October 23, 2017
Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Calendar Year 2018 Clinical Laboratory Fee Schedule (CLFS) Preliminary Private Payor Rates and Crosswalking/Gapfilling Determinations

Dear Administrator Verma:

The National Independent Laboratory Association (NILA) and American Association of Bioanalysts (AAB) appreciates the opportunity to submit comments on the preliminary payment rates published by the Centers for Medicare and Medicaid Services (CMS) for the calendar year (CY) 2018 Clinical Laboratory Fee Schedule (CLFS)[1]. NILA and AAB represent 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/AAB members actively participate in Medicare, and the majority of NILA/AAB members provide 30-50 percent of their testing services to Medicare beneficiaries. Some NILA/AAB laboratories provide a full range of clinical diagnostic testing services, while many 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. These laboratories are a primary laboratory provider for complex patient markets, including rural areas and post-acute care settings, where the cost to providing laboratory services is higher than in other markets served because patients are harder to reach and where on the ground, community-based testing services are required to meet physician and patient needs. These laboratories also make up the sentinel surveillance network for public health, partnering with state public health laboratories to address emergency and infectious disease testing. Without these laboratories, specific patient needs and locations cannot and will not be served in a consolidated market.

After conducting an assessment of CMS's data and proposed preliminary CLFS rates, **NILA and AAB urge CMS not to finalize the proposed CLFS rates at this time and take immediate action to address the significantly deficient data collection process used to derive these payment rates. We join stakeholders across the medical, hospital, public health, and laboratory communities in asking that CMS suspend implementation of the draft payment rates until deficiencies in the data can be addressed and validated**.

[1] Preliminary payment rates and crosswalking/gapfilling determinations for CY 2018. https://www.cms.gov/Medicare/Medicare-Fee-For-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html.

As expressed in meetings with CMS and the HHS Office of the Secretary, we believe that the regulatory requirements included in the final PAMA regulation failed to comply with section 216 of the *Protecting Access to Medicare Act of 2014 (PAMA)*, which required CMS to establish a market-based payment system for clinical and other laboratories paid on the CLFS, including hospital outreach, independent, and physician office laboratories. It is evident in the preliminary rates and analysis published by CMS on September 22, 2017, that CMS's process did not result in capturing data that appropriately reflects all sectors of the clinical laboratory market paid on the CLFS. Further, the concerns repeatedly raised by NILA before the reporting process began and thereafter regarding the limitations of a retrospective reporting process and data integrity challenges under that process have proven to be true given the extreme variances and irregularities noted in the published rate and data files released by CMS and used to set the preliminary rates. CMS's implementation of the preliminary rates without adjustments to correct inaccuracies and without an expansion of market representation within the data set, threatens the existence of small and mid-size laboratories, compromising access to laboratory testing for Medicare beneficiaries.

Having only conducted an assessment of less than one percent of the laboratory market, with over 50 percent of the data provided to CMS by only the two national publicly-traded laboratories, estimates on the impact of new rates are six times greater than the original Congressional Budget Office (CBO) scoring of PAMA. CMS estimates the proposed rate adjustments result in $670 million in cuts to laboratory tests for CY 2018 and $3.6 billion over three years compared to CBO's score of $100 million in the first year and $2.5 billion over a 10-year period. These cuts are far steeper than CMS's estimates included in the final regulation of $390 million in the first year and $3.9 billion over a 10-year period.

The three-year adjustment outlined in the preliminary rates is untenable for the small and mid-size laboratory market. Many of the tests physicians use to direct patient care every day and to meet new requirements under MACRA/MIPS will see cuts of 10 percent per year for three years. If implemented in their current form, these cuts will devastate access to physician-ordered lab testing for Medicare beneficiaries, with the most grave impact being on access to testing for our most vulnerable Medicare beneficiaries that reside in rural communities and post-acute care settings. Because a significant number of state Medicaid laboratory fee schedules are inextricably linked to the Medicare fee schedule, access to testing within the Medicaid and Medicaid Managed Care population will also see a significant decline, affecting public health testing and access to specialty tests for rare diseases and conditions. As the elimination of laboratory services and laboratory closures and acquisitions result, PAMA will ultimately lead to excessive consolidation in the market, eliminating market competition. The end result will be few laboratory providers, geographic locations unserved, and significant growth in Medicare costs. The growth in Medicare expenditures will be primarily on two fronts: the result of patients not being able to obtain diagnostic tests that direct and ensure the appropriate management of their care and ending up more costly to treat; and a duopoly or otherwise limited laboratory market that results in higher negotiated laboratory contracts in the private sector to which Medicare will be linked under the PAMA statute.

