September 12, 2017

Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program (CMS-1676-P)

Dear Administrator Verma:

The National Independent Laboratory Association (NILA) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule entitled *Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B in CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program* ("Proposed Rule").

NILA's comments on the Proposed Rule are organized into two parts as detailed below, responding first to CMS's solicitation of public comments on the initial data collection and reporting periods for the Clinical Laboratory Fee Schedule; and second to CMS's Request for Information on CMS flexibilities and efficiencies to address health care improvements and the reduction of unnecessary burdens on clinicians.

NILA's response to both of these noted sections reflects the association's significant concerns with an overly burdensome regulatory process that is threatening access to laboratory services for Medicare beneficiaries as well as the future viability of the small and mid-size clinical laboratory market. The comments also address the association's continued interest in having a dialogue with CMS to ensure that Medicare beneficiaries continue to have needed access to clinical laboratory testing without disruption.

Solicitation of Public Comments on Initial Data Collection and Reporting Periods for Clinical Laboratory Fee Schedule

NILA Laboratories Experienced Major Difficulties Complying with CMS's Retrospective and Burdensome Data Collection and Reporting Requirements Leading to Errors in Reported Data

NILA represents a broad spectrum of independent laboratories, from small community laboratories to larger multi-state regional laboratories, which primarily work with physician practices, hospitals, skilled nursing facilities, and homebound patients. NILA members actively participate in Medicare, and the majority of NILA members provide 30-50 percent of their testing services to Medicare beneficiaries. Some NILA laboratories provide a full range of clinical diagnostic testing services, while most others offer limited testing services, primarily offering routine and emergency (STAT) clinical diagnostic services that allow physicians to manage chronic diseases in patients with multiple health care conditions and medical needs and address and manage infectious disease. Many NILA members spend significant time providing high-quality services to some of the more vulnerable Medicare populations including beneficiaries who live in

rural geographic areas, reside in skilled nursing facilities, or are homebound. The majority of independent laboratories are small businesses under the U.S. Small Business Administration size standard for clinical laboratories (<$32.5M/year) with very limited billing systems and administrative staff and lacking resources to redo billing systems to comply with significant new regulatory requirements.

NILA's members experienced extreme difficulties in their attempts to comply with and understand CMS's requirements for data collection and reporting for the Medicare Clinical Diagnostic Laboratory Tests Payment System[1]. On the whole, NILA laboratories expressed deep frustration and concerns regarding the lack of guidance, time, and preparation on the part of CMS to ensure even a somewhat uniform and accurate reporting process. The overall process was extremely burdensome for NILA member laboratories, particularly small business operations. There was frustration as to why the agency did not seek to work with laboratories that meet small business requirements in advance to understand their billing procedures or limitations. Establishing a retroactive reporting process, which was not required under statute, set the course for a near-impossible process for laboratory compliance, significantly threatening the integrity of the data to be received by the agency. Laboratories also expressed continued frustration in the lack of training and guidance for laboratories and their billing vendors to understand how to appropriately determine final payment rates under the regulatory requirements.

We appreciate CMS's solicitation of comments included in the Proposed Rule and hope NILA's comments express the gravity of our concerns regarding the integrity of the data received as a result of this flawed collection and reporting period and the necessity of a revised process and validation mechanism to address data errors.

In response to the questions included in the RFI for response, the following details NILA member laboratory experiences in working through the reporting process and in the submission of data to CMS.

1. Was the CMS data reporting system easy to use? Please describe your overall experience with navigating the CMS data reporting system. For example, describe the aspects of the CMS data reporting system that worked well for your reporting entity and/or any problems the reporting entity experienced with submitting applicable information to us.

NILA member laboratories frequently and repeatedly experienced significant difficulty navigating the CMS data reporting system. Many laboratories attempted to upload and submit data, in some cases 20 times or more, before the data submission was accepted due to line-item errors in the CMS data reporting system. One NILA member stated that after numerous attempts, the laboratory finally submitted the data successfully and by deadline only to then receive an alert from CMS that the submission did not go through and was otherwise "lost" in the system. Perplexed by how the data could simply be lost and lacking any further justification or assistance from CMS, the laboratory then had to re-enter the entire data submission – creating additional, unnecessary financial and administrative burden for the lab – even though the error was due to the failures of CMS's data reporting system and not because of any missteps on the part of the laboratory. These examples represent just a few of the myriad of cases whereby applicable laboratories made their best efforts to comply with the highly burdensome PAMA reporting requirements only to have the CMS data reporting system malfunction. Without the agency making

[1] 81 FR 41036.

modifications, the data reporting system will serve as a significant impediment in efficiently, effectively, and accurately collecting PAMA data for purposes of setting CLFS payment rates in the future.

2. Did the applicable laboratory (or its reporting entity) request and receive assistance from our Help Desk regarding the CMS data reporting system? Please describe your experience with receiving assistance.

NILA members generally found the CMS Help Desk unresponsive and uninformative in addressing PAMA data collection and reporting requirement questions. Laboratories reported routinely leaving voicemails to which the Help Desk did not respond on a variety of PAMA implementation issues. Specific examples include but are not limited to voicemails on how to address variances in payment information for specific toxicology codes; how to address pro-rated data examples imbedded in existing data sets; and how to determine whether a laboratory is applicable for purposes of reporting. With certain, very limited exceptions, CMS consistently failed to respond to these voicemail messages, leaving laboratories without any meaningful assistance from the agency as they attempted to comply with the burdensome PAMA data collection and reporting requirements. NILA firmly believes that CMS could have obviated at least some of the many PAMA implementation issues if the agency simply had responded and answered questions in voicemails left by labs via the CMS Help Desk. In other examples, laboratories received "form letter responses" to questions needing more elaborate answers to allow for the submission of accurate data.

