September 10, 2018

Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1693-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program

Dear Administrator Verma:

The American Association of Bioanalysts (AAB) and the National Independent Laboratory Association (NILA) welcome the opportunity to provide comments on the "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program; CMS-1693-P." AAB and NILA represent independent community and regional laboratories that work with physician practices, hospitals, outpatient care settings, skilled nursing facilities, and homebound patients.

NILA members are community-based businesses that range in size from small to large multi-state regional laboratories. For the majority of NILA members, 30-50 percent of their testing services are provided to Medicare beneficiaries. Some NILA laboratories provide a full range of testing services, while others are focused primarily on providing routine and emergency (STAT) diagnostic services to allow physicians to manage chronic diseases.

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.

These comments specifically reference sections II. K. and III. A. regarding changes to the Clinical Laboratory Fee Schedule (CLFS). However, we believe, first and foremost, that the single change to the

Protecting Access to Medicare Act of 2014 (P.L. 113-93) (PAMA) implementation suggested by CMS in the proposed rule does nothing to address the fundamentally flawed implementation and data collection process undertaken by CMS. Since its passage in 2014, AAB and NILA have been extremely concerned about the impact of CMS's implementation of Section 216 of PAMA on access to essential laboratory services for Medicare beneficiaries. Further, AAB and NILA have commented numerous times to CMS that the implementation of Section 216 of PAMA is flawed. The purposefully deficient data collection process used to establish new clinical laboratory payment rates resulted in unreliable data and unsustainable rates that fell short of Congress' goal to establish a market-based system. The result has been detrimental to AAB's and NILA's members, causing many community-based laboratories to limit services, including home visits and emergency STAT testing, and has caused many laboratories to reduce their workforce.

Earlier this year, NILA released a report[1] that describes the adverse impact CMS's implementation of PAMA is having on community laboratories. NILA found that in the first quarter of 2018 many laboratories had already reduced their workforce to adapt to the financial pressures of PAMA, which for some marked the first time in their laboratory's history that the workforce was reduced. Additionally, PAMA is eliminating access to laboratory services for many Medicare beneficiaries as laboratories reduce flexible, personalized services. If the implementation of PAMA continues as scheduled, the community and regional laboratory infrastructure in the U.S. will continue to erode, leaving extreme gaps in coverage that will not be filled by the large national laboratories. The nation's network of clinical laboratories is complex, and the services provided vary by population, geography, size of laboratory, and myriad other factors. Much like the rest of healthcare, laboratory science is not a one size fits all approach, and CMS's new payment model will destroy this essential piece of our healthcare system.

Additionally, an independent study conducted by the Galen Institute[2] concludes that CMS failed to base laboratory reimbursement rates on a market-based system. The Galen Institute report states that CMS "produced a reimbursement system that does not reflect payments for lab tests in the private marketplace and that does not abide by statutory intent," and concludes that "both Congress and CMS need to reassess the fledgling CMS plan in order to rationalize [laboratory] payments and not lock in a policy that could well put access to necessary diagnostics in jeopardy for millions of seniors."

While CMS's implementation of PAMA is detrimental to community and regional laboratories, the ultimate burden is shouldered by Medicare beneficiaries. Without access to timely laboratory tests and diagnoses, Medicare beneficiaries, especially those in rural and underserved communities, have few options. Millions of Americans who are managing diabetes, heart disease, liver disease, kidney disease, prostate and colon cancers, anemia, infections, opioid dependency, and countless other common diseases and conditions rely heavily on routine laboratory tests that may now be unavailable or much

[1] The Protecting Access to Medicare Act Jeopardizes the Nation's Community and Regional Independent Clinical Laboratory Infrastructure: https://www.nila-usa.org/images/nila/PAMA%20Key%20Informant%20Summary_FINAL.pdf
[2] Can Medicare Pay Market Rates? A Study of the Clinical Laboratory Fee Schedule Methodology: https://galen.org/assets/Can_Medicare_Pay_Market_Rates_Badger_072418-1.pdf

more difficult to obtain. This leads to costly interventions, disrupts the efficacy of prevention efforts, and hinders the ability to provide care in the early stages of disease, ultimately driving up the cost of Medicare.

