September 2, 2014

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015; 79 Fed. Reg. 133; CMS–1612–P; July 11, 2014

Dear Administrator Tavenner:

The National Independent Laboratory Association (NILA) appreciates the opportunity to comment on the Calendar Year 2015 Medicare Physician Fee Schedule Proposed Rule. Our comments below address the proposals regarding the Clinical Laboratory Fee Schedule (CLFS) and the Local Coverage Determination Process for Clinical Diagnostic Laboratory Tests.

NILA represents community and regional clinical laboratories that work with physician practices, hospitals, outpatient care settings, skilled nursing facilities, and home health care agencies. NILA members range in size from community-based small businesses to large multi-state regional laboratories. For the majority of NILA's members, 30 percent or more of their work is in the Medicare program, and many serve rural geographic locations and unique service markets, including skilled nursing facilities (SNFs). NILA's members typically provide traditional and "stat" (immediate) diagnostic laboratory services relied on by physicians across the country to diagnose and manage chronic diseases that are primarily reimbursed through the Medicare Part B CLFS.

III. Other Provisions of the Proposed Regulation

C. Clinical Laboratory Fee Schedule

NILA is pleased that the proposed rule rescinds CMS's final rule to revise CLFS payment rates based on technological changes and states that because of the Protecting Access to Medicare Act (PAMA), the agency will no longer move forward with the technological review of the test codes on the CLFS. NILA is concerned about how PAMA addresses the process for developing new Medicare laboratory payment rates and will continue to work with the agency regarding

implementation of the new law to ensure it assesses the entire laboratory market and does so in a manner that does not provide a competitive disadvantage to independent community and regional laboratories.

NILA submitted comments to the agency on June 13, 2014, following a meeting with CMS staff on April 17, 2014. NILA also attended and presented at the CMS Public Meeting for New Clinical Laboratory Fee Schedule Services on July 14, 2014, and outlined its concerns with PAMA during that meeting. While the aforementioned comments contain more details regarding NILA's position on PAMA implementation, we would like to emphasize that NILA is extremely concerned about the impact this law will have on regional and community laboratories and the Medicare beneficiaries they serve.

NILA does not support the approach of this law, however as implementation moves forward, we want to ensure that the new process for determining Medicare reimbursement rates does not force community or regional laboratories out of Medicare or, perhaps, out of business altogether—negatively affecting access to Medicare laboratory services. We are particularly concerned about how Medicare's payment changes could affect competition in rural communities and with laboratories that perform a majority of laboratory testing for specific sites of service, including skilled nursing facilities, home health, homebound patients, and federally qualified health centers. We strongly believe that the agency's focus on implementation of the new program must be about more than deriving a savings by cutting payment rates. The agency must ensure that regulatory implementation of the law allows for continued competition in the market and continued access to laboratory services.

Sample (Specimen) Collection Fee Adjustment:

NILA was disappointed that CMS did not address another provision within PAMA in the proposed rule, which requires an increase in the sample (specimen) collection fee for collection services conducted by a laboratory in a skilled nursing facility or on behalf of a home health agency from a nominal amount of $3.00 to a rate of $5.00. NILA asks that CMS immediately move to initiate this rate adjustment for this service in compliance with PAMA, recognizing that the payment rate for this service has been below market level for many years, having been set in 1984 with no increase in payment for 30 years. Had it kept pace with inflation, this rate would currently be $6.88.

F. Local Coverage Determination Process for Clinical Diagnostic Laboratory Tests

The proposed rule outlines a revised process for Local Coverage Determinations (LCD) for clinical diagnostic laboratory tests published on or after January 1, 2015. CMS' process includes a review of the current LCD process, an analysis of the ongoing pilot project that CMS launched with Palmetto GBA, and it addresses the requirements set forth in PAMA.

NILA is concerned about ensuring transparency in the LCD process as called for under PAMA, and we do not believe the process proposed by CMS will result in a more transparent process.

Specifically, we are concerned that the new LCD process contains a potentially shortened period for public comments—from 45 to 30 days—once a proposed LCD is published. Further, as part of the new proposal, CMS states that there will be no open stakeholder meetings held to discuss new LCDs. Stakeholder input is an essential part of ensuring a transparent process. There are many different segments of the laboratory community, and it is critically important that all aspects of the community have an opportunity to address issues of interest and concern with the agency beyond a limited written comment period, particularly in relation to new coverage proposals. Laboratory stakeholders should have an opportunity to present evidence and engage with the agency directly in relation to coverage decisions. Not requiring a stakeholder meeting and shortening the period for receipt of public comments is a reduction in transparency, not an enhancement to the current LCD process.

The new LCD process, as proposed, does not outline any process for improving the transparency behind how CMS makes its proposed or final LCD decisions or the data associated with those decisions. It's essential that CMS outline a process that allows for such data to be shared in a transparent manner and allows for active engagement with the laboratory stakeholder community. PAMA requires the establishment of a federal Clinical Laboratory Payment Advisory Panel by January 1, 2015, and according to the law, this panel must provide input to CMS on the factors to determine coverage and payment for new tests, in addition to input on payment rates. CMS did not address the advisory panel in the proposed rule, which should have a role in the process for ensuring transparency and stakeholder input into the coverage of new tests. As CMS considers these comments and develops the advisory panel, it is important that the agency ensures that the advisory panel fairly represents the various segments of laboratory market, and includes expertise within those fields that address laboratory science in addition to clinical expertise. Laboratory representatives included must represent the diversity of the market and include a community and/or regional laboratory representative.

Conclusion

We thank you for consideration of our comments and want to work to ensure that together we endeavor to appropriately understand the value of laboratory services reimbursed under the CLFS. For more information or to address any questions in relation to these comments, please contact me directly at (314) 241-1445 or birenbaumm@birenbaum.org, or have your staff contact NILA's Washington, DC-based staff, Julie Scott Allen at (202) 230-5126 or Julie.Allen@dbr.com.

Sincerely,

Mark S. Birenbaum, Ph.D.
Administrator