3. Did the applicable laboratory (or its reporting entity) request and receive assistance from the CMS CLFS Inquiries Mailbox regarding policy questions? Please describe your experience with receiving assistance.

Similar to experiences with the CMS Help Desk, emails sent by our member labs on a variety of PAMA data collection and reporting issues to the CMS CLFS Inquiries Mailbox consistently went unanswered. Our members reported that they would email the same question three or four times to the CMS CLFS Inquiries Inbox without ever obtaining a response. In particular, laboratories routinely sent requests for clarification on the highly ambiguous subregulatory PAMA reporting guidance asking, for example, how to separate out individual test payment rates from bundled payments. The agency repeatedly did not respond to these email inquiries, causing unnecessary confusion for applicable laboratories, which left them stumped, bewildered and unable to determine with any reasonable level of confidence what CMS considered to be appropriate and accurate PAMA data submissions.

NILA also wants to underscore that, in addition to the agency's lack of responsiveness in the Help Desk and the CMS CLFS Inquiries Mailbox, there was frustration with the lack of engagement with the Association during beta testing of the reporting database or following meetings where NILA representatives shared concerns with CMS officials. NILA and its members wanted – and maintain a desire – to work with the agency to implement the PAMA requirements in the most effective, least burdensome manner possible to arrive at appropriate and accurate payment rates for the CLFS. However, NILA representatives and the members that traveled to in-person meetings with the agency and department staff often believed these encounters were ineffectual. For example, NILA was not asked to provide a small laboratory business for the purposes of beta testing the CMS reporting database, even after meeting with the agency to address the limitations of small businesses in being able to comply with the regulation or subregulatory guidance. For smaller laboratory businesses, the repeated lack of CMS response and

engagement with stakeholder voicemails, emails, and in-person meetings has proved particularly burdensome as these laboratories simply do not have the same level of resources, IT infrastructure, and staff as larger labs necessary to fulfill the PAMA requirements. Devoid of informative, meaningful guidance and technical assistance from the agency, small laboratory businesses had to dedicate a disproportionately larger amount of resources and staff time to determining how best to comply with regulatory requirements and even in the best case scenario they were left to hope that their interpretation and processes avoided inadvertent reporting errors. There is no question the lack of response and guidance from CMS added unnecessary financial and administrative burden to an already particularly onerous process for laboratories, particularly small businesses.

In the future, NILA strongly encourages CMS to: (1) engage much more consistently and meaningfully with stakeholders via the Help Desk, the CMS CLFS Inquiries Mailbox, and in-person meetings to better understand and address data collection and reporting issues prior to the next PAMA reporting period; and (2) Work in collaboration with representatives across the clinical laboratory community and their Associations to ensure that all segments of the laboratory community are engaged with the agency and involved in pre-testing of new regulatory requirements. Small independent laboratories, physician office laboratories and small hospital laboratories were at a disadvantage for not being included in CMS testing processes.

4. Did the applicable laboratory (or its reporting entity) use the subregulatory guidance on data reporting provided on the CMS CLFS website? If so, was the information presented useful?

CMS's subregulatory guidance on the data collection and reporting was incomplete, at times uninformed, imprecise and generally vague; and therefore, insufficient to properly instruct applicable laboratories. This is all the more evident, given the continued need for CMS to update website-based FAQs in response to questions as a result of information not included in the subregulatory guidance. Because the subregulatory guidance itself was vague and ambiguous, NILA laboratories were unable to determine how to most accurately and correctly collect and report data to CMS in a manner that complied with regulatory requirements. For example, the subregulatory guidance did not acknowledge or clarify how labs should identify individual test rates from lab systems including prorated data following receipt of bundled payment amounts, nor did it explain how labs should account for beneficiary coinsurance and deductibles when reporting test payment rates. The guidance envisioned laboratories utilizing contracts with payors to understand payment rates for reported tests, showing a complete lack of understanding by CMS that most laboratories, other than large national laboratories, do not have contracts with listed payment rates. The lack of clarity or understanding of the variances in the laboratory market and the impact that has on the data being requested resulted in applicable laboratories not collecting or reporting data on a uniform basis.

Moreover, CMS was significantly delayed and did not release the subregulatory guidance until September 2016, giving applicable laboratories even less time to meet the extensive and burdensome PAMA mandate following publication of the regulation in June 2016. CMS further intensified these burdens by requiring a retrospective data collection period for data reporting. Labs had less than three and a half months to reconstruct six months of billing data, certify, and submit data for a reporting process that began on January 1, 2017. This truncated period not only gave labs less actual time to report, but also gave them less time to engage with the agency on how to understand and implement the data submission requirements. The subregulatory guidance delay and the retrospective data collection requirement

imposed an extreme and unnecessary regulatory burden on laboratories – particularly for small labs that have limited resources, IT infrastructure and additional staff necessary to meet these requirements.