The consolidation in the market anticipated if the preliminary rates are finalized will lead to the elimination of thousands of highly skilled jobs in communities across the country. The anticipated magnitude of the cuts, following publication of the CMS final regulation already resulted in significant layoffs with nearly 500 jobs lost in the state of Oregon.[2] This announcement was followed by the sale of

[2] 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

a laboratory employing more than 1,600 people with approximately 850 in the state of Washington finalized in early May 2017.[3] Based on the evidence, we anticipate the new rates will result in a massive consolidation of the market and in closures of laboratory businesses. Indeed, the two publicly-traded national laboratories have referenced such acquisition plans following the release of the preliminary rates.[4]

Independent Community Laboratory Market

As CMS considers stakeholder feedback on data integrity and market limitation concerns regarding the data used by the agency and reflects on the implications of the preliminary rates, it is critically important that CMS 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. It is equally important that CMS understands the significant difference in the scope and representation of the market that primarily serves Medicare beneficiaries and the scope and representation within the private commercial market, as these differences are critical considerations when implementing PAMA and setting a new CLFS fee schedule that is based on the private market.

Medicare Market

Independent community-based clinical laboratories work with physician practices, hospitals, outpatient care settings, skilled nursing facilities, and homebound patients to serve Medicare beneficiaries. In contrast to the two large national, publicly-traded laboratories, community laboratories range in size from small businesses as defined by NAIC's codes to regional laboratories across multiple states. For most of these laboratories, unlike the two national laboratories, 30-50 percent or more of their revenues are from Medicare Part B because of the physician and hospital communities they serve to provide testing services to beneficiaries. Most community laboratories operate between one and five laboratory testing facilities compared to the national laboratories that operate around 200 or more testing facilities. The majority of community laboratories are privately-owned companies. Unlike their large national competitors, these laboratories have personal relationships with providers in their communities, offering emergency (STAT) testing, quick turnaround times of 2-24 hours 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 large 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

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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.

[3] http://www.spokesman.com/stories/2017/may/04/labcorp-completes-purchase-of-spokanes-paml/

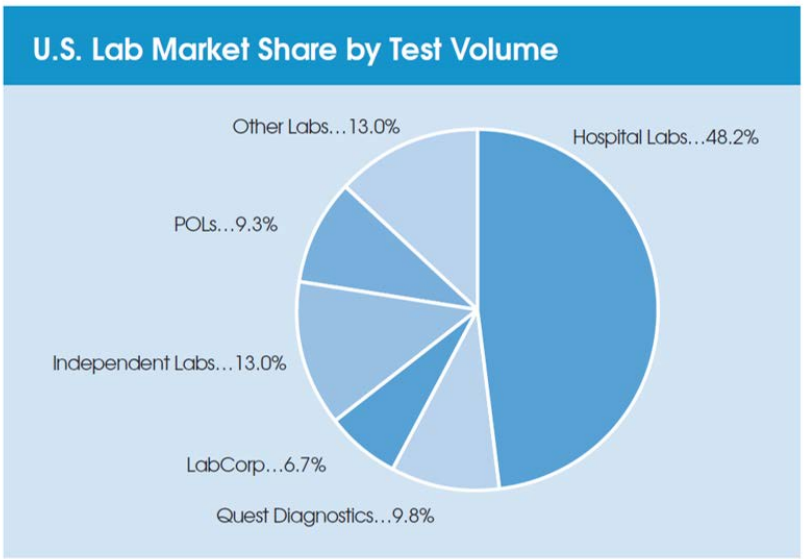
[4] "If the proposed fee schedule is finalized as it currently stands, we remain confident that we can achieve our long term outlook, though our earnings outlook is more likely to be at the lower end of the range we provided. That said, M&A [merger and acquisition] activity beyond our 1-2% growth target represents upside to this outlook." Quest Laboratories Q3 Investor Update.

to specialty testing for a specific purpose (e.g., infectious disease testing; allergy testing, toxicology/opiate 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, where the cost of providing laboratory testing services is far greater and not profitable. Community-based laboratories also tend to be the primary testing resource for rural communities.

