinical laboratory market (national independent, community and rural independent, hospital outreach, and physician office laboratories); and
- Provide a transparent process to allow for the validation of the data collected by CMS.

In light of these significant concerns, we call on Congress to take swift action to reform and modernize the CLFS as intended by PAMA and protect access to laboratory services for patients. We stand ready to work with you on ways to improve the PAMA data process and calculation and establish a clear path forward for the clinical laboratory community and the Medicare patients who rely on its services.

Sincerely,

AdvaMedDx  
Alliance for Aging Research (AAR)  
American Academy of Family Physicians (AAFP)  
American Association for Clinical Chemistry (AACC)  
American Association of Bioanalysts (AAB)  
American Association of Clinical Endocrinologists (AACE)  
American Clinical Laboratory Association (ACLA)  
American College of Physicians (ACP)  
American Health Care Association (AHCA)  
American Hospital Association (AHA)  
American Kidney Fund (AKF)  
American Medical Technologists (AMT)  
American Society for Clinical Laboratory Science (ASCLS)

American Society for Clinical Pathology (ASCP)  
American Society for Microbiology (ASM)  
American Urological Association (AUA)  
America's Essential Hospitals  
Association of American Medical Colleges (AAMC)  
Association of Pathology Chairs (APC)  
Association of Public Health Laboratories (APHL)  
California Clinical Laboratory Association (CCLA)  
California Society of Pathologists (CSP)  
Cancer Support Community (CSC)  
Caregiver Action Network (CAN)  
Clinical Laboratory Management Association (CLMA)  
College of American Pathologists (CAP)  
Infectious Diseases Society of America (IDSA)  
National Association for the Support of Long Term Care (NASL)  
National Consumers League (NCL)  
National Independent Laboratory Association (NILA)  
National Rural Health Association (NRHA)  
New York State Clinical Laboratory Association (NYSCLA)  
New York State Society of Pathologists (NYSSPATH)  
Personalized Medicine Coalition (PMC)  
Point of Care Testing Association (POCTA)  
Prevent Cancer Foundation