NILA wants to underscore that the ambiguous and delayed subregulatory guidance directly contributed to non-uniform data submission by applicable labs, bringing into question the integrity and accuracy of the data CMS intends to use for revising CLFS payment rates. This lack of uniformity in reporting makes any payment rates in the CLFS based on the first PAMA data submission period imprecise, inaccurate, and not representative of final payment rates in the market. In other words, the integrity of the data culled from this process is highly problematic at best and extremely inaccurate at worst. Inaccurate and insufficient payment will put beneficiary access to high-quality clinical laboratory services at risk, particularly those services performed by independent laboratories in rural and other areas where disparities in care and access to adequate services exist – an outcome not desired by CMS or NILA.

As such, NILA strongly urges CMS to defer implementation of the updated CLFS payment rates to allow for data validation and the corrections of data errors. In addition, to make the reporting process uniform and less burdensome for applicable labs in the future, NILA strongly recommends that CMS release new guidance that explicitly clarifies and defines how labs should report data to meet the PAMA requirements. In particular, NILA recommends, among other specifications, that CMS clarify exactly how labs should: (1) separate out payments for individual lab tests within broader payment bundles; (2) account for beneficiary coinsurance; and (3) account for beneficiary deductibles. NILA further recommends that CMS test any reporting specifications in both small and large labs – not just larger labs as it did under the first reporting period – prior to issuance of new guidance so that the agency better understands and can address specific reporting challenges in the guidance. Finally, NILA strongly urges CMS to release the new guidance at least six months in advance of data collection and reporting period, allowing for CMS to meaningfully address concerns raised by stakeholders through public comment and giving labs more time to prepare for this burdensome and challenging process going forward.

5. Was the information that the applicable laboratory was required to report readily available in the applicable laboratory's record systems?

The information required for reporting by applicable laboratories was *not* readily available for NILA member laboratories. This is primarily because payors – in most cases, but not all – often pay for test codes on a bundled rather than individual test basis, frequently doing so in a manner not consistent with CPT guidelines. This occurs even in certain instances when a clinician orders individual tests. The laboratory will only bundle the tests consistent with CPT guidelines when issuing a bill to a payor. However, the payor may review a claim with bundled tests and individual tests and determine they will pay one set amount for the bill. When payment is received in this manner, many laboratories will prorate the amount received across the tests billed for, in order to validate in their own accounting systems that the bill was addressed by the payor. These bundled payments make it impossible for laboratories to correctly assign specific payment amounts to individual tests included in the bundle. This was made worse since CMS made the reporting process retrospective, not allowing any time for laboratories to develop a mechanism to set modifiers in their billing software that could extrapolate prorated data that was based on bundled payments from the data to be reported to the agency. If the agency had allowed for a prospective reporting process, such a significant problem could have been reduced or eliminated. However, since the laboratories had to comply and report, and under threat of extreme financial penalties for not doing so if audited, the laboratories felt forced to report prorated data that was within their billing

systems. There was no time or ability under the regulatory terms or timeline for them to avoid reporting this inaccurate data to CMS.

Putting into perspective all of these elements combined – including an extremely compressed timeframe, guidance that failed to understand the nature of how private payors remit payments to laboratories, and retrospective reporting – it is clear this resulted in a highly onerous process for laboratories and the reporting of inaccurate data that will have a direct effect on final payment calculations for tests on the CLFS.

6. Did the reporting entity have a manual, automated, or semi-automated remittance process for data reporting?

NILA members used a combination of manual and semi-automated remittance processes for complying with data collection and reporting requirements, and in many cases, laboratories had to manually review claims to mine the data to be reported, reviewing millions of data sets. In no case did a NILA member lab utilize a fully automated process for purposes of reporting data to CMS. In every instance, labs had to modify their data to conform to CMS standards, requiring lab administrators to shift internal staff and resources away from ongoing important work with day-to-day business operations to data submission efforts. In certain cases, NILA member laboratories had to use external consultants to review and pull together data for submission. NILA member laboratories dedicated substantial time and resources to adjust claims data to comport with CMS submission requirements.

7. If the reporting entity used a manual or semi-automated remittance process for data reporting, what percentage of the process was manual?

On average, approximately 30 percent of claims reported by our member laboratories were collected on a manual basis and the vast majority of the remainder were collected and reported on semi-automated basis. However, for smaller independent laboratories the use of a manual process was much higher at more than 60 percent. As a result, this process proved to be administratively and financially burdensome for applicable labs – particularly small labs with limited resources, IT infrastructure and staff – trying to accurately and fully comply with PAMA requirements.

The potential for unintended errors in data is much higher with manual and semi-automated processes than automated processes – particularly in the first period of data reporting when labs and CMS do have significant experience with the submission process and the CMS data reporting system. To better ensure the integrity of the PAMA data and the accuracy of the payment rates, NILA strongly urges CMS to delay use of the revised CLFS for Medicare payment of lab services until labs and CMS can have confidence that the data submitted do not reflect inadvertent errors from manual and semi-automated admission processes.

8. How much time (hours) was required to assemble and report applicable information to CMS?

NILA members dedicated several hundreds of hours – and in some cases reported an excess of 2,000 hours – putting together the data necessary to comply with data collection, reporting, and certification requirements. One lab had two to three staff members working full time on data reporting. Another larger lab reported using various internal staff members from the finance, billing, compliance, accounts receivable, and IT programming teams – as well as additional external programmers – on a continuous basis to fulfill data reporting requirements. Yet another laboratory reported substantial costs for external

consultants to modify its data systems to conform with CMS requirements – in addition to the significant internal staff time devoted to culling and reporting PAMA data. These represent just a few examples of the immense amount of staff hours applicable labs dedicated to meeting requirements in the first data reporting period.

