



November 24, 2015

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1621-P
P.O. Box 8016
Baltimore, MD 21244-8016

RE: Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System; CMS-1621-P; RIN 0938-AS33

Dear Acting Administrator Slavitt:

The American Association of Bioanalysts (AAB) and the National Independent Laboratory Association (NILA) welcome the opportunity to provide comments on the Medicare Clinical Diagnostic Laboratory Tests Payment System; CMS-1621-P; RIN 0938-AS33. AAB and NILA represent independent community and regional laboratories, which work with physician practices, hospitals, outpatient care settings, skilled nursing facilities, and homebound patients. Organization members are community-based businesses that range in size from small to large multi-state regional laboratories. For the majority of AAB's and NILA's 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.

Background

Since its passage, AAB and NILA have been extremely concerned about the impact the *Protecting Access to Medicare Act of 2014 (P.L. 113-93)* will have on regional and community laboratories and the Medicare beneficiaries they serve. Section 1834A of the Act significantly alters how clinical laboratories providing diagnostic testing services included on the Clinical Laboratory Fee Schedule (CLFS), regardless of type of laboratory, will be paid going forward. Our organizations did not support the law for several important reasons: (1) an unrealistic, limited statutory timeframe for implementation of a complex first-time system where the IT infrastructure is not currently in place and where data collection and assessment capabilities and resources vary substantially within the laboratory community; (2) the immense financial and administrative strain of an unfunded mandatory reporting requirement on community-based laboratories, particularly small laboratory businesses; (3) the fallacy of a system to evaluate Medicare rates based on comparisons to a weighted median of private payment rates, which are primarily and sometimes exclusively negotiated and set by national laboratories to achieve sole source contracts and narrow provider networks; and (4) the lack of recognition in the law that

community laboratories have different business economics given their size, structure, and limited test menus and cannot absorb across-the-board cuts that could amount to as high as 55 percent for some tests under the statute.

AAB and NILA are alarmed that Congress passed Section 216 of PAMA without ever holding a congressional hearing or allowing for deliberations on legislation to address the complexity of laboratory payment reform. Our organizations are also alarmed that this was attached to and rushed through on an unrelated piece of legislation only a few years after the Senate Judiciary and Finance Committees began an investigation to examine arrangements between national private insurers and national, publicly-traded laboratories for establishing and accepting predatory pricing practices in order for such laboratories to obtain greater Medicare market share over their competitors.

The only way for CMS and Congress to ensure Medicare is paying an appropriate price for laboratory services and to ensure continued access to laboratory services for beneficiaries regardless of where they reside is to ensure there is a competitive Medicare market for laboratory services. In the absence of that competition, not all markets in the United States can be served by two dominant national laboratories. CMS should recognize that if the statute and its regulatory implementation result in a substantially smaller number of laboratories participating in the Medicare program, this will result in significant long-term price increases and reduced access to testing services.

NILA and AAB truly appreciate the significant task CMS has before it to issue regulations to implement Section 216 of PAMA. However, AAB and NILA want to strongly emphasize to CMS that the agency must be more thoughtful and thorough in its approach to the regulation than Congress ever was in its crafting and passage. CMS has a responsibility to ensure that implementation of the law is about far more than deriving a savings to Medicare by cutting payment rates. The best outcome for the Medicare program is for the regulations to take a surgical approach, rather than an ax, to the Part B Clinical Laboratory Fee Schedule in order to protect competition in the market and ensure continued access to laboratory services. While our organizations did not support the law's approach in addressing Medicare laboratory payment reform, we want to work with the agency to ensure its fair implementation. We appreciate the agency's willingness to engage in a dialogue with us thus far on implementation, and we hope to continue the dialogue to ensure the terms of the regulation are achievable for community laboratories and the statutory provisions are correctly interpreted as intended by Congress.

Our organizations are extremely concerned by the approach of the proposed regulation as outlined. We are likewise concerned that CMS has not sought to engage with community laboratories to ensure the utility of any new agency system under development for collecting the laboratory data associated with the proposed rule. Such a data system is not even described in the proposed rule the agency envisions finalizing less than five weeks from the date of this letter. Thus far, community laboratories have had no ability to respond to whether the data system can correspond with the variances in laboratory information systems that have no uniformity across the industry. It is of paramount importance that CMS understands NILA's and AAB's concerns about the approach of the proposed rule and does not move to issue final regulations that ultimately: goes into place without first testing a new data collection system with laboratories that represent variances in the size and structure of the industry; results in an inability for

community laboratories with limited resources to comply with requirements while under threat of extreme penalty; limits the market assessment process by not having the full laboratory market represented in the data; and creates a process with little-to-no transparency so laboratories cannot appropriately provide feedback to the agency when new CLFS rates are proposed.

Independent Community Laboratory Market

As CMS works to finalize regulations, it is critically important that the agency understands the diversity in the types of laboratories that make up the independent laboratory market in size and structure, testing focus, and purpose for that focus. Independent community-based clinical laboratories work with physician practices, hospitals, outpatient care settings, skilled nursing facilities, and homebound patients. In contrast to the two large national, publicly-traded laboratories that make up more than 50 percent of the laboratory market by test volume, community laboratories range in size from small businesses to large multi-state regional laboratories. For most of these laboratories, unlike the two national laboratories, 30-50 percent or more of their revenues are from Medicare Part B. Most community laboratories operate between one and five laboratory testing facilities compared to national laboratories that operate around 200 or more testing facilities. The majority of community laboratories are privately-owned companies, and many are family-owned and operated since their establishment, decades ago. Unlike their national competitors, these laboratories have personal relationships with providers in their communities, offering emergency (STAT) testing, quick turnaround times when results are immediately needed for patients with multiple comorbidities and sensitive health conditions, and employing a skilled workforce through locally-based and operated testing facilities. Community laboratories also provide an essential infrastructure during natural disasters and other emergency situations when air traffic is limited or otherwise not available. During September 11, 2001, and the immediate timeframe thereafter, when national laboratories were unable to ship specimens by air for processing, community laboratories maintained the infrastructure needed to ensure testing was available and timely.

The testing offered by independent community-based laboratories and the costs of doing so vary considerably from their national competitors. Testing by community laboratories tends to be limited to a menu of tests that best serves their clientele (e.g., routine testing for chronic conditions) or limited to specialty testing for a specific purpose (e.g., infectious disease testing; allergy testing). Community laboratories are the facilities providing the majority of testing to niche care settings such as skilled nursing facilities, assisted living facilities, federally qualified health centers, and to physicians providing care to homebound patients. Community-based laboratories also tend to be the primary testing resource for rural communities. Maintaining the testing market infrastructure to ensure that community laboratories are able to continue providing access to testing services must be a priority as CMS seeks to finalize its regulations and implement this new program. It is important that CMS understands the role that community laboratories play in providing Medicare beneficiaries needed testing services and the strain and implications any new Medicare laboratory rate evaluation system and such payment adjustments can have on this particular segment of the market.

NILA and AAB Comments on the Proposed Rule

Provisions of the Proposed Rule

Definition of Applicable Laboratory

The statute defines “applicable laboratory” as a *laboratory* that receives the majority of its Medicare revenues under the CLFS or PFS. The statute itself did not seek to define laboratory, but it did make clear that the appropriate evaluation of whether a laboratory is considered applicable is by looking at the *laboratory’s* revenue sources and whether services provided for and reimbursed through either the CLFS or PFS make up the majority of where the laboratory’s revenues are derived. When evaluating the different types of laboratories that exist today in terms of where they derive their revenues, it is clear that the statute sought to exclude from the definition of applicable laboratory those laboratories that receive the majority of their revenues from global diagnosis-related group (DRG) payments are bundled for hospital inpatient laboratory services. It is also clear that the statute sought to exclude those laboratories that receive the majority of their revenues from ambulatory payment classifications (APCs) where payments are bundled for hospital outpatient laboratory services. The only other way the statute sought to exclude laboratories from reporting was through a low expenditure or low volume threshold exemption, providing discretion to the agency for setting the parameters for such a threshold. Under the statute, CMS has the authority to exclude laboratories from reporting private payor rates for three specific statutory reasons: (1) If the laboratory does not receive the majority of its Medicare revenue from the CLFS or PFS; (2) if the laboratory meets a low expenditure threshold; or (3) if the laboratory meets a low volume threshold.