Private Market

In the private market, independent community-based laboratories struggle to participate as in-network laboratory providers and many can only participate as out-of-network providers. Private payor rates with commercial carriers are primarily and often exclusively negotiated and set by the two large national laboratories to achieve sole source contracts with payors and establish narrow provider networks. Independent community laboratories, whether they serve as in-network or out-of-network providers are not provided rate schedules and are required to accept whatever rates are paid by a payor. Payments received are often inconsistent and incomplete and paid in the form of a lump sum (bundled) payment, requiring laboratories to prorate the payment information across the tests billed within their accounting systems. This frequently results in payments that do not in any way represent final payment rates and could be recorded in amounts as low as $.01 in rates.

The large national laboratories as high volume test providers have the ability to negotiate contracts with private payors. They tend to negotiate significant discounts on high volume tests and varied rates on other tests within their broader testing menus. They avoid high-cost service areas, including rural markets and post-acute care settings. They otherwise dominate the private market with more than 50 percent of the test volume. The other large segment of the private market by test volume is the hospital outreach testing market, ranging from large hospital/health systems with separate outreach businesses to small community hospitals with outreach businesses. Hospital outreach laboratory businesses represents 26 percent of test volume in the private market.



Source: Laboratory Economics, June 2017

NILA Comments on Preliminary CLFS Rates

Our comments address the following primary issues of concern regarding the preliminary CLFS rates and data used to establish the rates:

- The insufficient representation of the laboratory market paid on the CLFS in the data reviewed by CMS.
- Errors in the data submitted to CMS, affecting the calculation of a weighted median price.
- Proposed cuts would undercut efforts to transition to a value based health care system affecting acute and post-acute care and negatively impact Medicare costs.
- Proposed cuts that exceed statutory limitations for many test codes, including those test codes without CY 2017 National Limitation Amounts (NLAs).
- The lack of a transparent system to validate the data and data calculations.

Market Representation

The preliminary rates and analysis released by CMS does not adequately represent the laboratory marketplace as required under statute and as Congress intended. Less than one percent - a mere 0.7 percent of laboratories paid under Medicare Part B on the CLFS - reported applicable information to CMS. In 2016, the Health and Human Services' (HHS) Office of Inspector General (OIG) estimated five percent of the laboratory market paid by Medicare on the CLFS would report under CMS's final regulation. This estimate was already shockingly low to industry stakeholders and policymakers who voiced repeated concerns to CMS regarding the anticipated lack of market representation due to regulatory prohibitions. The 0.7 percent of laboratories reporting fails to include within it significant segments of the private laboratory market, resulting in radically skewed payment rate calculations with test volume and rate data dominated by the two largest national independent laboratories. An analysis of data dominated by two laboratories when there are 261,524 laboratories paid under Medicare Part B is not a market analysis.

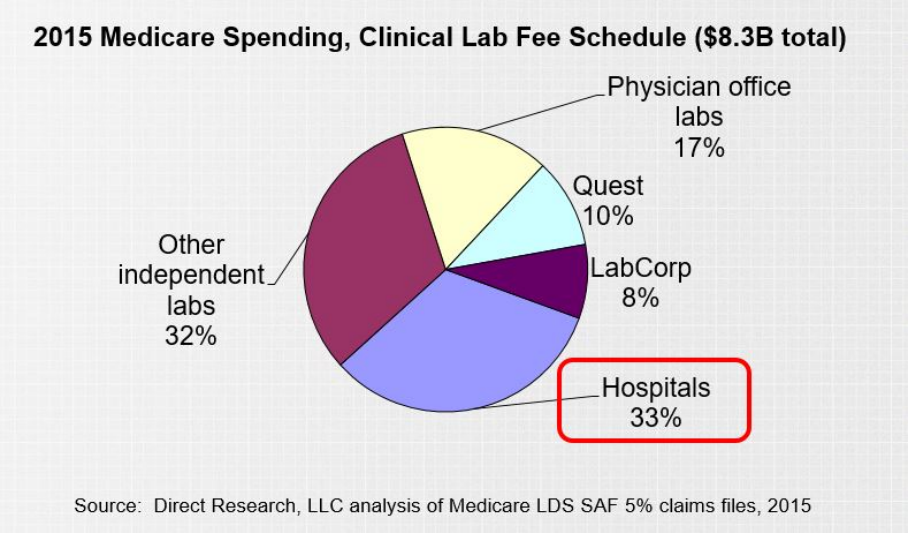
For independent laboratories, CMS indicates about 20 percent of independent laboratories reported as compared to the 44 percent estimated by OIG. For physician office laboratories, less than one percent reported compared to the still inadequate 4.8 percent estimated by OIG. Similar to physician office laboratories, CMS received data from less than one percent of hospital laboratories – only slightly more than the 0 percent estimated by OIG – and CMS stated that they believe reporting by these hospitals was an error as it was unlikely the hospitals met the agency's definition of applicable laboratory.