We estimate laboratories spent at minimum $75,000, but are aware of instances where more than $100,000 was spent to comply with this unfunded regulatory mandate. This represents an immense administrative and financial burden on labs – particularly smaller labs with very limited resources and staff – that had to fulfill this mandate in a very short period of time without clear and informative guidance from CMS. It is important to note that for many this cost is not inclusive of costs to establish a new software system as many lacked the time and financial resources to do so.

It is additionally a concern that this unfunded mandate is not a one-time occurrence: applicable laboratories face ongoing significant financial and administrative burden to collect and report data for CLFS payment rates in future years. While there may be some one-time costs associated with the initial reporting period, laboratories will continue to experience unending administrative and financial burden to collect and report PAMA data. Unfortunately, given the lack of uniformity and consistency throughout this initial data collection period, applicable labs will not benefit in future years from much of the costs they bore during this initial reporting period.

9. Is there any other information that will inform us regarding the reporting, recordkeeping, and other compliance requirements from the first data collection and reporting periods?

NILA has significant concerns about the integrity, sufficiency, and accuracy of the data received in the first data collection and reporting period under the PAMA process and is alarmed that no process has been outlined by the agency to allow for the validation of data or correction of inaccurate information. Inaccurate and incomplete data collection occurred during the initial reporting period for multiple reasons.

- Most independent laboratories, many of which are small businesses, do not have contract rate arrangements with private payors, and therefore are provided no clarity on private payment rate amounts they will receive for tests performed. Many of these laboratories are out of network providers or in-network if they agree to abide by terms set by the payors.
- Private payors frequently pay tests as a bundle, disregarding CPT guidelines. Laboratories are then unable to separate out individual test payment rates from payment rates received, particularly under a retrospective reporting process. Laboratories felt compelled under the threat of audits and penalties to submit the data included in their billing systems, which included prorated payment amounts not reflective of final payment rates for tests performed. Such data could not be extracted from billing systems under a retrospective reporting process.
- The data collected by CMS under the first reporting cycle does not represent all segments of the national laboratory market, as it excludes most data from hospital outreach labs and physician office labs. The HHS Office of the Inspector General (OIG) found that CMS regulatory decisions will exclude virtually all hospital data from PAMA reporting.[2] Separately, the low economic

[2] HHS OIG Data Brief. 'Medicare Payments for Clinical Diagnostic Laboratory Tests in 2015: Year 2 of Baseline Data." September 2016. 14 n.25.

threshold established by CMS will eliminate data that otherwise could be reported from 96 percent of physician office labs. Exclusion of data from these key providers of services in the national lab industry which cover broad swathes of the private market – particularly hospital outreach labs – will result in a limited and biased calculation of rates under the rate setting process with rates that are dominated by the largest volume independent laboratories, which consist of only two national laboratories.

- The initial collection period required use of extensive manual and semi-automated processes, as well as retrospective data collection, raising significant concerns about the inadvertent and unintended submission of erroneous and incomplete data. As explained above, all of our member labs use manual and semi-automated processes to comply with the PAMA reporting obligations. Despite making their best efforts, our member labs likely unintentionally submitted at least some erroneous or incomplete data during the first PAMA reporting period, especially since CMS did not test or meaningfully engage with our labs during the process. This issue is especially problematic given CMS's decision to require retrospective data submission under a very short timeframe for compliance.

NILA finds the data integrity, sufficiency and accuracy concerns with the initial PAMA reporting period highly concerning given CMS's decision to not validate or audit the data submitted. Indeed, the HHS Office of the Inspector General (OIG) recognized NILA's concern when assessing CMS's progress on implementation of the revised CLFS payment rates:

> *"Absent processes to verify whether applicable labs report their data or to verify the quality of data that labs report, CMS may set inaccurate Medicare payment rates for lab tests. PAMA required CMS to set Medicare payment rates for lab tests by using a market-based approach – specifically, by using private payer data submitted by labs. If CMS does not have appropriate safeguards to ensure that all applicable labs report complete and accurate data, it may result in new Medicare payment rates that are inaccurate."*[3]

Inaccurate payment rates threaten meaningful loss in access to clinical laboratory testing for Medicare beneficiaries – particularly those who use community laboratories in rural areas and others that reside in alternate home settings – who require the support of laboratories in their community that can conduct same day testing and emergency testing.

NILA Recommendations

To ensure continued beneficiary access to high-quality lab testing services, NILA recommends the following to address the significant data integrity and payment accuracy concerns raised with the initial PAMA reporting period.

1) CMS should issue an interim final rule to postpone lab payment rate calculations and incorporate updated data from a broader swath of lab participants in the private market. As discussed above, the HHS OIG concluded in September 2016 that the PAMA process as finalized in the CMS final rule excludes virtually all hospital laboratory outreach data. Moreover, the final rule established a very low economic threshold for exclusion, eliminating 96 percent of physician office labs and

[3] Murrin, Suzanne. HHS OIG. "Changing How Medicare Pays for Clinical Diagnostic Laboratory Tests: An Update on CMS's Progress," page 11. OEI-09-00100. September 2016.

52 percent of independent labs. Both policy choices result in data coming from just a small portion of all labs, making payment rates inaccurate and not reflective of the actual market. This is clearly not the intent of PAMA, which is to set CLFS amounts based on private payor rates, as emphasized by Senator Hatch (R-UT) and Senator Burr (D-NC) in Statements for the Record on this issue.[4],[5] To ensure that CLFS rates fully reflect the laboratory market, inclusive of physician offices, hospitals, and independent laboratories, CMS either should:

- Amend the definition of "applicable laboratory" to explicitly include hospital and physician office laboratory providers of testing services; or
- Identify for public comment a statistically valid approach that adjusts data proportionate to market representation (e.g., survey validation) to ensure adequate rate inclusion across all segments of the laboratory market.