Response to Provisions in the Proposed Rule

AAB and NILA strongly believe that the adjustments proposed by CMS in the Physician Fee Schedule Proposed Rule are insufficient to correct the flawed implementation of PAMA. As such, we urge CMS not to implement the next round of cuts to the CLFS on January 1, 2019, and to take adequate steps to revise the implementation of PAMA to accurately capture a market-based reimbursement system as intended by Congress. Until then, CMS is doing an immense disservice and creating irreversible harm to Medicare beneficiaries, the public's health, independent and community and regional laboratories, and the nation's laboratory infrastructure.

AAB and NILA strongly believe that CMS must:

- Delay cuts that are scheduled to go into effect on January 1, 2019;
- Work with Congress to modify PAMA to address data integrity concerns and avoid market exclusion through a statistically valid process that ensures access for patients;
- Ensure that the private payor data collected accurately represents all segments of the clinical laboratory market (national, regional and community independent laboratories; hospital outreach laboratories; and physician office laboratories); and
- Provide a transparent process to allow for the validation of the data collected.

In addition to the immediate need to delay further implementation of PAMA, AAB and NILA offer the following recommendations in response to CMS's request for feedback in the proposed Physician Fee Schedule rule. It should be emphasized that these comments are intended to guide CMS in its necessary overhaul of the implementation of PAMA and should not be used as a patchwork solution to the existing faulty framework. It is not sufficient to merely revise the process for the next round of data collection; by that point three rounds of cuts will have gone into effect, slashing many routine clinical laboratory tests by 30 percent—leaving no option for many community and regional laboratories. Further implementation of PAMA must be halted before laboratories are forced to curtail services or go out of business.

Section II. K. Solicitation of Public Comment on the Low Expenditure Threshold Component of the Applicable Laboratory Definition under the Medicare CLFS

AAB and NILA recommend that CMS leave the low expenditure threshold at $12,500 as originally implemented, because adjustments otherwise will not make a significant impact on the overall flawed implementation of PAMA.

Section *III. A. Clinical Laboratory Fee Schedule*

Proposed Changes to the Majority of Medicare Revenues Threshold in Definition of Applicable Laboratory

In the CMS final rule implementing Section 216 of PAMA, the agency defined the majority of Medicare revenues as having at least 50 percent of payments received from the Medicare program including fee-for-service payments under Medicare Parts A and B, as well as Medicare Advantage (MA) payments under Medicare Part C, and prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance amounts for Medicare services furnished during the data collection period coming from the Physician Fee Schedule (PFS) or the CLFS. However, in the proposed changes in this PFS rule, CMS proposes removing Medicare Advantage Plan payments under Part C from total Medicare revenues that are considered in calculating the CLFS and PFS constitute a majority of a laboratory's Medicare revenues. The agency suggests this as a solution to increase the number of laboratories under the definition of applicable laboratory.

This change would not only be acceptable to AAB and NILA, but it is also mandated by the PAMA statute and underscores the error made in the final regulations where it reflected Medicare Advantage payments in the calculus.

The recognition by CMS that Medicare Advantage payments should not be counted as Medicare revenues for this purpose, and that by doing so the number of reporting laboratories will increase, is an acknowledgement that the methodology used pursuant to the final rule was in error and inconsistent with statute and, therefore, it should be changed not just prospectively, but retrospectively as well.

It is deeply concerning to AAB and NILA that CMS's categorization of Medicare Advantage plans as Medicare revenue from the outset was in conflict with the clear statutory directive, and therefore unlawful. AAB and NILA believe that CMS ignored the PAMA statute concerning Medicare Advantage as Medicare Advantage payments were clearly meant to be treated as revenues from private payors that an applicable laboratory was required to report. Within the PAMA statute, the law clearly states that the term "private payor" means the following:

- A health insurance issuer and a group health plan;
- **A Medicare Advantage plan under part C;**
- A Medicaid managed care organization

Current inclusion of Medicare Advantage payments in the calculus in the final rule reflects CMS's unlawful redefining of a clear and unambiguous term defined in the statute. Congress only authorized CMS to promulgate regulations on **how** to collect the applicable information for each clinical diagnostic laboratory test for each applicable laboratory, not to create or modify definitions of terms that were

already statutorily defined. Eliminating Medicare Advantage payments from the regulatory definition of a majority of revenues threshold would now be consistent with the PAMA statute.