COMPARISON OF OIG 2016 REPORT ESTIMATES TO CMS ACTUAL LABORATORIES REPORTING

Laboratory Sector	OIG Estimate # of Labs Reporting by NPI	CMS Actual # of Labs Reporting by NPI	OIG Estimate Total # of Labs Paid Under CLFS by NPI
Independent	1,398	658	3,211
Physician Office	11,149	1106	235,928
Hospital	0	21	6,994
Other	--	157	--
Total	**12,547**	**1,942**	**261,524**
%	**4.8% (rounded by OIG to 5%)**	**.7% (< 1%)**	**100%**

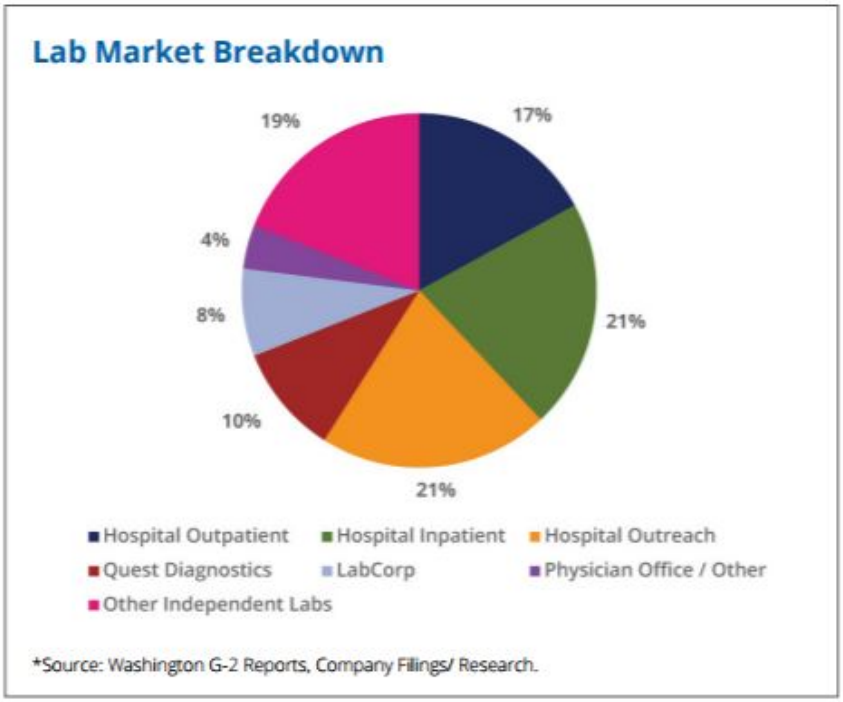
Sources: OIG 2016 Report and CMS Summary Data Analysis

In looking also at the chart below of 2015 Medicare CLFS spending, it is apparent that the independent community laboratories make up approximately one-third of Medicare spending for beneficiary test services. However, the data collected by CMS is entirely dominated by rates negotiated by the two largest national independent laboratories in the private market. In addition, hospital outreach laboratories make up approximately one-third of CLFS payments for Medicare beneficiary test services and yet these laboratories were almost entirely excluded from CMS's data collection and reporting process. As mentioned previously, the services offered by these sectors of the laboratory market vary considerably from their large national competitors, as do the costs associated with these tests.



Similarly, in looking at an analysis of the laboratory market by total revenues and it clearly demonstrates the significance of hospital outreach laboratories with 21 percent of total laboratory revenues. Even more apparent is the significant of hospital outreach laboratories in the non-hospital patient portion of the market, generally paid for under the CLFS and therefore applicable to report data under the PAMA statute. Therefore, it is of extreme concern that nearly all or the vast majority of these payments are excluded from CMS's data collection, analysis and preliminary rates.