2) CMS should establish a transparent data collection and reporting process. CMS should further amend the PAMA regulation to establish a transparent validation process for data collection and appropriately address any data integrity concerns. This transparent process must:
   - Make available all data through a public comment period well in advance of the preliminary rate announcement;
   - Include information on how many labs reported by type of laboratory (national independent, small independent, hospital outreach, and physician office), as well as data volume and rate range by test type, laboratory type, and geographic region; and
   - Disclose the complete adjustment by weighted median for each three-year period following a reporting cycle.

3) CMS should more thoroughly engage with stakeholders to understand implementation concerns prior to initiation of the next PAMA reporting period and should provide more education and technical assistance on the process, both prior to and during that time. Specifically:

   - CMS should expand testing of the PAMA process to include small laboratory businesses as defined by federal small business size standards. As the agency surely recognizes, smaller labs face different data collection and reporting challenges than larger labs; smaller labs often have very limited resources and little to no IT infrastructure necessary to facilitate a minimally burdensome and smooth process. Therefore, NILA requests that in the future, CMS test data collection and reporting processes in some of our smaller member labs, in addition to larger labs, so that the agency can better address the

[4] "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 that receive payment on a fee for service basis under the fee schedule." 160 Congressional Record S2381, S2860 (May 8, 2014). Statement of Senator Burr.

[5] "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 market should be represented, including independent laboratories and hospital outreach laboratories. 160 Congressional Record S2381, S2860 (May 8, 2014). Statement of Senator Hatch.

reporting burdens and challenges our member labs face and our member labs, in turn, can better meet and respond to the PAMA requirements.

- CMS should provide more outreach beyond MLN notices and webinars. CMS did not directly notify applicable labs beyond Medicare Learning Network (MLN) notices and webinars announced on its website. As a result, many laboratories were entirely unaware of the data collection and reporting requirements and reached out to associations late in the process for assistance.

4) CMS should work with stakeholders, including NILA, to plan for ways to improve the reporting of data in subsequent reporting periods, including the aggregation of data as allowed for under statute. The volumes of data reported, largely in error and the inconsistency in approach by individual laboratories necessitates a streamlined process for the reporting of data. NILA has established a PAMA reporting workgroup and would be pleased to work with CMS on recommendations for the aggregation and streamlined reporting of data for subsequent reporting periods.

Request for Information on CMS Flexibilities and Efficiencies

NILA Concerns Regarding CMS's Implementation of PAMA and the Negative Impact on Medicare Beneficiaries' Access to Testing and Quality Health Care Services

Congress passed the *Protecting Access to Medicare Act of 2014*, including Section 216, requiring CMS to establish a market-based payment system for clinical and other laboratories paid on the Clinical Laboratory Fee Schedule (CLFS), including hospital outreach, independent and physician office laboratories. The intent of the law was to ensure CLFS rates are consistent with the market value for laboratory tests as paid by commercial insurers. It is NILA's strong belief that the final regulation to implement Section 216 of PAMA, *Medicare Program: Medicare Clinical Diagnostic Laboratory Tests Payment System (CMS-1621-F),* fails to comply with statute and the intent of Congress in the following three ways:

(1) CMS's retrospective reporting requirements, compressed timeline and delayed guidance – necessary to ensure compliance with regulatory requirements – resulted in many labs being unable to report payment and test volume data or to report data with significant errors[6];

(2) CMS's data collection and reporting requirements exclude a significant portion of the laboratory market paid under the CLFS and are insufficient to set new payment rates that are representative of the laboratory market[7]; and

[6] *HHS OIG Data Brief: Medicare Payments for Clinical Diagnostic Laboratory Tests in 2015: Year 2 of Baseline Data (OEI-09-16-00040), Sept 2016,* https://oig.hhs.gov/oei/reports/oei-09-16-00040.pdf.
[7] Id.

(3) CMS's rate setting process lacks the transparency required to verify the accuracy and appropriateness of data and new rates prior to a revised fee schedule becoming effective on January 1, 2018.

The implications of PAMA are significant. CMS's implementation of PAMA as currently outlined threatens the existence of the small and mid-size laboratory market, compromising access to laboratory testing for Medicare beneficiaries. If the regulation results in the anticipated massive consolidation in the market and closures of laboratory businesses serving rural and other vulnerable patients not currently served by large national laboratories, the resulting effect will be significant increases in Medicare costs for laboratory testing.

The magnitude of payment cuts expected as a result of the regulation's approach have already resulted in significant layoffs, affecting rural communities. The announcement of laboratory sales and closures in February 2017 resulted in nearly 500 jobs lost in the state of Oregon.[8]

Collection and Reporting Requirements Finalized by CMS Unduly Burden Clinical Laboratory Businesses and Raise Significant Concerns Regarding Data Integrity

CMS finalized PAMA regulations in June 2016, a year past statutory deadline requirements. The regulation was absent significant information needed for laboratories to begin preparing to meet a multitude of requirements, and CMS did not release subsequent information through subregulatory guidance until mid-September 2016. This delay resulted in clinical laboratories having less than three and a half months to prepare for, verify, and report millions of data entries to CMS, while under threat of penalty. This delay imposed a massive and wholly unrealistic timeline for many laboratories to establish systems to collect and review data and assemble it in a manner compatible with the CMS data reporting system. Further, laboratories experienced significant difficulties submitting data into the CMS data reporting systems, facing multiple rejections and requests for resubmission after CMS notified some laboratories that data had not been fully received by their system.

