



For Immediate Release

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National Independent Laboratory Association (NILA) Applauds House Freedom Caucus Recommendation on Immediate Repeal of Medicare Laboratory Payment Reform Rule

WASHINGTON, DC -- Yesterday, the House Freedom Caucus, a bloc of Republican members of the U.S. House of Representatives, issued a special report, "First 100 Days: Rules, Regulations and Executive Orders to Examine, Revoke, and Issue." Included in this report is a recommendation to repeal the Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule, which implemented Section 216 of the *Protecting Access to Medicare Act of 2014* (PAMA).

The Centers for Medicare and Medicaid Services (CMS) issued the clinical diagnostic laboratory test regulation in June 2016, following it with complex subregulatory guidance through late-September 2016. The regulation requires clinical laboratories to design retroactive reporting structures to forward private payor payment information to the government or risk penalties up to \$10,000 per day. Despite only issuing instructions to the laboratories in September, the regulation requires reporting to begin January 1, 2017. CMS' regulation goes against statute and congressional intent by limiting the data it will use to re-set payments under the Medicare clinical laboratory fee schedule, effectively skewing the data and ultimately the final payment rates. In September 2016 the Office of Inspector General (OIG) issued a report stating that CMS did not plan to assess the quality of the reported laboratory data, and as a result "CMS may set inaccurate Medicare payment rates for lab tests."

"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. "At a time when Congress just invested in Precision Medicine through the *21st Century Cures Act*, the current Administration is implementing a regulation that will have devastating consequences on clinical laboratory testing relied on by physicians and patients for medical diagnoses, treatment, and monitoring of care.

On behalf of community independent laboratories, NILA thanks the House Freedom Caucus for including this regulation on its list of priorities for repeal. We look forward to collaborating with the caucus, congressional committees, and the new Administration to address this regulation in the first

100 days, and ensure that we preserve a competitive laboratory market, a strong community-based workforce, and access to laboratory testing services.”

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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.