Laboratory Market Segment Analysis by Revenues



Sources: *Industry Flash Report – Laboratory Services,* Kaufman, Hall & Associates, LLC. November 2016.

Data Simulation

Instead of addressing the extremely limited amount of data received and used to conduct rate calculations, CMS used the little applicable information it had received to simulate the impact if more laboratories - by specific type of laboratory - had reported information to the agency. While the fact that CMS conducted such data simulations seems to be an acknowledgement by the agency that the data received by CMS grossly underrepresents the laboratory market, we are concerned about the significant flaws in CMS's modeling. CMS simulated the impact on the weighted median rates if 10 times the number of hospitals reported data or double the number of physician office laboratories reported the same exact rates the agency received. The simulations in no way reflect a diverse marketplace where private market rates vary considerably between laboratory types and laboratory size. For example, smaller community providers typically have limited negotiating authority with payers and receive far lower rates in comparison to larger medical groups or larger hospital/health systems. Without a broader data set and range of rates by provider type, CMS cannot accurately model or simulate the impact of greater participation by any segment of the laboratory market. CMS's definition of an applicable laboratory

excluded all but 21 of nearly 7,000 hospital laboratories[5] and those that were not considered applicable – more than 99% – are not represented in CMS's data simulations. In other words, the miniscule data set received from the 21 hospital laboratories is, by definition, insufficient to reflect the private payments made to laboratories that did not meet CMS's definition of an applicable laboratory.

We find the data simulations and analysis conducted by CMS particularly troublesome as the factors – appearing arbitrarily chosen by CMS – to increase the volume of hospital and physician office laboratories reporting are woefully insufficient to accurately represent the actual market share of these segments. We are concerned that CMS also did not appropriately evaluate in its simulations the impact of having the laboratory market report in proportion to their share of CLFS payment volume. According to the OIG, in 2016, hospital laboratories received 24 percent of payments under the CLFS representing over a quarter of the Medicare market.[6] Under the design of CMS's data modeling, hospitals would have received only a 10 percent share of payments. CMS's data simulations fail to accurately represent the impact on weighted median calculations if additional laboratories reported applicable information to the agency.

Data Integrity

The preliminary payment rates and data released by CMS raise significant concerns regarding the number of errors presented in the data and the integrity of the weighted median calculations. Equally concerning is CMS' selective efforts to remove some data outliers believed to be in error and seek corrections from a small number of reporting entities, while leaving significant additional outliers in place that were clearly in error. It is evident even from a cursory review of the data files that extreme incongruities and anomalies remain in the data reported that warrant additional review and validation processes. Before proceeding with a revised CLFS, CMS must first ensure that the payment rates reported for laboratory test codes accurately correspond to private market payor rates for laboratory tests.

In meetings with CMS and with Congress, NILA raised several concerns about the ability for laboratories to comply with CMS regulatory requirements as outlined and the extremely short timeline provided by the agency to comply with burdensome regulatory requirements. NILA explained that CMS' regulatory requirements did not seem to understand how laboratory businesses, particularly smaller laboratory businesses, engage with private payers to participate as in-network or out-of-network providers, are paid for the testing services they provide, how these laboratories record their payment information, and the variance and limitations in laboratory billing and recording systems. We frequently felt that our concerns were not taken seriously or addressed in any way. The quality of the data received by CMS and used to set preliminary payment rates more than validates our concerns.

Laboratories Unable to Comply With CMS Regulatory Requirements

CMS finalized PAMA regulations on June 23, 2016, and when issued, the regulation was absent significant information needed for laboratories to begin preparing to meet a multitude of requirements. CMS subsequently released needed information three-months later through subregulatory guidance in mid-September 2016. The release of the guidance needed to comply with CMS' regulatory requirements 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 the threat of significant financial penalties. This delay imposed a massive and wholly unrealistic timeline for many laboratories to establish systems to collect and review

[5] Medicare Payments for Lab Tests in 2015: Year 2 of Baseline Data (OEI-09-16-00040)
[6] Id.

data and assemble it in a manner compatible with the outlined 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/AAB member lab utilize a fully automated process for purposes of reporting. In every instance, laboratories had to review and modify their data to attempt to conform to CMS standards.