Retroactive Reporting and Significantly Compressed Timeline Prohibited Laboratories from Establishing Automated Systems to Guarantee Data Accuracy

The difficulties of complying with such a compressed timeline were magnified by CMS's mandate for laboratories to collect and report retroactive data for payments received and finalized from January 2016 – June 2016. Community laboratories, many of which are small businesses under the U.S. Small Business Administration size standard for clinical laboratories (<$32.5M/year), did not have billing systems in place that could comply with CMS requirements for older billing data within their billing systems. Therefore, the majority of their payment data was not readily available in the manner required by CMS. The mandate that laboratories report retroactive payment data meant that even if a laboratory had the financial means to establish an automated billing system during the brief period before reporting was to begin, the new system still could not be designed to capture data from prior pay periods. As a result, many laboratories

[8] PeaceHealth Laboratories, a large hospital outreach laboratory serving rural communities across Oregon, Washington, and Alaska, announced the closure and sale of its hospital outreach business. The announcement was followed by significant layoff notices of up to 500 jobs. PeaceHealth publicly explained that the projected losses from PAMA were a significant determining factor in the decision to sell and close the laboratory.

were forced to manually review millions of data sets on paper claims and attempt to call on payors for clarification to determine what information should be reported.

The majority of laboratories used a combination of manual and semi-automated remittance processes for collecting and reporting data. In no case did a NILA member lab utilize a fully automated process for purposes of reporting. In every instance, laboratories had to review and modify their data to attempt to conform to CMS standards. The burdens of reporting required lab administrators to shift internal staff and resources away from the important work of providing laboratory testing services for patients and their day-to-day business operations. Some laboratories also had to afford the expense of hiring costly external consultants to assist in this process. For many other community laboratories, the costs of hiring outside consultants was too high and not within budget. These laboratories, many of which are small businesses, dedicated substantial time and resources to adjust claims data in an effort to comport with CMS submission standards. Many expressed concern with submitting likely inaccurate data, as they were unable to meet requirements.

Due to the extreme difficulties experienced by laboratories in trying to collect and report data in the unreasonably brief window, we believe the opportunity for errors in the data is high. The U.S. Department of Health and Human Services' (HHS) Office of the Inspector General (OIG) confirmed errors are likely in their September 2016 report, stating concerns regarding data integrity and the quality of data to be received by CMS. While CMS granted a 60-day grace period at the end of the reporting period that had been outlined in the final regulation,[9] CMS further established a burden on laboratory providers by communicating the extension to laboratories only 24 hours in advance of the original deadline. For the majority of laboratories, the 60-day extension came too late to address concerns regarding potentially flawed data many had already scrambled to submit in order to comply with the original deadline and requirements to avoid potentially extreme financial penalties that small laboratory businesses could never meet.

CMS Requirement for Laboratories to Report Payments Incompatible with How Private Payors Remit Payment

Prior to receiving the CMS guidance issued September 2016, laboratories had received no insight from CMS on which tests they would be required to report and how such data was to be reported. After reviewing the guidance, it was clear to laboratories that CMS does not understand how private payors remit payments to laboratories. The system devised to collect and report laboratory data is entirely inconsistent with the laboratory billing and private payment process.

Regardless of how laboratories bill a given payor, a payor will remit payment in several different ways. For example, many times, payors pay for test codes on a bundled basis, rather than on an individual test basis. Sometimes, payors pay on a bundled basis even when physicians order the tests as individual tests and even when the tests being bundled would not otherwise be recognized as a bundled set of tests by other payors. Laboratories bill for the tests in the manner they were ordered, unless the physician ordered a set of tests that should be billed as a recognized panel in accordance with Medicare and CPT guidelines. When this occurs, it is not possible for a laboratory to break out what is payed for each test because the payment as received is not attributed to the CPT codes billed. It is also inaccurate for a lab

[9] Under regulation, data was to be reported to CMS by March 30, 2017. Announcement on www.cms.gov permitted data to be submitted without subjecting a laboratory to civil monetary penalties up to May 30, 2017.

to apportion the amount paid between the CPT codes in the absence of any additional data from the payor. Other payors remit payments on individual tests that were billed, but the amount varies by how many tests are billed rather than which specific tests are billed. Therefore, it is inaccurate and inappropriate to attribute the bundled payment across tests as final payment rates. The payment rate is reflective of a bundle, not individual test rates.

For small community laboratories, in particular, trying to identify or verify payments for individual tests can be extremely burdensome, and for many, an impossible undertaking. Small laboratories generally have a higher level of inconsistency in payments received from private payors than larger laboratories because the majority of smaller laboratories do not have contract agreements with private payors. In many cases, these laboratories also serve as out-of-network providers with unique and varying payment rates.

As a result of the challenge of reporting rates to CMS under PAMA requirements, many laboratories reported prorated data or bundled payment amounts as final payment rates on individual tests because it was impossible for them to extrapolate and exclude that data from their billing systems as they worked to manage a retrospective reporting process. CMS's regulation excludes bundled payments from the definition of "applicable information" to be reported. Yet, in the face of drastic financial penalties for non-compliance with reporting[10] and the resulting potential audits, laboratories that had no way of identifying prorated or bundled payment data from individual final payment rates, ultimately reported the data they had recorded in their billing systems – data that would often not constitute final payment rates as required under the regulation.