The statute was clear in its use of the word laboratory. The standard for evaluating whether a laboratory is applicable is by looking at the laboratory itself and whether it meets the requirements under statute for the purposes of reporting data to the federal government. In drafting the legislative language, Congress could have instead used the word “entity” instead of laboratory, and in that case, the standard for evaluating whether the entity is applicable for the purpose of reporting data would be by looking at the entity in its entirety to determine where the majority of its revenues are derived. With the ever-changing health care marketplace and growth of integrated health care delivery systems, surely Congress would have defined applicable laboratory as an entity rather than a laboratory if that had been its intention. By using the word laboratory, Congress limited the definition of applicable laboratory directly to the laboratory business unit itself, whether that laboratory is independent, a hospital outreach laboratory serving non-hospital patients, a physician office laboratory, or a laboratory of any other type.

Hospital outreach laboratories are a growing business for hospitals and health care systems and have separate and distinctly identifiable cost centers. These laboratories obtain specimens from patients that are seen in physician offices and otherwise provide direct testing services to non-hospital patient Medicare beneficiaries in the same manner as independent laboratory businesses. Hospital outreach laboratories are paid under the CLFS for the testing services provided, and CMS has long recognized that these laboratories function as independent laboratory practices.¹

¹ Medicare Claims Processing Manual, Pub. No. 100-04, Chapter 16, 10.1.

Congress's expressed purpose in drafting Section 216 of PAMA and including it into what ultimately became statute was to have Medicare payment rates for clinical laboratory services be evaluated against and then aligned with the weighted median of rates paid for the same services in the private market.² In order for such a rate evaluation and reassignment to occur and to not be unfairly skewed or biased, the Medicare rate and volume data collected by CMS as structured under statute must reflect the entire laboratory market.³

To not have the full laboratory market represented, will result in the data submitted to CMS for evaluation being dominated by the largest independent laboratories in the market, where smaller market competitor rates cannot be fairly assessed when evaluating a weighted median rate. The volume of test rates submitted by the largest national players in the independent laboratory market are expected to be in the millions for some tests, whereas the rates submitted by other national laboratories are expected to collectively be in the thousands. The two largest national independent laboratories in the market together make up more than 52 percent of the test volume in the United States. It is not possible for CMS to fairly evaluate the weighted median of each test rate without ensuring that the information collected is statistically significant and represents all segments of the laboratory industry. Congress' intent to have broad laboratory market representation in the data can also be understood by the statutory provision that applies the revised payment rates to "a clinical diagnostic laboratory test furnished by a hospital laboratory if such a test is paid for separately, and not as part of a bundled payment under section 1833(t)." Congress would not subject hospital laboratories to revised rates unless their rates were part of the mandatory reporting and rate evaluation process outlined under statute. Otherwise, it would be tantamount to Congress establishing under statute a government program to reprice hospital laboratory payments by using only their competitors' rates.

CMS Proposed Definition – Applicable Laboratories

NILA and AAB strongly disagree with CMS's definition of applicable laboratory as outlined in the proposed rule. CMS proposes to define applicable laboratory as "an entity that reports tax-related information to the Internal Revenue Service (IRS) and a Taxpayer Identification Number (TIN) with which all of the NPIs in the entity are associated..." Unlike the statute, this definition would identify which laboratories are applicable for the purposes of reporting data based on an evaluation of an entity that might own and provide laboratory services as well as many other health care services. As a result, this definition would most likely result in the exclusion of hospital outreach laboratories from the reporting process since most hospital outreach laboratories are owned by hospital networks under one TIN.

CMS also proposes to accept the authority provided in the statute to define a low expenditure threshold in order to allow laboratories whose Medicare expenditures fall under a specific amount to be excluded from the reporting process. Combined with the low expenditure threshold, which would exempt nearly 96 percent of all physician office laboratories and a majority (52 percent) of independent laboratories, setting the applicable laboratory standard at

² See 160 Congressional Record S2860; May 8, 2014; Colloquy between Senate Finance Committee members on the intent of PAMA Section 216.

³ As allowable under PAMA where the majority of revenues come from the CLFS or PFS or Section 1834A under the Social Security Act.

the TIN level results in an exclusion of the majority of the laboratory marketplace. According to the Department of Health and Human Services Office of the Inspector General (OIG), in 2014, hospital laboratories represented one quarter (24 percent) of Medicare Part B spending on clinical laboratory tests.⁴ This percentage is only anticipated to grow as health care systems continue to integrate and more physicians sell their practices to hospitals and health systems. Between 2000 and 2012, the American Hospital Association reports that the number of physicians employed by hospitals grew from 20 percent to 40 percent, and there are projections that the percentage will increase to 75 percent by 2017.⁵ As physician groups integrate, the hospital outreach laboratories become the primary testing source for patients served by these practices. With the projections in the growth of physician practices to be employed by hospitals, CMS should anticipate that hospital outreach laboratory testing will continue to grow and become a much more significant part of the Medicare laboratory spend. If CMS excludes hospital outreach data, by 2017, this data could make up almost half of the testing market for Medicare Part B.

Congress did not intend to have the new laboratory reporting and rate calculation process be placed squarely on the backs of independent laboratories, and less than a majority of independent laboratories, at that. As outlined in the comments above, Congress intended to have the new rate evaluation and payment reform process be of the laboratory market, specifically all sectors of the market that are paid under the CLFS. To do anything otherwise, is to violate the statute and set up a system that is biased toward the rates negotiated by and paid to the largest most dominant players (by test volume) in the independent laboratory sector. CMS's proposed process for assessing who qualifies as an applicable laboratory prohibits the range of payment rates for laboratory tests in the private market to be assessed, basing new Medicare payment calculations on a limited and skewed assessment of what is a much larger market.

Again, if Congress had intended to measure the standard for whether a laboratory is an applicable laboratory in the way CMS outlines in the proposed rule, it would have defined applicable laboratory as "an entity" or "an entity which has at least one component that is a laboratory" that receives the majority of its Medicare revenue from either the CLFS or PFS. By using the word laboratory, Congress instead limited the definition of applicable laboratory directly to the laboratory business unit itself. Therefore, the evaluation of what it means for an applicable laboratory to receive a majority of Medicare revenues from the CLFS or PFS must be applied directly to the laboratory itself, whether that laboratory is a stand-alone operation or a business unit within an organization (e.g., hospital) offering multiple health care services. If CMS uses TIN-level data it would not be able to determine whether a majority of a given laboratory's Medicare revenue comes from the CLFS or PFS, which is required by statute. Therefore, TIN cannot and should not be used to determine which laboratory is considered applicable for the purposes of reporting data to CMS.

Where TIN or another identification mechanism, including the National Provider Identifier (NPI) could be of utility to CMS and to the laboratory community is for the purpose of determining how laboratories should physically report their data to the agency. TIN and/or NPI could be used to define how laboratories are to report data to CMS. For example, use of TIN or NPI could help

⁴ Medicare Payments for Clinical Laboratory Tests in 2014: Baseline Data (OEI-09-15-0021).

⁵ American Hospital Association's Hospital Statistics Report, 2012 Edition.

a regional laboratory network or a hospital laboratory that is part of a larger health system determine who has the responsibility for reporting private payor data and test volume information to the agency on the applicable laboratory's behalf. Later in our comments we explain why NILA and AAB believe that CMS must separate the process of reporting information from the process of determining which laboratories are "applicable" and required to report their data.