The burdens of reporting required lab administrators to shift internal staff and resources away from the important work of providing laboratory testing services for patients and their day-to-day business operations. Some laboratories also had to afford the expense of hiring costly external consultants to assist in this process. For many other community laboratories, the costs of hiring outside consultants was too high and not within budget. These laboratories, many of which are small businesses, dedicated substantial time and resources to adjust claims data in an effort to comport with CMS submission standards. Many expressed concern with submitting likely inaccurate data, as they were unable to meet requirements.

Due to the extreme difficulties experienced by laboratories in trying to collect and report data in the unreasonably brief window, we believe the data reported includes significant errors. The OIG confirmed errors were 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,[7] 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.

[7] 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.

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

In its data summary analysis, CMS states that applicable laboratories were provided a six-month window to review their data for accuracy and completeness following the data collection period. This is simply not true. With the issuance of the final regulation, laboratories were provided no insight from CMS on which tests they would be required to report and how such data was to be reported prior to the release of guidance documents long after the release of the regulation, leaving three and a half months for laboratories to review and certify their data before data reporting was to begin. Laboratories were also required to review and certify at the same time they were trying to build new systems for obtaining the data requested by CMS.

The applicable information and system devised by CMS to collect and report laboratory information is entirely inconsistent with the laboratory billing and private payment process, particularly for smaller community laboratories with non-contracted rates. 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 lump sum (or bundled) basis, rather than on an individual test basis. Sometimes, payors pay on a bundled basis even when physicians order the tests as individual tests and even when the tests being bundled would not otherwise be recognized as a bundled set of tests by other payors. Laboratories bill for the tests in the manner they were ordered, unless the physician ordered a set of tests that should be billed as a recognized panel in accordance with Medicare and CPT guidelines. When this occurs, it is not possible for a laboratory to break out what is payed for each test because the payment as received is not attributed to the CPT codes billed. It is also inaccurate for a lab to apportion the amount paid between the CPT codes in the absence of any additional data from the payor. Other payors remit payments on individual tests that were billed, but the amount varies by how many tests are billed rather than which specific tests are billed. Therefore, it is inaccurate and inappropriate to attribute the bundled, lump sum 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 excluded bundled payments from the definition of "applicable information" to be reported. Yet, in the face of drastic financial penalties for non-compliance with reporting[8] 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

[8] 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.

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.

Reported Data Ranges Not Allowable Applicable Information

We were alarmed to see extreme and bizarre disparities in the distribution of rates reported that CMS then used to calculate weighted medians. The *Weighted Median Distribution for all HCPCS Codes* shared by CMS shows reported minimum and maximum payment rates from $.01 on the low end to as high as $99,999.99 for a single test. The following are some examples of these bizarre ranges:

- Metabolic panel (CPT code 80048): $01 to $27,356.01
- General health panel (CPT code 80050): $.01 to $92,702.94
- Comprehensive metabolic panel (CPT code 80053): $.01 to 65,081.33
- Lipid panel (CPT code 80061): $.01 to $94,234.12
- Renal function panel (CPT code 80069): $.01 to $51,061.49

We understand and have repeatedly explained to CMS why low-end rates in the amount of $.01 were reported to the agency. Laboratories were unable when complying with the terms of the regulation to extrapolate this data from their systems under a retrospective reporting system. CMS' design of the regulation prohibited this from occurring. CMS did not bother to correct this problem or provide laboratories support to allow for this data exclusion. CMS had an opportunity to address these data outliers during its calculation of the weighted median rates and chose not to do so. So, we are certain that data that would not be considered applicable information under the terms of the regulation was included in the calculation used to set preliminary CLFS payment rates.

CMS selective correction of data lowers weighted median

Despite not removing data associated with statistical outliers, including payment rates of $.01 before calculating weighted medians, CMS did decide to eliminate higher-priced reported data that, in the agency's own opinion, too far exceeded 2017 National Limitation Amounts.

CMS' selective editing of the data does not comply with statute. Nothing in the statute or in CMS' regulation allows CMS to make selective decisions on what data can be used to set weighted median rates and exclude certain data and include other data based on how the agency believes it could or would affect the weighted median. CMS is required to set rates under PAMA based on the reported data received not by the reported data it wants to use to set rates.

With the high volume of reported errors that are the direct result of a retrospective reporting process coupled with CMS exceeding its authority under statute by self-selecting data for exclusion, NILA/AAB believe that the proposed weighted medians are not accurate and the resulting preliminary payment rates are in error.

