



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; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs Request for Information (CMS-1678-P)

Dear Administrator Verma:

The National Independent Laboratory Association (NILA) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Request for Information included in the Fiscal Year (FY) 2018 Proposed Changes to the Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems concerning flexibilities and efficiencies that could be implemented throughout the Medicare program to increase quality of care, lower costs, reduce burden, improve program integrity, and make the health care system more effective, simple, and accessible for beneficiaries and providers.

NILA represents a broad spectrum of laboratories, from small independent community laboratories to larger multi-state regional independent 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 others primarily provide routine and emergency (STAT) diagnostic services to allow physicians to manage chronic diseases in patients with multiple health care conditions and medical needs.

In response to the request for information, NILA's comments serve to reiterate the urgent need for CMS to address the overly burdensome regulatory requirements imposed by the agency's flawed 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). The implications of the act are significant, and as currently outlined threaten 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 national publicly-traded laboratories, the resulting effect will be significant increases in Medicare costs for laboratory testing.

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 errors¹;
- (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 market²; and
- (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.

¹ 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>.

² Id.

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.³

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 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

³ 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.

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,⁴ 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 paid for each test because the payment as received is not attributed to the CPT codes billed. It is also inaccurate for a lab to apportion the amount paid between the CPT codes in the absence of any additional data from the payor. Other

⁴ 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.

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 reporting⁵ 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

⁵ 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.

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 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.⁶

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

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>, page 7, Figure 4; page 8, Figure 5.

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 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 fall⁷ 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 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

⁷ CMS announced during the July 2017 CLFS Public Meeting that rates would be released in September 2017.

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,

A handwritten signature in blue ink that reads "Mark S. Birenbaum". The signature is fluid and cursive, with a long horizontal flourish at the end.

Mark S. Birenbaum, Ph.D.

Administrator