Recommendation on Defining Applicable Laboratory

In the absence of Section 1834A or the broader Medicare statute defining the term "laboratory," CMS rightfully turned to the Clinical Laboratory Improvement Amendments (CLIA) for the purpose of defining laboratory within the term applicable laboratory. The CLIA definition focuses specifically on laboratory facilities providing testing services.

The utility of the CLIA definition and the requirements associated with the CLIA program, however, go much further to support CMS's regulatory efforts than simply supporting the definition of "laboratory." For a statute that requires a laboratory that receives the majority of its revenues under the CLFS or PFS to be considered applicable and required to report data, CLIA provides a simple and clean way for CMS to determine which laboratories are applicable under the requirements of the 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 number.

NILA and AAB strongly urge CMS to define an applicable laboratory as a laboratory facility identifiable by a CLIA number and where more than 50 percent of its Medicare fees are derived from the CLFS or PFS. All clinical laboratories regardless of type (e.g., independent, hospital, or physician office) are required to have a CLIA certificate number. Defining applicable laboratory in this way provides a seamless, clear, and accurate way for CMS to determine where a majority of an individual laboratory's Medicare revenues are obtained regardless of laboratory type. It also ensures that there is broad representation of the laboratory market in the data reported to CMS for the purposes of determining a weighted median of payment rates, as intended by Congress.

CMS's approach in the proposed rule focuses far too much on - and seems to prioritize - reducing the number of laboratories that would be defined as applicable laboratories for the purposes of reporting data to the agency. There is much discussion in the preamble about not having hospital laboratories of any type report if TIN becomes the determining factor; not allowing laboratories who are not deemed applicable to voluntarily report; and establishing a low expenditure threshold that eliminates nearly half of the independent laboratories and nearly all of the physician office laboratories from reporting. CMS argues that despite reductions in the proposed number and type of laboratories that would report under the terms of the proposed rule, the agency believes this would be appropriate since it would still capture "a high percentage of Medicare utilization (96 percent of CLFS spending on physician office laboratories and more than 99 percent of CLFS spending on independent laboratories) from applicable laboratories that would be required to report."⁶ But CMS's assertion is incorrect, as the intent of Section 1834A as added by the Protecting Access to Medicare Act (PAMA) is to collect and assess private

⁶ 80 Fed. Reg. 59394.

market payment rates and the associated test volumes across the laboratory market. The large amount of Medicare spending on laboratory services represented by those CMS believes to be applicable laboratories is irrelevant and misleading. Nowhere in the proposed rule does CMS address the necessity of ensuring that the agency's evaluation is comprehensive and outlines the broad spectrum of payment rates within the private market. In order to ensure that all competitive rates are captured and the data can be appropriately assessed, CMS must make this a priority as it outlines its requirements for implementation.

Low Medicare Revenue (Expenditure) and Volume Thresholds

CMS proposes to accept the statutory authority to establish a "low revenue" threshold for excluding a laboratory entity from the definition of applicable laboratory, and therefore, removing such laboratories from any statutory or regulatory requirement to report payment and volume data to the agency. For the purpose of CMS's proposal, revenue is meant to equate to expenditure as the term exists in statute. CMS proposes to set the low revenue threshold at the amount of \$50,000 or less in Medicare revenue in a period of 12 months or \$25,000 or less in Medicare revenue in a period of six months reflective of the mandatory data collection periods. NILA and AAB do not object to the proposed low revenue threshold. Our organizations are more concerned with ensuring that CMS puts in place a regulatory process that captures statistically relevant information regarding private market rates that broadly represents the whole clinical laboratory market. Later in our comments we address the time period for data collection, advising that such a period permanently be for six months as opposed to a 12-month collection period going forward. With that recommendation in place, we advise that CMS maintain its low revenue threshold at the \$25,000 or less in Medicare revenue over a period of six months.

CMS states that with a low revenue threshold set at \$50,000 or less, the agency estimates that there are "only 17 tests whose utilization is completely attributed to laboratories that would not be reporting because they fell below a \$50,000 threshold."⁷ NILA and AAB ask that CMS clarify which tests are represented in this group.

CMS states that it is not proposing a low volume threshold at this time, and will reevaluate threshold options in the future through notice and comment rulemaking. Many NILA members are small businesses, as defined by the standard set by the U.S. Small Business Administration. However, their Medicare revenues exceed the low revenue threshold as proposed by CMS, given that between 30-50 percent of their practice is focused on serving Medicare beneficiaries. These small laboratory practices are concerned about the extreme financial and administrative burden of complying with the reporting requirements as outlined without yet knowing all of the requirements or the format for reporting the data. The challenge these small laboratory businesses face is how they balance concern over that burden with the necessity of ensuring that the data examined by CMS to set the weighted median adequately represents the full laboratory market. We agree that CMS should not set a low volume threshold at this time. The agency should continue to engage with small laboratory businesses after the first reporting process and evaluation has taken place to determine whether such a threshold is necessary.

⁷ 80 Fed. Reg. 59394

Estimate of the Number of CLIA Certificates that Would Qualify as Applicable Laboratories – After the Low Expenditure Threshold

CMS's July 2015 CLIA Update⁸ lists 252,384 laboratories currently holding CLIA certificates. Of these, 48.41 percent are Physician Office Laboratories (POLs) or 122,189. Under CMS' assessment in the proposed rule, 96 percent of POLs would not qualify as "applicable laboratories," which equals 117,301 laboratories. CMS also projects that 52% of independent laboratories would not be "applicable laboratories," or 0.52 x 6,177 independent laboratories, which equals 3,212 laboratories. This results in 120,514 independent and POL laboratories (47.7 percent) of the total CLIA laboratories being exempt from reporting.

The total number of laboratories holding CLIA Certificates of Waiver is 174,122. The number holding Provider Performed Microscopy Procedures (PPMP) Certificates is 35,150. Both of these types of laboratories, totaling 209,272 (82.9 percent) of CLIA certificates, tend to be small facilities. Nearly two-thirds (63.1 percent) of CLIA Certificate of Compliance laboratories perform less than 10,000 tests per year, so we can project that a significant number of all CLIA certified laboratories will fall below \$50,000 in Medicare revenues per annum (assuming 40 percent of their test volume is Medicare, that means a great majority of CLIA laboratories are performing less than 4,000 Medicare-reimbursed tests per year). Since the average Medicare payment per test on the CLFS (historically) is \$10:00-\$12.00, almost all of these laboratories will be receiving less than \$50,000 per year from Medicare.

So it is reasonable to project that at least 60-70 percent of all CLIA certified laboratories would not be "applicable laboratories," leaving a maximum of 30-40% (75,600 – 100,800 laboratories) to be defined as applicable laboratories. If most waived and PPMP laboratories are exempted under the low expenditure threshold, the number of "applicable laboratories" could fall to 42,840 laboratories.

For hospital laboratories, the number of anticipated "applicable laboratories" is well under 9,000, as only hospitals with outreach (non-hospital patient) laboratories could be "applicable laboratories." If hospitals without outreach programs and hospital laboratories receiving less than \$50,000 of Medicare revenues per annum are excluded, the number of hospitals that could be defined as "applicable laboratories" becomes significantly less than the 8,978 currently listed by CLIA.

How Laboratories Should Report

NILA and AAB strongly believe that the process for determining which laboratories qualify as "applicable" and are required to assess and report should be separate and apart from determining which laboratories should physically report applicable information to the agency. CMS seeks to combine these issues by identifying an applicable laboratory based on a laboratory's TIN and requiring that the same TIN to report its applicable data. As outlined in our comments above, we disagree with this approach and believe applicable laboratories should be identified based on their CLIA numbers, as this would meet the statutory obligation of specifically identifying and assessing laboratories, given that each laboratory under law is required to have a CLIA number.

