For Immediate Release
AAB and NILA Comment on Unlawful Implementation of PAMA by CMS

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Contact: Mark S. Birenbaum, Ph.D., NILA Administrator
St. Louis, MO – The National Independent Laboratory Association (NILA) and the American Association of Bioanalysts (AAB) formally commented to the Centers for Medicare and Medicaid Services (CMS) that the agency was unlawful in the methodology it used to implement Section 216 of the Protecting Access to Medicare Act (PAMA) by double counting Part C Medicare Advantage payments as both Medicare and private payor revenues. The comments were submitted in response to the CY 2019 Physician Fee Schedule proposed rule.

The comments filed by NILA and AAB specifically address the agency's methodology error regarding the inclusion of Part C Medicare Advantage plans as both "Medicare revenues" to determine the definition of an applicable laboratory and in the "private payor revenue" data that laboratories were required to report to the agency—therefore double counting the Part C Medicare Advantage revenues and ultimately impacting the number of laboratories that qualified under the definition of an applicable laboratory. The comments state, "It is deeply concerning to AAB and NILA that CMS's categorization of Part C Medicare Advantage plans as Medicare revenue from the outset was in conflict with the clear statutory directive, and therefore unlawful." The statute clearly defines "private payor" to include Part C Medicare Advantage plans.

NILA and AAB argue that the change proposed by CMS to remove Part C Medicare Advantage plans from the calculation of Medicare revenues to determine an applicable laboratory does not go far enough to address the fundamentally flawed implementation of Section 216 of PAMA, which according to a report by NILA, has already caused harm to the laboratory infrastructure in the United States and could ultimately threaten patient access to life-saving clinical laboratory tests.

According to Mark Birenbaum, Administrator of AAB and NILA, "Double counting Part C Medicare Advantage revenues is not just an error, it is unlawful and it means the 2018-2020 Clinical Laboratory Fee Schedule (CLFS) rates established by CMS cannot be sustained and must be halted until accurate data can be collected. CMS must remedy its mistake before it is too late and Medicare beneficiaries are left without access to routine clinical diagnostic tests."

NILA and AAB also highlight their concerns that CMS continues to attempt to limit the types of laboratories that are required to report laboratory reimbursement data. AAB and NILA support using CMS-1450 bill type 14x to identify Medicare revenues from hospital outreach laboratories as a way to ensure that hospital outreach laboratories are applicable laboratories for reporting purposes. Although CMS argues that inclusion of hospital outreach laboratories goes against Section 216 of the PAMA statute, NILA and AAB provide statements from two U.S. senators explicitly acknowledging that private payor data from hospital outreach laboratories should be included in CMS's Clinical Laboratory Fee Schedule calculations so that all sectors of the laboratory market are represented.

NILA members are independent community and regional 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.

The American Association of Bioanalysts (AAB), founded in 1956, is a professional association representing bioanalysts (clinical laboratory directors, owners, managers and supervisors), medical technologists, medical laboratory technicians, and physician office laboratory technicians.