For Immediate Release

March 24, 2017
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National Independent Laboratory Association (NILA) and Other Stakeholders Ask HHS to Delay the Medicare Laboratory Payment Reform Rule

WASHINGTON, DC – Today, 10 national organizations representing stakeholders across the clinical laboratory community, including the National Independent Laboratory Association (NILA), asked Health and Human Services Secretary Tom Price, MD, to delay and make needed changes to the Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule, which implemented Section 216 of the *Protecting Access to Medicare Act of 2014* (PAMA). [Letter to Secretary Price]

The stakeholders reiterated concerns that had been expressed in a September 2016 report issued by the HHS Office of the Inspector General that the regulation may lead to inaccurate Medicare payment rates for laboratory tests. The stakeholders are requesting that CMS delay the implementation of laboratory payment reforms under PAMA for one year in order to resolve significant concerns – data collection and reporting errors and restrictions that prohibit the government from assessing data from all segments of the laboratory market.

"The data reporting period for PAMA is scheduled to conclude on March 31, 2017, but many laboratories are still in the data *collection* phase as they struggle with CMS regulatory requirements," the letter states. "Beyond operational data issues, the significant regulatory definition for "applicable laboratory" must be reassessed and redefined. PAMA payment reforms depend on an accurate measurement of true market rates; however, the Health and Human Services (HHS) Office of Inspector General (OIG) analysis of the current CMS definition for "applicable laboratory" assessed that only 5 percent of clinical laboratories will report data, with an estimated complete exclusion of hospital laboratories."

The regulation provided laboratories less than four months following the release of complex regulatory guidance to design retroactive reporting structures and begin submitting all of their private payor payment information to the government under the threat of penalties of up to $10,000 per day for not reporting or for each data error.

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"As our members, including small community-based businesses have struggled to comply, it feels as if they were set up for failure. Implementation of this rule, as finalized by the Obama Administration, will facilitate the destruction of a skilled laboratory workforce in communities across our country and threaten Medicare beneficiary access to laboratory testing," says Mark Birenbaum, Ph.D., NILA Administrator. "This Administration has an opportunity to hit the pause button, and seriously reflect on the concerns raised by NILA and the broad laboratory stakeholder community. To ensure affordability and access to laboratory testing within Medicare and across our health care system, we must preserve a competitive laboratory market and maintain a strong community-based workforce. NILA stands willing to work in collaboration with Secretary Price and CMS Administrator Seema Verma to address our concerns and protect access to the clinical laboratory testing relied on by physicians and patients for medical diagnoses, treatment, and care management."

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The National Independent Laboratory Association (NILA) is made up of members who are small community and multi-state regional independent clinical laboratories working with physician practices, hospitals, outpatient care settings, skilled nursing facilities, and home health patients to provide essential clinical laboratory services to Medicare beneficiaries, particularly those in underserved communities and hard-to-reach care settings. Every day, NILA members provide diagnostic laboratory services and results, upon which physicians base their clinical decisions for the Medicare beneficiaries they serve.