⁸ CLIA Update – July 2015; Division of Laboratory Services; Centers for Medicare and Medicaid Services.
American Association of Bioanalysts & National Independent Laboratory Association
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It would also ensure broad representation within the laboratory market. We believe CMS should provide applicable laboratories flexibility in determining how applicable information should be reported, as every laboratory is structured differently. For example, some multi-state regional laboratories may determine that for them, since negotiations with private payors occur at the individual community laboratory level as opposed to by any one laboratory within the regional network, each laboratory within their network should report to CMS by NPI. For other regional laboratories, applicable laboratories in their network may not have the capabilities to report applicable information, and to have data reported by TIN for the overall laboratory network, may make the most sense. Still, for other laboratories that are small in size and structure, reporting by TIN may be the most seamless way of capturing their laboratory test and volume data.

Our organizations recommend that CMS allow an applicable laboratory to report applicable information based on one of the following: (1) an individual applicable laboratory reporting its own information based on TIN or NPI; (2) a TIN-level entity that has multiple laboratories associated with the TIN reporting a single report that represents all of the laboratories; and (3) a TIN-level entity that has multiple laboratories with individual NPIs having each laboratory in its region report data based on NPI. Nothing in the statute prohibits CMS from granting applicable laboratories the flexibility to determine how to report their comprehensive data to the agency without compromising the data. CMS would receive the same data on rates and test volumes regardless of whether it is reported uniformly across all laboratories or not.

Prohibition on Voluntary Reporting

CMS proposes to prohibit “any entity that does not meet the definition of applicable laboratory from reporting applicable information to CMS.”⁹ The statute does not require such a prohibition, and it is unclear why CMS is proposing to put this prohibition in place. As has been stated throughout these comments, NILA and AAB are extremely concerned about ensuring that the new laboratory payment reporting and assessment process reflect the participation of the broad laboratory market. We believe it is critical to ensure that the data is robust and not skewed toward rates reported by one segment of the market over another or consumed by the rates reported by the most dominant players in the market. Given that CMS anticipates that the terms of the proposed rule will exclude over half of the independent laboratory market, nearly the entire physician office laboratory market, and nearly all of the hospital laboratory market, there is significant reason to question whether the market assessment process as outlined in the regulation will sufficiently capture the market and not result in skewed and biased data for evaluation. While NILA and AAB believe strongly that voluntary reporting should not be the allowed standard set in a final regulation for any segment of the laboratory market, such voluntary reporting should be permitted within the regulation. Because the statute requires that hospitals and others paid for non-bundled tests under the CLFS will be subjected to the revised CLFS rates following CMS’s examination of the weighted median, some laboratories not defined as applicable by CMS may opt to report their information. NILA and AAB recommend to CMS that the prohibition be removed and such voluntary reporting be permitted under the regulation.

⁹ Id. at 59393.

Definition of Applicable Information

In carrying out the statute, CMS proposes to define applicable information as “with respect to each CDLT for a data collection period, each private payor rate, the associated volume of tests performed corresponding to each private payor rate, the specific HCPCS code associated with the test, and not information about a test for which payment is made on a capitated basis.”

CMS’s interpretation seems to be in-line with the statute, but clarification is needed on a few issues to ensure that the statute is carried out as intended as outlined in our comments below.

Test Payment During a Collection Period

NILA and AAB read the statute and CMS’s proposed regulation to state that applicable information represents tests that are furnished by the laboratory during a data collection period and that are paid during that same data collection period. What should be clarified in the regulation is that CMS expects laboratories to only provide test rate information they have received from the payor by the last date of the data collection period. This clarification is important given that payors can take weeks or months to pay after the date in which a test was performed. There are also circumstances (e.g., appeals, etc.) where such payment rates can take substantially longer to finalize between the payor and the laboratory. There are also situations where a laboratory conducts tests as ordered for which the payor determines they will not cover or reimburse for the testing provided. There are various reasons why this might be the case, and at times these decisions will be appealed and take months to reconcile. To ensure the data reporting process of applicable information is manageable and predictable, setting an end date of the close of the collection process for defining what data must be submitted is critically important. Also, a decision not to reimburse for a given test performed should not be considered reportable as applicable information, as the decision by the payor is not to provide a final payment rate for a given test at \$0.00, it is rather to let the laboratory know that the test is an uncovered service for the purpose of their submitted claim. We ask that CMS clarify in the rule that applicable laboratories are only required to report final test rate and volume data that is available to them before and up to the final date of each data collection period.

Private Payor Rates

In the preamble to the proposed rule, CMS clearly articulates its rationale for the inclusion of patient deductible, coinsurance, and copay amounts in the private payor rates reported by applicable laboratories. NILA and AAB agree with this rationale and believe that final reported rates should reflect the total approved payment rate provided within a given reporting period, and include any copay, coinsurance, or deductible amounts. In 414.502, however, CMS defines private payor rates as being inclusive of “any patient cost sharing amounts if applicable,” but it does not specify what it considers to be cost sharing. Given that cost sharing frequently is used to mean copayments and coinsurance, we recommend that CMS clarify its intent in the regulation to have payor rates be inclusive of “any patient cost sharing and deductible amounts if applicable.”

We do anticipate applicable laboratories sometimes facing challenges in how they apply coinsurance, copayments, and deductibles to the final rates submitted to CMS, given the

complexity in how some private payors apply or reference these amounts when payment is made to the laboratory. For some payors, a flat copay amount is provided when a certain number of tests are conducted. For example, some payors will assess a \$15 copay on a laboratory requisition that provided for four tests. CMS should seek to provide some clarification in the rule or in sub-regulatory guidance as to how an applicable laboratory should apply and report this copay data when outlining final rates for test codes to ensure there is consistency throughout the community. In the absence of guidance, the laboratory is left to determine whether to divide the copay among the tests provided on a given requisition or apply the copay in another manner.

HCPCS Codes Associated With the Test

In addition to private payor rates and the associated volume of tests performed corresponding to each private payor rate, CMS is proposing to have laboratories report the specific HCPCS code associate with each test. For the majority of tests provided by clinical laboratories under the CLFS, such a process makes sense. However, there are tests laboratories perform that do not appear on the CLFS because they are priced separately by the Medicare Administrative Contractors, and there are tests that do not have a permanent HCPCS code. There are also situations where private payor codes will not match CLFS codes/tests. To avoid confusion as laboratories seek to report their data, NILA and AAB ask that CMS provide a list of the HCPCS codes it wants the laboratory community to reference when providing applicable information.

Exceptions from Applicable Information

CMS proposes to follow the statute's requirement that applicable information not include information in relation to payments made on a capitated basis or other similar payment basis. Under statute and as proposed in the rule, this data would be excluded from reporting. What the statute and what CMS have failed to recognize and address is that there are other payment challenges that require consideration under a new payment analysis. Not every private payor issues payments in the same way to clinical laboratories. For many community laboratories, there is no upfront reimbursement amount outlined by payors for tests performed, particularly for those laboratories that are engaging with payors as out of network providers. These laboratories do not necessarily know up front how much they will be paid on any given test. This adds to the complexity of the reporting process as laboratories have to reconcile payment rates with tests they bill on a given laboratory requisition, and those test rates are not always broken down by HCPCS test code.

NILA and AAB ask that CMS exclude from reporting certain types of payments that would not have any bearing on establishing the weighted median for payment rates, but would otherwise be immensely burdensome for laboratories to report and increase the likelihood that information reported would be in error. These types of payments include those where payors have grouped or "bundled" test payments on individual tests conducted into a general "encounter" payment.