The complexity and inconsistency of how payors pay for tests, coupled with CMS's decision to impose a retrospective reporting process that laboratory billing systems could not comply with, raises significant concern about the integrity of the data CMS received and plans to utilize that data to set new CLFS payment rates. As planned and as reported in September 2016 by the OIG, CMS has no plan to validate the data it has received before setting a revised fee schedule.

CMS Data Collection System Lost Laboratory Data and Forced Numerous Re-Submissions

We are further concerned that the CMS data collection system was not functioning at adequate capacity as many operational problems from the 2016 test phase were unresolved at the time reporting began, hampering laboratory data submissions.

NILA member laboratories described numerous challenges navigating the CMS data reporting system. Many laboratories attempted to upload and submit data 20 times or more before ultimately succeeding due to line-item errors in the CMS data reporting system. One of NILA's largest member laboratories also reported that it submitted the data on time and then received an alert from CMS that the submission did not go through or was otherwise lost by the system. The lab then had to redo the entire data submission – creating unnecessary financial and administrative burden for the lab. These represent just some of a myriad of cases whereby applicable laboratories made their best efforts to comply with the highly burdensome PAMA reporting requirements only to have the CMS data reporting system malfunction. Without the agency making modifications, the data reporting system will serve as a significant

[10] Under the PAMA statute and as accepted under the PAMA regulation, Civil Monetary Penalties can be up to $10,000 per day per reporting error or per day for failing to report data to the agency by the deadline imposed.

impediment in efficiently, effectively, and accurately collecting PAMA data for purposes of setting CLFS payment rates in the future.

Throughout this process, laboratories found CMS was unresponsive to questions on data collection and reporting. NILA member laboratories routinely left voicemails with the Help Desk or sent emails to the CMS CLFS Inquiries Mailbox, and despite repeated inquiries both consistently went unanswered or "form answers" providing no clarity to the specific questions being asked were provided. Given the lack of clear guidance and numerous difficulties laboratories experienced with data collection and reporting we expected CMS to be prepared to offer clarification and assistance on implementation. Unfortunately, that was not the case and the lack of response was made even more troubling given the significant penalties laboratories then faced for errors or failure to report.

NILA firmly believes that CMS could have eased some of the burden associated with the many reporting issues by simply responding to laboratories' inquiries or offering technical assistance specifically for small laboratory businesses. The lack of engagement on the part of CMS to work with laboratories on PAMA implementation and to respond to stakeholder inquiries proved particularly burdensome for smaller laboratories as they do not have the same level of resources, IT infrastructure, or staff as other laboratories to fulfill the PAMA requirements.

CMS's Definition of "Applicable Laboratory" Excludes 95% of Laboratory Market Paid Under CLFS According to HHS OIG

Congress intended for PAMA to adjust Medicare rates to reflect market rates paid under the CLFS to independent laboratories, physician office laboratories, and hospital outreach laboratories that serve patients outside of the hospital. Under the law, all "applicable" laboratories – those that receive a majority of their Medicare revenues from the clinical laboratory or physician fee schedules – are required to report to CMS all payment rates and test volumes for each of their private payor arrangements. However, CMS's definition of applicable laboratories, as defined by the final rule, is so restrictive that the OIG in its September 2016 report estimated that only five percent of clinical laboratories are allowed to report private market data under PAMA. Further, OIG estimated 0 of 6,994 hospital laboratories and only 11,149 of the 235,938 physician-office laboratories are allowed to report private market data.[11]

The exclusion of 95 percent of laboratories, particularly hospitals operating large outreach laboratories, is significant. In some regions of the country, hospital laboratories dominate the market by as much as 50 to 60 percent of test volumes. The absence of such a large portion of the laboratory market from the data CMS uses to set a revised CLFS will result in a limited and skewed calculation of rates under PAMA, allowing the calculation to be dominated by the most significant discounts offered by the highest test volume providers, which are the two publicly-traded laboratories in the U.S. The 95 percent of laboratories excluded from reporting their private payor information, including hospital outreach laboratories, are still subject to the new CLFS rates despite not being represented or allowed to participate in the reporting and rate setting process. Without a full market prospectus for calculation, the limited financial data received by CMS for the purpose of calculating a revised fee schedule will result in the closure of many laboratory businesses across the country and the elimination of more costly laboratory services offered to vulnerable populations, especially in rural and underserved areas. If this major

[11] HHS OIG Data Brief: Medicare Payments for Clinical Diagnostic Laboratory Tests in 2015: Year 2 of Baseline Data (OEI-09-16-00040), Sept 2016. https://oig.hhs.gov/oei/reports/oei-09-16-00040.pdf, page 7, Figure 4; page 8, Figure 5.

problem is not addressed, PAMA will eliminate beneficiary access to laboratory test services that support patient clinical care management and current value-based health care arrangements.

It is critical that the laboratories reporting data to CMS are representative of the marketplace. CMS's plan to use National Provider Identifier (NPI) numbers to identify laboratories that must report data is too limiting because it prohibits hospital laboratories without their own NPI (separate from the larger hospital system they belong to) from reporting. As finalized in the regulation, the NPI methodology results in Medicare payment rates that fail to reflect information from important segments of the laboratory market, especially hospital outreach laboratories.