From its initial implementation and the foundation in which data was collected, CMS should have never included Part C Medicare Advantage plan payment data as Medicare revenue, because this data is statutorily defined as private payor data. As currently implemented, CMS is unlawfully double counting Part C Medicare Advantage payments as both Medicare revenues and private payor data, which is not only inappropriate, but in violation of the PAMA statute. Proposed changes in the PFS attempt to fix this issue, but AAB and NILA remain concerned that the data set CMS collected from the outset was fundamentally flawed and in direct opposition to the law, making the data invalid. As such, the new rates as currently implemented are unlawful and should be halted until new, accurate data can be collected to determine appropriate payment rates for the CLFS.

Importance of Including Hospital Outreach Laboratories in Data Collection

AAB and NILA are deeply concerned that CMS continues to attempt to limit the types of laboratories that are required to report laboratory reimbursement data. Within the proposed rule, CMS claims that "it [is] important to facilitate reporting of private payor rates for hospital outreach laboratories to ensure a broader representation of the national laboratory market to use in setting CLFS payment amounts," but CMS follows this statement directly with "we believe that Congressional intent was to effectively exclude hospital laboratories as applicable laboratories… therefore, we believe that the statute intended to limit reporting primarily to independent laboratories and physician offices."[3] CMS later goes on to state that "we believe that if we were to utilize [CMS-1450 bill type 14x] in defining an applicable laboratory, all hospital outreach laboratories would meet the majority of Medicare revenues threshold. At this time, we believe that this approach would be inconsistent with the statute."[4] However, CMS's exclusion of hospital outreach laboratories from establishing a market-based reimbursement system flies in the face of Congressional intent. Both Senators Orrin Hatch and Richard Burr are quoted in the Congressional record from 2014:

- Statement of Senator Burr: "It is my understanding that the intent of this provision is to ensure that Medicare rates reflect true market rates for laboratory services, and as such, that all sectors of the laboratory market should be represented in the reporting system, including independent laboratories and ***hospital outreach laboratories*** [emphasis added] that receive payment on a fee for service basis under the fee schedule."[5]

- Statement of Senator Hatch: "The Senator is correct…[T]he intent is to ensure that Medicare rates reflect true market rates, and that commercial payment rates to all sectors of the lab

[3] CMS-1693-P: Page 412
[4] CMS-1693-P: Page 417
[5] 160 Congressional Record, S2860 (May 8, 2014). Statement of Senator Burr

market should be represented, including independent laboratories and ***hospital outreach laboratories*** [emphasis added]."[6]

It is clear that Congress intends for PAMA to capture true market rates, which includes hospital outreach laboratories. AAB and NILA fundamentally disagree with CMS's interpretation that including hospital outreach laboratories is inconsistent with the PAMA statute. There is a difference between causing undue burden to reporting entities and simply ignoring a critical component of the laboratory market, as CMS is doing. Hospital outreach laboratory work is different from inpatient and outpatient hospital services. For this outreach work, hospitals are essentially functioning as independent laboratories and should be included in the data collection. While it will take some effort to report this data to CMS, it is available and the burden will be no greater than the burden for the rest of the laboratory community to report their private payor data. More importantly, it ensures that the revised CLFS rates are based on the comprehensive landscape of the laboratory market.

Using Form CMS-1450 bill type 14x to Determine Majority Medicare Revenues and Low Expenditure Thresholds

As is made clear above, hospital outreach laboratories must be included in the definition of applicable laboratory to ensure that the clinical laboratory market is accurately represented in the process to derive new payment rates on the CLFS. The definition of applicable laboratory is clear and unambiguous and not within the authority of CMS to redefine in the regulations. The ongoing statements from CMS suggesting that hospital outreach laboratories should be excluded from the definition of applicable laboratories is in clear violation of the statute. Therefore, AAB and NILA support the suggested approach to 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. In the proposed rule, CMS outlined four concerns using this approach. Below are AAB and NILA's responses to these concerns:

1. *CMS is concerned that the 14x bill type is merely a billing mechanism that is used for a limited set of services and that hospitals may need to develop their own mechanisms to identify and report private payor rates associated with outreach laboratory services.*

   A 14x bill type is used by hospitals to submit claims for hospital outreach services only, so indeed it would accurately capture a hospital laboratory's outreach work, therefore making the laboratory applicable under the majority of Medicare revenues definition. CMS should not be concerned that hospitals will have to develop additional mechanisms to identify applicable private payor data as the hospital laboratory can simply report its private payor data for all of its fee for service work that is not part of a capitated plan. Further, all other reporting entities have

[6] 160 Congressional Record, S2860 (May 8, 2014). Statement of Senator Hatch

the burden of identifying and reporting accurate private payor data even if it means adjusting or revising internal billing systems—this would be no different for hospital laboratories.

2. *CMS is concerned that hospitals would not have sufficient time to implement systems prior to the start of the next data collection period*.

   As previously stated, CMS should delay the next data collection period until new and accurate data can be appropriately captured. A delay will allow all reporting entities (including hospitals) to have adequate time to respond and make necessary system changes.

3. *CMS is concerned about the burden the 14x form would create on hospital outreach laboratories that perform few outreach services under Medicare Part B.*

   Hospital outreach laboratories must be treated in the same manner as other reporting entities. There are clinical laboratories that also perform very few services under Medicare Part B, but CMS has addressed this by establishing the low expenditure threshold, thereby relieving these laboratories from reporting. For hospital outreach laboratories that perform minimal outreach services, the same system should spare them from reporting.

4. *Finally, CMS believes that including hospital outreach laboratories goes against the PAMA statute.*

   As outlined above in our comments, it is clear that Congressional intent is to capture a market-based system that includes hospital outreach laboratories.

Using CLIA Certificate to Define Applicable Laboratory

CMS had no authority to redefine what is a "laboratory" as that term is clear and unambiguous. A laboratory has been statutorily defined since at least 1967 as a "facility for the biological, microbiological, serological, chemical, immune-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings."[7] This same definition was adopted by Congress when it enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA). This has also been recognized by CMS in the regulations where CMS acknowledged previously that a laboratory is one that has a CLIA certificate or state equivalent.[8] The CLIA definition focuses specifically on laboratory facilities providing testing. As stated in previous comments by AAB and NILA, a CLIA certificate is a simple and clean way to determine which laboratories are "applicable laboratories" under the requirement of the

[7] 42 U.S.C. 263(a)
[8] 42 C.F.R. 493.2

law. Whether a laboratory is a stand-alone laboratory, part of a national structure, or exists within a larger entity, it is required to have a CLIA certificate. For hospital laboratories that perform outreach, inpatient, and outpatient laboratory work under the same CLIA certificate, the hospital laboratory's 14x bill type to distinguish the outreach work is an additional mechanism to establish how CMS is authorized to collect applicable information from applicable laboratories.

Conclusion

AAB and NILA urge CMS to preserve the nation's laboratory infrastructure by restructuring the implementation of PAMA. This process should rely on the following components:

1. Delay the January 1, 2019, cuts to the CLFS and revert back to 2017 rates before PAMA was implemented until CMS can collect data that accurately reflects the laboratory market;

2. Implement the intent of the statute and not redefine clearly defined statutory terms and issue regulations on how data is to be collected by all facets of the clinical laboratory market (independent, hospital outreach, and physician office laboratories).

We thank CMS for considering AAB's and NILA's comments on the proposed changes and encourage the agency to reevaluate the basic framework on which the cuts to the CLFS have occurred. The community-based and multi-state regional laboratories we represent are extremely concerned that CMS's flawed implementation of PAMA's laboratory provisions has already affected the laboratory market and negatively impacted access to clinical laboratory services for Medicare beneficiaries. PAMA must maintain a strong and healthy laboratory infrastructure that provides essential laboratory tests to Medicare beneficiaries, while establishing fair and market-based payment rates, not just generate Medicare savings that weaken and damage the country's laboratory infrastructure.

Sincerely yours,

Mark S. Birenbaum, Ph.D.
Administrator