Definition of Advanced Diagnostic Laboratory Tests (ADLTs) and New ADLTs

The statute defines ADLTs as “a clinical diagnostic laboratory test covered under this part [Medicare Part B] that is offered and furnished by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner) and meets one of the following criteria: (A) the test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result; (B) the test is cleared or approved by the Food and Drug Administration; (C) The test meets other similar criteria established by the Secretary.” While NILA and AAB understand the need for CMS to be vigilant in its oversight of which tests are determined to be ADLTs given the unprecedented list price payments authorized for new ADLTs under statute, our organizations are concerned that the proposed rule outlines an interpretation of the ADLT definition that in many ways is contrary to the statute itself or violates the statute’s intent.

Single Laboratory

In its description of the ADLT definition, CMS defines “single laboratory” as a laboratory with a single CLIA certificate. CMS specifically states that an entity with multiple CLIA certificates would not be considered a single laboratory. NILA and AAB do not support this interpretation of the statute, as it could prohibit small and mid-size laboratories from competing in this specific testing market if they hold multiple CLIA certificates. It is not uncommon for a laboratory to have different facilities that are unrelated to the development of an ADLT but require a different CLIA certificate for the other work being conducted (e.g., research). The same concern exists for those laboratories that have opted to expand their testing services into a geographic area in need (e.g., rural location) and are required to obtain a different CLIA certificate for that location. There are numerous reasons why a single laboratory would obtain multiple CLIA certificates, but those reasons should have no bearing on whether such a laboratory is permitted to offer and receive payment for ADLTs under the law. The standard that CMS should focus on in defining single laboratory for the purpose of addressing ADLTs is that the test is not sold for use by a laboratory other than the original developing laboratory or a successor owner.

Our organizations request that CMS amend its definition of “single laboratory” to be “a laboratory and its wholly-owned subsidiaries.”

Exclusion of Protein Biomarkers

In the preamble to the proposed rule, CMS states that “the statute also requires that the test analyze “multiple” biomarkers of DNA, RNA, or protein. Therefore an ADLT might consist of one test that analyzes multiple biomarkers or it might consist of multiple tests that each analyzes one or more biomarkers.”¹⁰ CMS seems to acknowledge that there are tests that specifically analyze proteins and are covered as ADLTs. However the proposed regulation at 415.502 excludes proteins from the definition of ADLTs. NILA and AAB believe this exclusion is in violation of the statute, which clearly states that proteins are included in the same manner as DNA and RNA.

¹⁰ 80 Fed. Reg. 59398.

Our organizations request that CMS amend the definition of ADLT under regulation to follow the exact terms of the statute: “the test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result.”

Data Collection and Data Reporting

In establishing Section 1834A under PAMA, Congress outlined a timeline for implementation of a new data collection, data reporting process, and agency reevaluation of Medicare payment rates for laboratory services that in no way understood, appreciated, or respected the complexity of what such a system would require of CMS or individual laboratories. NILA and AAB have been significantly concerned about the expedited time schedule outlined in the statute. However, our level of concern has since been significantly heightened, given CMS’s delay in producing a proposed rule and outline of a process in that regulation to still maintain the other timelines outlined under statute.

The statute envisioned at least a six-to-twelve month window between the date a final regulation would be released by CMS and the start of the initial data reporting period (January 1, 2016). In publishing a proposed rule on October 1, 2015, CMS has shrunk that window down to a matter of days between the date a final rule may come out following the comment period and the start of the initial data reporting period. CMS’s proposal to maintain the statutory timeline is impossible and unrealistic and threatens community laboratory businesses that do not appropriately comply with a regulation that is not yet final but with which they must respond to in short order under risk of major penalty. It is inappropriate and wrong for CMS to expect laboratories to carry the burden because the agency was unable to produce a final regulation well in advance of the implementation timetable outlined in statute.

NILA and AAB urge CMS to carefully re-think and re-issue its timeline for implementation of the data collection and reporting process. It is not in the Medicare program’s interest to have this collection and reporting process rushed into place with numerous opportunities for non-compliance or an inability to comply resulting in major data errors from bad data. To rush such a complex system into practice to meet statutory deadlines that have no direct purpose or meaning does not make any sense. CMS’s priority should be in ensuring that the new system will work for laboratories so that they can comply correctly with the requirements and so CMS has accurate data to work with when assessing the weighted median of payment rates.

First Data Collection and Data Reporting Process

A new data collection and data reporting process of the magnitude outlined in PAMA requires a thoughtful approach and recognition that not all laboratories currently have the infrastructure (e.g., information systems, staffing, etc.) to seamlessly respond to new requirements. In the absence of regulations, NILA and AAB laboratories have not been able to work with software vendors to establish new data collection protocols. Such an investment would not occur in the absence of any final PAMA regulatory requirements.

CMS proposes to have the first data collection process run from July 1, 2015 through December 31, 2015 with the first reporting process beginning on January 1, 2016 and concluding on March 31, 2016. The agency states that sub-regulatory guidance will be provided to specify how

applicable information is to be reported prior to the date of the first reporting period. Separate from the proposed regulation, the agency has announced that an electronic data system requiring advance registration will also be set up for laboratories to enter their payment data. Neither the sub-regulatory guidance or the database have been provided to the laboratory community as of the date of this letter, just five weeks out from the beginning date of the first reporting period. Even if the guidance and reporting system are made available by December 31, 2015, it is essential that CMS provide the laboratory community a chance to respond to the guidance with questions to ensure they understand all requirements in advance of the reporting start date. There is no way to implement changes in business practices “on the fly” and for immediate implementation. What CMS is proposing will require changes in practice management, data collection, IT software, staff training, and a potentially major reallocation of resources to support implementation. To assume that any of this can be done by community laboratories without any lead time is unfair and unreasonable and places a tremendous burden on clinical laboratory practices, especially small laboratory businesses that would be applicable under the terms of the regulation.

NILA and AAB are recommending a revised schedule below for the initial data collection and reporting periods that will support CMS in ensuring that its proposed requirements and systems under development can work within the community laboratory sector of the industry; to support community laboratories in complying with CMS’s requirements; and provide an opportunity to appropriately assess new payment data before it becomes final. The following outlines the recommended initial timeline.

EFFORT	SUGGESTED TIMELINE
CMS Tests Data System With Clinical Laboratories	January 2016 – March 2016
Final Rule & Guidance Published	June 2016
Laboratories Build New IT Systems To Collect Data	July 2016 – December 2016
First Data Collection Period	January 2017 – June 2017
Data Review and Assessment by Laboratories	July 2017 – December 2017
Initial Data Reporting Period	January 2018 – March 2018
Notice & Comment Rulemaking on Proposed Rates (outlining 3-year rates)	September 1, 2018
Final Rule on Published Rates	November 1, 2018
Revised CLFS Rates Take Effect	January 1, 2019

CMS Tests Data System with Clinical Laboratories

CMS has stated its intention to build and provide an electronic, web-based collection system for laboratories to utilize in providing test rate and volume data to the agency. However, to the best of NILA and AAB's knowledge, such a system has not ever been tested by CMS within the laboratory community itself. CMS must appreciate that not all clinical laboratories utilize the same information systems to currently collect test rate and volume data. There is no uniformity in how laboratories operate their billing systems, and there are numerous differences in how payors engage with laboratories and provide their information to the laboratories. Given the variance in size and structure of the laboratories in the independent laboratory market itself, it is unfair for CMS to make assumptions about the capabilities, staffing, and finances of the laboratories themselves. Many laboratories will struggle to comply with the new regulatory requirements and to engage with a new electronic reporting process. This struggle will be magnified if CMS introduces a new system without first testing that system with at least a small number of diverse laboratories to ensure laboratories can comply with the requirements outlined. Envisioning a short window for data reporting, CMS and the laboratory community must have confidence that reporting can be done seamlessly and correctly. To put a new system in place without engaging those that will have to utilize it to provide the data is inappropriate, and will lead to the potential of errors and bad data to which CMS is utilizing to revise Medicare payment rates for clinical laboratory testing services. To ensure the data reporting system is done right from the start will save the agency from enormous challenges down the road and provide the laboratory community greater assurance that CMS is working with appropriate data. Given the variances in laboratory information system capabilities, NILA and AAB urge CMS to conduct testing of the new, anticipated electronic data collection system with a small group of diverse laboratories, ensuring that community laboratories are represented in this testing group and that such testing occur at the beginning of 2016 with a recommended window of January 2016 through March 2016. Our organizations also strongly advise CMS to hold training webinars on use of the electronic data reporting system to ensure that laboratories of all types understand the data reporting fields and requirements and appropriately respond.

