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CMS Ignored Congressional Intent in Implementing New Clinical Lab Payment System Under PAMA, ACLA Charges in Suit

Complaint Claims CMS Final Rule Resulted in Flawed Process That Fails to Protect Access to Laboratory Services for Medicare Beneficiaries, Violates Congress's Statutory Directives

(Washington, D.C.) – The government agency that runs the Medicare program failed to follow a congressional directive to implement a market-based laboratory payment system, thereby jeopardizing Medicare patients' access to vital laboratory services, according to the American Clinical Laboratory Association (ACLA) in a lawsuit filed today against the Acting Secretary of the U.S. Department of Health and Human Services (HHS) in the U.S. District Court for the District of Columbia.

The lawsuit asserts that the Centers for Medicare & Medicaid Services (CMS), operating under the purview of HHS, ignored congressional intent and instituted a highly flawed data reporting process in advance of setting market rates under the Protecting Access to Medicare Act (PAMA). Contrary to Congress's directives, the overwhelming majority of laboratories were prohibited from reporting private payer data. As a result, CMS failed to protect access to laboratory services for Medicare beneficiaries. This flawed process could cause serious financial harm to potentially thousands of hospital, independent and physician office laboratories, and make it harder for Medicare beneficiaries to get access to medical testing, particularly in remote rural areas and in nursing homes that depend on laboratory testing services.

“We have repeatedly advised CMS that there are significant, substantive deficiencies in the final rule, which fails to follow the specific commands of the PAMA statute,” said Julie Khani, president of ACLA. “Contrary to Congress's intent, instead of reforming Medicare reimbursement rates to reflect the broad scope of the laboratory market, the Secretary's final rule will disrupt the market and prevent beneficiaries from having access to the essential laboratory services they need.”

“CMS clearly disregarded and violated the statute's specific, unambiguous directives requiring commercial rate information to be reported and collected from a broad, diverse group of market participants,” said Mark D. Polston, partner at King & Spalding, the law firm which will represent ACLA in the suit. Polston is a former Chief Litigation counsel for CMS, with decades

of experience in Medicare reimbursement policy. “Instead, information was collected from less than one percent of U.S. laboratories. More than 99 percent of laboratories were prohibited from reporting their data.”

“Every day, this industry provides laboratory services that are vital in preventing illness, diagnosing disease, and monitoring medical treatment,” said Curt Hanson, MD, ACLA Board Chair and Chief Medical Officer of Mayo Medical Laboratories. “This lawsuit reflects our obligation to those who are providing critical testing services, and to those millions of Americans who rely on the services our industry provides.”

ACLA continues to support modernizing the Clinical Laboratory Fee Schedule (CLFS) under PAMA, assuming the process would be based on the clear direction of Congress to establish a Medicare payment system based on the collection of private payor rates across the wide spectrum of the clinical laboratory community.

ACLA’s Khani stated: “From the beginning, ACLA has supported a fair and predictable market-based system that encourages innovation and recognizes the value of clinical laboratory testing in health care services for Medicare beneficiaries. It is reckless and damaging to Medicare beneficiaries for the Secretary to implement a payment system based on a specious data collection process that actually threatens the viability of some laboratories to continue operations and jeopardizes access to important lab tests.”

To view the complaint in its entirety, [click here](#).

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ACLA is a not-for-profit association representing the nation’s leading clinical and anatomic pathology laboratories, including national, regional, specialty, hospital, ESRD and nursing home laboratories. The clinical laboratory industry employs nearly 277,000 people directly, and generates over 115,000 additional jobs in supplier industries. Clinical laboratories are at the forefront of personalized medicine, driving diagnostic innovation and contributing more than \$100 billion to the nation’s economy.