HHS' baseline assessments for 2014 indicated roughly 24% of Medicare Part B lab test payments were made to hospital-based laboratories. Nearly one-quarter of the Medicare Part B payments for laboratory tests is not insignificant. In the private sector, hospital lab payments dominate at nearly 50 percent of the market. It is critical that this portion of the clinical laboratory market is not marginalized when assessing market data for the purpose of setting Medicare laboratory payment rates. Without the hospital laboratory sector, CMS then gives artificial weight and favor to the commercial rates paid to the largest national laboratories that dominate the volume of data received by CMS through the reporting process. Unlike independent community laboratories, the two largest national laboratories have negotiated discounted contracted rates with private payors. In the private market, these two laboratories now make up more than 54 percent of the test volume for the independent laboratory sector. If PAMA is implemented as defined by the current regulation, the resulting payment reductions will devastate access to laboratory testing for beneficiaries, as the laboratories serving rural markets and vulnerable beneficiaries in alternate care sites, will not be able to afford to offer testing to more costly service areas. If implemented without needed fixes, closures and acquisitions will persist eliminating needed market competition. The reduction in competition could quickly create a duopoly in the Medicare laboratory testing market that will lead to higher costs for Medicare, and markets served by community-based laboratories today will not be served.

We urge CMS to seriously re-evaluate its methods for assessment of the fee schedule rates and request that adjustments be made to ensure the assessment is of the complete laboratory market. CMS needs to be concerned about the incongruous nature of the system established by regulation as compared to that which was intended by Congress; the significant burden and impact this will have on existing laboratory businesses and services; and the threat such a system creates on access to beneficiary testing services. The success of PAMA's payment reforms is entirely dependent on an accurate measurement of true market rates and this cannot be achieved with such an extremely limited market assessment.

CMS Rate Setting Process Requires Transparency and Methods to Validate Data

The September 2016 OIG report notably stated that the chance of errors in the reported data is high based on the compressed timeline created by agency and delays in finalizing the PAMA regulations and issuing guidance to laboratories.

CMS's regulation states that after CMS conducts its data assessment, the Agency will release preliminary rates for public comment in the fall[12] and finalize those rates after a brief comment period in 2017. The regulation does not outline any process to ensure transparency in how CMS derived its rates, any method

[12] CMS announced during the July 2017 CLFS Public Meeting that rates would be released in September 2017.

for validation of the data, or a process to provide the data needed for stakeholders to help the agency identify errors in the data received. When asked to provide comments in the fall of 2017, it is unclear what information will be publicly released to allow for an appropriate evaluation and comment period.

In the lead up to the release of the regulation, NILA advocated for CMS to provide data in advance of finalizing a revised fee schedule, making that data available at least six months in advance to allow for data concerns to be addressed with the agency. NILA also asked that the agency provide the data in such a manner that protects the confidentiality requirements outlined in statute and ensure that the data includes such information as: (1) how many laboratories reported certified data by laboratory type (large national independent laboratories, other independent laboratories, physician office laboratories, hospital outreach laboratories); (2) the volume of data reported per test code; and (3) the ranges in rates and volumes by laboratory type. CMS must also disclose the complete rate adjustment for a three-year period for each test, given that PAMA allows adjustments to the clinical laboratory fee schedule for three years after each reporting cycle has occurred. CMS and laboratories simply must have time to address data integrity concerns as this will impact final PAMA rates.

Recommendations to Address Concerns with PAMA Implementation

NILA offers the following recommendations to CMS on how to address the overly burdensome regulatory requirements imposed by CMS' implementation of Medicare payment reform to the Clinical Laboratory Fee Schedule (CLFS) as enacted by Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA): (1) HHS/CMS issue a delay of the PAMA regulation for a period of at least one year to allow the agency time to address and make corrections to the current regulation; (2) CMS work with the stakeholder community to address concerns with data integrity and streamline and reduce reporting burden on laboratory businesses; (3) CMS either amend the definition of applicable laboratory through regulation or work with the community to identify for public comment a statistically valid approach to ensure PAMA-reported data reflects the full laboratory market – physician, hospital and independent laboratories; (4) CMS establish a transparent validation process for the data collected and to appropriately address data integrity concerns; and (5) CMS work with the stakeholder community to establish an approach to appropriately aggregate data for subsequent reporting cycles to streamline administrative burden on providers and ensure the appropriate type and amount of data is captured to appropriately cover and calculate market payment rates.

Conclusion

If the PAMA laboratory regulation is implemented as outlined in the final rule without change to address the significant errors and limited data, we anticipate many laboratories will be forced to close operations, particularly in rural and underserved areas that are more costly to service. The consequences would be immense for Medicare beneficiaries. Patients will be forced to forego testing or travel hours to obtain services that are needed for physicians to maintain their care. The consequences are equally substantial on the laboratory community-based workforce. The regulation and the magnitude of cuts expected has already resulted in significant layoffs in rural communities.

While NILA has worked closely with our members, CMS and Congress toward PAMA implementation, we believe that under the current regulatory requirements, the new program will not reflect accurate private market rates for clinical laboratory services as required by statute. Given the significance of

these ongoing concerns, we respectfully request that CMS delay implementation of the CLFS reforms under PAMA to allow time to resolve these significant issues. By ensuring smooth and successful implementation, we can maintain Medicare beneficiary access to clinical laboratory services without disruption. If you have questions concerning these comments, please contact Julie Allen, NILA's Washington Representative, at 202-230-5126, Julie.allen@dbr.com.

Sincerely yours,

Mark S. Birenbaum, Ph.D.

Administrator