Final Rule & Guidance Published

NILA and AAB are concerned that CMS believes it can finalize a rule before January 1, 2016, just five weeks after the close of the proposed rule comment period. The proposed regulation raises many questions for the laboratory community to answer, and addresses many complicated issues that are problematic as outlined. To rush a final regulation into place is not to respond to stakeholder comments in a thorough manner, as required under law, and threatens to put into place a system that sets laboratories up for failure, all while under the risk of massive penalties on the laboratories for non-compliance.

The proposed rule also makes numerous references to the need for sub-regulatory guidance, saying that such guidance will be issued prior to the publication of a final rule. NILA and AAB are concerned by the suggestion that such guidance could be published in advance of a final rule. Final regulatory requirements are necessary before any other terms or instructions can or should be provided to the laboratory community. For example, how could sub-regulatory guidance address requirements associated with an "applicable laboratory" in the absence of having a final rule in place to define applicable laboratory? In the absence of a final rule, guidance cannot

appropriately reflect on the rule's requirements, and it is not possible for laboratories to understand who has to report data, what data they must report, or how they are to report the data.

It is reasonable to expect that it will take CMS longer than the agency anticipates the release of a final rule and the associated sub-regulatory guidance. NILA and AAB recommend that the agency aim to have a final regulation and corresponding sub-regulatory guidance in place by June 2016 to allow an opportunity for laboratories to begin reviewing, planning, and complying with the rule's requirements. This delay, of course, will result in delaying other aspects of the statute on implementation of reporting, conducting the weighted median review, and issuing revised Medicare payments for clinical laboratory testing services. This situation is far from unique, as there are many other reporting programs and other regulations where CMS has implemented final regulations well past the statutory deadlines without any legal other consequences. Such a delay would also have no effect on the cost savings anticipated from the statute's implementation, as the savings itself is not dependent on a specific timeframe.

CMS was delayed in releasing a proposed rule presumably because of the complexity of the issues involved. NILA and AAB believe this is an incredibly complicated system with immense consequences to competition within the clinical laboratory market and Medicare beneficiary access if done wrong. CMS has a duty to be more thoughtful than Congress was as it seeks to implement the law's requirements. The risks to the Medicare program, patients, and the laboratory market itself are far too great otherwise.

Laboratories Build New IT Systems to Collect Data

Following the publication of a final regulation and related guidance, and before community laboratories are able to appropriately respond to requirements, laboratories must build new information technology (software) systems to collect and report their data. In reflecting on the data collection and reporting system outlined in the proposed rule, many NILA and AAB members responded that their current systems are not capable of outlining or providing the data as envisioned. Many responded that they will need to work with outside auditors and with outside IT software vendors to put their data into a system that will allow them to correctly sift through and reconcile data received from payors and correspond with data reporting requirements. For example, our members report that many times what they submit as claims to private payors are returned differently once payment is made. Tests can be bundled instead of paid individually, copays can be paid as a flat lump sum rather than applied on a test-by-test basis, and deductibles may be applied to a group of tests without explanation. To ensure laboratories are providing accurate data in response to agency requirements will require a very careful and deliberate process and a new level of automation that does not currently exist within community laboratories. Building such systems will not happen overnight, and it's impossible to construct such systems in advance of knowing the final rule's requirements.

In considering our organizations' request for a window of time to allow for the development of new IT systems, CMS must remember that clinical laboratories just recently undertook a process to revise systems to appropriately comply with ICD-10 requirements in addition to other regulations to ensure data can be made available to patients upon their request, and so physicians can receive laboratory reports in a way that is seamless with the patient's electronic medical

record. Substantial investment has already been made by clinical laboratories, and the final rule CMS produces and the terms on data collection and reporting will result in a request for further significant investment.

First Data Collection Period

Time is needed to allow laboratories, particularly many small and medium-sized laboratory businesses to get their data collection capabilities (IT and accounting systems) and staff trainings in place prior to reflecting on and collecting data that will be reported to the agency. To overlap the timelines for data collection with the development of new internal laboratory reporting systems is unfair and burdensome, particularly to community laboratories with far less resources than their larger, national competitors. NILA and AAB, therefore, propose that CMS make the focus of 2016 on testing a new electronic data reporting process with a small and diverse group of laboratories, including community laboratories; establishing a final rule and associated guidance; directly notifying all clinical laboratories across the country of the new data collection and reporting system as many laboratories are not yet members of a national association and may not be familiar with the law or regulation itself; hosting webinars on aspects of the regulation's requirements; and allowing laboratories to build the information systems needed to collect data for the purpose of reporting.

NILA and AAB believe the first data collection period should occur during the first six months of 2017 (January 1, 2017 through June 30, 2017), allowing enough time for CMS to finalize a rule and related guidance and for community laboratories to build the systems and processes needed to comply. Our organizations support CMS's proposal to have the first data collection process cover six months of test rate and test volume data. We advise CMS to have each subsequent data collection period also cover a term of six months rather than a term of 12 months, as it is highly unlikely a longer collection period will show much, if any, variance in private payor rates for tests or their associated volumes given that private payor contracts do not typically change from one half of the year to the next half of the year. Having the collection process focus on a six-month term will also cut down on some of the reporting burden on small- and medium-size laboratories.

Data Review and Assessment by Laboratories

NILA and AAB urge CMS to provide a period of at least six months between the end of the data collection period and the beginning of the data reporting period to allow laboratories to assess the data for inclusion, ensure its accuracy, and reconcile any final rate information with private payors. It is not feasible or logical for laboratories to begin reporting data immediately at the close of the collection period as is envisioned in CMS's proposed rule. Receiving final payment rates from private payors can typically take four weeks or more to be finalized and submitted to laboratories. For dates at the end of the given data collection period, in particular, time is needed to ensure all rate information can be received, addressed with a multitude of payors as needed, and assessed for its accuracy before the data is reported to CMS.

Initial Data Reporting Period

Following the timeline recommendations offered by NILA and AAB, the initial data reporting period should be held from January 1, 2018 through March 31, 2018. Provided there is at least a window of six months between the data collection and data reporting process, we believe a three month window is an acceptable window of time for reporting the data.

Our organizations appreciate that our proposed timeline has the initial data reporting period happening two years from the data envisioned by CMS in its proposed rule. However, we believe it is important that CMS understand the immense challenges that so many laboratories, namely small- and mid-size community laboratories, will face in implementing the requirements of a complex statute and final regulation all while maintaining regular business practices, providing and billing for laboratory testing services. The timeline is necessary for laboratories to be able to build the systems necessary to accurately comply with the terms of the statute and requirements of the regulation. To do this any other way risks the agency receiving data fraught with errors and laboratories being falsely accused of wrongdoing. We would envision that subsequent reporting periods would follow using the same time period of three months at the beginning of the given year, and would follow the same cycle as outlined under statute with CDLTs being reported every three years and ADLTs being reported every year.

The statute allows for CMS to make adjustments to data collection and reporting processes in later years. Such adjustments could be made in an effort to reduce reporting burden while still ensuring completeness of the data (e.g., aggregated reporting). NILA and AAB would like to continue to engage with the agency on what adjustments could be made to enhance the reporting and ensure that such adjustments do not place further burden on community laboratories.

Notice & Comment Rulemaking on Proposed Rates (outlining 3-year rates)

Our organizations were alarmed to see CMS propose a process for disclosing the proposed weighted median rates in a manner that lacks information and seems to retrofit into the annual process currently utilized by CMS to disclose new and revised test coding and payment rates. We believe that this massive new rate reporting and evaluation system requires much more than CMS outlining a list of revised rates for comment. Given that CMS will be receiving millions if not trillions of data sets, it is expected that errors could occur in rate calculations due to inaccurate calculations themselves or inaccurate data being reported in the first place.

With any new system of the magnitude of this new reporting system, there are concerns about whether data will be submitted in any uniform (apples to apples) manner between laboratories of different types. Mistakes can be anticipated, and there must be a way for laboratories to appropriately comment on what concerns it has so that considerations can be made by CMS before new rates are ultimately finalized and applied to the CLFS. NILA and AAB believe that a transparent process is necessary and that CMS should issue the preliminary weighted median rates through a formal notice and comment rulemaking process. We recommend that such a process include the following type of data, particularly for CDLTs, in order to allow laboratories an opportunity to provide thoughtful comments and address any concerns: how many laboratories reported rate and volume data; breakdown in reporting by type of laboratory

(independent, hospital, physician office); data volume received by test type; ranges in reported rates (broadly or by geographic breakdown); what challenges CMS faced in assessing the data (e.g., where data lacked clarity).

NILA and AAB support having CMS release data and information on the preliminary weighted median rates in September of the year data is reported to and evaluated by the agency. We likewise support allowing for a public comment period, but we urge CMS to formalize this comment period through notice and comment rulemaking instead of simply issuing a list of proposed rates. Although the statute prohibits administrative or judicial review of payment amounts, it in no way prohibits CMS from having a process to accept requests to question and review proposed payment rates. Issuing proposed rates through a formal rulemaking process that discloses more information would support laboratories in providing helpful information to the agency to ensure that the data used by CMS to calculate proposed rates and the calculations themselves are accurate. NILA and AAB believe that the agency can provide information in a rule that in no way violates the confidentiality of the data assessed by the agency, but provides laboratories better insight into the adjustments as proposed.

Our organizations also believe that it is essential that any rate adjustments proposed by CMS include an outline of the full adjustment planned for a given test rate. The statute requires that CMS phase-in adjustments from the weighted median calculations, limiting adjustments for the first three years to no more than 10 percent per year for the first three years following CMS's review process. In its proposed rule, CMS is silent as to whether it would outline the full adjustment when it released the preliminary weighted median rates or whether it would only outline the adjustment that would take place in January of the following year. Clinical laboratories, particularly small and mid-size laboratories that offer limited testing menus and those that serve areas and settings at an increased cost (e.g., rural communities; unique service areas, including skilled nursing facilities) need to have comprehensive data on anticipated payment adjustments to help guide their business operations and planning.

Final Rates

NILA and AAB agree with CMS's proposal to publish final rates from the weighted median calculations 60 days in advance of the rates going into effect. As outlined in the proposed rule, CMS should publish final rates on November 1, putting such rates into effect on January 1 of the following year. Our recommended timeline varies from that proposed in the rule, as described above, but we support the window of time the agency has proposed between release of the new preliminary rates, publication of final rates, and the date new rates would go into effect. Again, we ask that CMS formalize its process beyond providing a list of revised rates in order to ensure that laboratories can appropriately comment on the rates and outline concerns or insight based on the data CMS received in order to ensure transparency in the process. We believe such a process can be put into place without violating the confidentiality of the data assessed by the agency.

Data Integrity

Penalties for Non-Reporting

The statute gives the agency discretion to impose a civil monetary penalty against applicable laboratories that fail to comply with reporting requirements, misrepresent or omit applicable information. In the proposed rule, CMS states its intention to implement such a penalty in the amount of \$10,000 per day, per violation to mirror penalty levels the agency currently applies against pharmaceutical manufacturers that report their average sales prices for drugs under Medicare Part B.

NILA and AAB are vehemently opposed to CMS threatening such significant penalties against clinical laboratories that are facing a new, first-of-its-kind, untested laboratory reporting system. The new reporting requirements under statute constitute a significant unfunded mandate on the clinical laboratory community that is being fast-tracked under the requirements of the law and under the proposed rule issued by the agency. The opportunity for glitches and mistakes, both on the part of the agency and the applicable laboratories are immense as the new system is put in place. NILA and AAB urge CMS not to establish significant threatening penalties in the face of a newly established program, especially penalties that could never be financially met by small community laboratories that are being asked to implement a new system under an extremely tight timeframe. These laboratories understand the need to comply with statute and regulations, but as has been noted throughout these comments, there is much challenge and complexity the laboratories will face in doing so. CMS itself states that the rule is expected to have a substantial impact on small businesses. To make that statement in regulation and then issue a proposal for such significant penalties does not make any rational sense.

CMS fails to address in the proposed rule any process for laboratories accused of wrongdoing to appeal those decisions and provide evidence to the contrary. There is much opportunity in the complexity of the new process outlined by CMS for laboratories to accidentally report inaccurate or incorrect information. Laboratories should not be accused of wrongdoing and threatened to be significantly penalized when such errors occur. NILA and AAB request that CMS outline a process for laboratories to address such errors and “clear their name” before any penalties or other punishment is ever applied.

While proposing to implement significant penalties, CMS also indicates in the regulation that they expect full implementation of the new regulations to take the agency between five and six years for completion.¹¹ In addition to opposing the extent of the penalties as outlined in the rule, we request that the agency delay imposing penalties until such time as they reach full implementation. If CMS is indicating it will take between five and six years to reach full implementation, no penalties should be assessed before that benchmark is met.

The rule does not provide any clear definition of what constitutes an error and what, as a result, would warrant a penalty. NILA and AAB are concerned that the level of complexity associated with a new payment data collection and reporting system could result in inadvertent errors, particularly if CMS moves forward with the aggressive implementation timeline outlined in the

¹¹ 80 Fed. Reg. 59414.

proposed rule. Given this complexity, along with the absence of any announcement by CMS to test the new reporting system to ensure compliance within the laboratory community, we urge CMS to consider a stipulation that penalties only be assessed in cases where there is evidence that a laboratory intentionally provided inaccurate or mistaken information. Given the expected burden that the new reporting system will bring on community-based independent laboratories, we strongly believe that imposing penalties of this level is unreasonable. It is a guarantee that there the agency and laboratories will face immense challenges in the implementation of the new reporting and rate assessment system, and we expect CMS to recognize this as it moves forward in finalizing any decision on penalties.

Data Certification

CMS proposes that the President, CEO, or CFO or other designated officer of an applicable laboratory sign a certification statement that the applicable information provided is “accurate, complete, and truthful, meeting all of the reporting parameters.”¹² The agency plans to issue additional certification requirements through subregulatory guidance not yet released at the time of the rule.

As previously stated, accidental errors could occur in the data reported by applicable laboratories and CMS has outlined no due process for laboratories to appeal accusations or decisions made against them. To expect certification in the absence of such a process is inappropriate and grossly unfair.

NILA and AAB recommend that CMS establish a document for signature upon submission of applicable information from an applicable laboratory that clarifies that the information being submitted is accurate and complete to the best of the laboratory’s knowledge and the submission is made in good faith.

Coding for Certain Clinical Diagnostic Laboratory Tests (CDLTs) on the CLFS

Under statute, the Secretary is to adopt temporary HCPCS codes for new CDLTs cleared or approved by the FDA and new ADLTs. CMS proposes in the regulation to assign a unique G-code to these tests. NILA and AAB are concerned about the use of G-codes for these tests given that private payors typically do not accept these codes and an influx of G-codes could result in immense burden to community laboratories when trying to collect private payor rate data under the requirements of the regulation.

NILA and AAB support using the American Medical Association’s Common Procedural Terminology (CPT) Editorial Panel to assign HCPCS codes to new CDLTs and ADLTs (as those tests are defined under statute) rather than assigning HCPCS Level II G-codes. We understand that the AMA CPT Editorial Panel is finalizing a new neutral coding infrastructure to facilitate a process of providing new CPT codes on a quarterly basis. We encourage CMS to engage with the stakeholder community on this approach as a possible coding solution.

¹² 80 Fed. Reg. 59402

Payment Methodology

Calculation of Weighted Median

Under the terms of the statute, CMS is to calculate the weighted median for a CDLT following the data reporting and collection period, and that this is to become the new Medicare payment rate. The new rate is phased-in on a schedule set under statute. CMS outlines how it plans to calculate the weighted median, providing examples of test data and the process for calculation. CMS specifically addresses how it would address calculation of payment for tests where no applicable information is reported in which to calculate a weighted median. CMS does not explain, however, if or how it would consider whether the applicable information reported is statistically significant enough for a given test code in order to justify a payment adjustment based on the weighted median. For example, if CMS receives minimal data from one laboratory, and that data shows variance from the current Medicare rate for a given test, the assumption is that CMS would calculate the weighted median based on information reported by a single laboratory to assign a new payment rate. NILA and AAB are concerned about skewed payment being assigned based on a non-statistically significant data reported on test codes. We ask that CMS consider this issue further and ensure that any data used in which to assign a weighted median represent more than one laboratory's data as submitted under the data reporting process.

Phased-in Payment Reduction

As stated earlier in these comments, NILA and AAB request that the weighted median calculations and how they are applied to Medicare test rates over the phased-in payment reduction period be disclosed to laboratories when CMS releases the preliminary payment determinations. CMS should make clear how the calculations will apply over the entire duration of the phase-in period following each reporting cycle and not only disclose what reductions will apply for a given calendar year. The proposed rule is silent on this issue, and NILA and AAB want to ensure that laboratories are provided the complete weighted median calculation and understand how that calculation is applied to adjust current Medicare payment rates over a three-year period. Such data is critically important to support laboratory planning over the course of several years. Community laboratories, in particular, are unable to absorb losses to their fees without having to make other and potentially significant adjustments in their operations.

Local Coverage Determination Process and Designation of Medicare Administrative Contractors for CDLTs

The statute includes a requirement that local coverage determinations (LCDs) are to be developed according to existing statutory requirements and regulations. In its proposed regulations, CMS does not outline any process for ensuring this statutory requirement is addressed. NILA and AAB have been extremely concerned about recently issued LCD policy decisions, including for example, policies regarding cardiovascular tests that were quietly announced with an abbreviated period for comment, and where significant adjustments were being proposed, eliminating coverage for tests. The transparency behind these proposed decisions and the rationale frequently do not exist. We ask that CMS address how it will revise

existing processes to ensure that the statutory requirement under PAMA is adhered to going forward.

The statute also allows the Secretary to adjust the number of Medicare Administrative Contractors (MACs) currently in place to designate one or more (up to four) MACs to both establish coverage policies and process claims for clinical diagnostic tests. Our organizations agree with CMS's statement in the proposed rule that consolidation in the number of MACs requires careful consideration. This issue must be about more than simply reducing the number of contractors. We are concerned that a significant reduction in the number of MACs for coverage decisions, particularly a reduction to one MAC, is tantamount to establishing national coverage policy decisions and that such a move by CMS could have grave implications for the ability of laboratories to provide certain testing services going forward. CMS must also ensure that any consideration on reducing the number of MACs used for claims processing purposes would not impede payment for services rendered by clinical laboratories, as this would have substantial impact on current payment systems.

NILA and AAB request that CMS have this issue addressed by the PAMA Advisory Panel with opportunity for stakeholder oral and written comments before moving to make any adjustments.

Other Provisions

Advisory Panel on Clinical Diagnostic Laboratory Tests

Under statute, the advisory panel must be composed of a section of individuals with a broad range of expertise. NILA and AAB strongly recommend that in addition to the diverse areas of listed of relevance to the agency, that CMS work to ensure that there are panel members that understand how community-based clinical laboratories operate and understand the costs associated with providing testing services in a diversity of settings (geographic, specific service sites, etc). Laboratory-specific panelists – those that run and operate clinical laboratories - must understand the variances in how different segments of the laboratory community operate and the associated economics for providing such services. Presently, there is only one community laboratory representative on the panel. NILA and AAB encourage CMS to ensure greater representation of community-based laboratory expertise as the panel moves forward and opportunities for appointments become available.

Sample Collection Fee

The statute increases the sample (specimen) collection fee for collection services conducted by a laboratory in a skilled nursing facility or on behalf of a home health agency. As noted by CMS, the fee is increased under statute by a \$2.00, raising the total rate to \$5.00. Our organizations will note that until the PAMA statute, this fee had not been adjusted for 30 years.

NILA and AAB are extremely frustrated with how the adjustment has been implemented and believe it has been restricted in such a way to prohibit laboratories that provide this unique service from receiving the increase in payment. The statute intended for laboratories that provide specimen collection services to patients in SNFs and NFs receive the increase in payment. The statute also intended for laboratories providing services to patients designated by physicians as “homebound” to receive the increase in payment. There was no intention to restrict the specimen adjustment so that laboratories cannot receive it if they provide homebound services or provide services to residents in a nursing facility.

CMS’s implementation of the statutory reimbursement adjustment only allows home health agencies to collect the increased specimen rate; however, these agencies cannot be paid specimen collection under Part B.¹³ In its implementation, CMS also restricts the increased specimen collection rate to SNF patients, not permitting laboratories that service patients that go back and forth within a shared SNF/NF facility to receive the payment adjustment if the patient is technically within the NF. This disregards the fact that specimen collection fees can be collected under Medicare Part B for NF residents.

The challenge with implementation of the specimen collection fee can be easily rectified, by allowing laboratories that provide specimen collection services to receive the increase in the fee by billing for three specific place of service codes. CMS has a listing of Place of Service Codes used to bill all laboratory services. There are place of service codes for SNF (31) and NF (32) and for homebound patients in a private residence (12). NILA and AAB would note that there is no place of service code for home health agency patients.

The increase in the specimen collection rate (the first increase since its origination in 1984) was intended by Congress to recognize and support the need for continued access to laboratory testing services for SNF/NF and homebound patients. Unfortunately, with the way CMS has interpreted the statute, it has eliminated access to the increase for many laboratories that service these populations. These unique laboratories will be under particular strain from PAMA, given that they typically provide a limited testing menu of services that could receive rate adjustments.

NILA and AAB ask that CMS make adjustments to its implementation of the statute and allow laboratories to receive the increased reimbursement for specimen collections that are also provided for NF and homebound patients.

¹³ Section 1833(h)(3)(A) of the Social Security Act for the specimen (sample) collection notes that the sample can be collected for homebound and or those in an inpatient facility (other than a hospital); however, the travel fees associated with the specimen collection rate are limited to homebound and nursing facility residents. There is no reference to home health agency.

Conclusion

We thank CMS for consideration of NILA's and AAB's comments on the proposed regulation to address clinical diagnostic laboratory test payment reform. The community-based and multi-state regional laboratories we represent are extremely concerned how this law and its implementation will affect the laboratory market and continued access to clinical laboratory services. CMS must understand that this law must be about more than deriving a Medicare savings. It must be implemented keeping in mind that a competitive laboratory market is necessary for Medicare and the beneficiaries served by the program.

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