Adjustments needed to tests with no National Limitation Amounts

There are a large number of tests where CMS does not specify a National Limitation Amount (NLA) for CY 2017 and for which CMS is proposing that there be no statutorily-required phase-in of new rates. Instead, CMS proposes the calculated weighted median amount from reported data as the new rate to take effect on January 1, 2018. For an estimated 17 codes this would result in cuts that drastically exceed the statutory limit of 10 percent adjustments per year. According to statute, the new payment rates shall not result in a reduction in payment for a clinical diagnostic laboratory test for the year of greater than the applicable percent of the amount of payment for the test for the preceding year. In 2018, the applicable percent is 10 percent. In final regulation, CMS set out the NLA as the applicable previous year payment amount, but it did not address the calculation of new rates for test codes that did not have an existing NLA. Since the statute requires CMS to compare new rates to the previous year's Medicare payment amount and not specifically to the NLA, CMS must identify a previous year's payment amount if such an amount exists. The OIG considered this issue in its September 2016 report assessing PAMA's implementation and in its estimation of revised payment rates. For tests without a NLA amount, the OIG utilized the state and local standard rates for comparison when setting revised payment rates.

The chart below shows HCPCS codes without a NLA and for which CMS proposes proposed rates without statutory phase-in we believe to be in violation of the law.

Preliminary Payment Rates in 2018, 2019, and 2020 (with 10% Reduction Cap-where applicable)

Table 1. Payment rates with 10% phase-in reduction in 2018, 2019 and 2020
*Note: *HCPCS codes with one asterisk indicate codes that had payment and/or volume amounts equal to 0.*
***HCPCS codes with two asterisks indicate codes are new for 2017 and 2018.*

							2018 Payment vs NLA		2018 Payment vs. S/L Max	
Sort Order	HCPCS Code	HCPCS Code Description	2017 NLA	2017 State and Local Max	Weighted Median	2018 Payment w/ Cap	Payment Difference	Pct. Change in Payment	Payment Difference	Pct. Change in Paymen
			.		.	.				
13	80061	Lipid panel	$0.00	$18.37	$11.23	$11.23	$11.23		-$7.14	-38.87%
15	80074	Acute hepatitis panel	$0.00	$65.34	$38.79	$38.79	$38.79		-$26.55	-40.63%
118	80400	Acth stimulation panel	$0.00	$44.74	$28.80	$28.80	$28.80		-$15.94	-35.63%
119	80402	Acth stimulation panel	$0.00	$119.28	$76.16	$76.16	$76.16		-$43.12	-36.15%
120	80406	Acth stimulation panel	$0.00	$107.35	$63.49	$63.49	$63.49		-$43.86	-40.86%
121	80408	Aldosterone suppression eval	$0.00	$172.15	$109.94	$109.94	$109.94		-$62.21	-36.14%
122	80412	Crh stimulation panel	$0.00	$452.16	$801.62	$801.62	$801.62		$349.46	77.29%
123	80414	Testosterone response	$0.00	$70.83	$42.26	$42.26	$42.26		-$28.57	-40.34%
124	80415	Estradiol response panel	$0.00	$76.66	$40.60	$40.60	$40.60		-$36.06	-47.04%
125	80416	Renin stimulation panel	$0.00	$181.02	$209.32	$209.32	$209.32		$28.30	15.63%
126	80417	Renin stimulation panel	$0.00	$60.34	$38.89	$38.89	$38.89		-$21.45	-35.55%
127	80420	Dexamethasone panel	$0.00	$98.83	$161.88	$161.88	$161.88		$63.05	63.80%
128	80422	Glucagon tolerance panel	$0.00	$63.20	$40.94	$40.94	$40.94		-$22.27	-35.23%
129	80424	Glucagon tolerance panel	$0.00	$69.27	$34.69	$34.69	$34.69		-$34.58	-49.92%
130	80426	Gonadotropin hormone panel	$0.00	$203.58	$133.40	$133.40	$133.40		-$70.19	-34.48%
131	80428	Growth hormone panel	$0.00	$91.50	$59.53	$59.53	$59.53		-$31.97	-34.94%
132	80430	Growth hormone panel	$0.00	$107.66	$129.33	$129.33	$129.33		$21.67	20.13%
133	80432	Insulin suppression panel	$0.00	$185.32	$165.61	$165.61	$165.61		-$19.71	-10.64%
134	80434	Insulin tolerance panel	$0.00	$138.78	$285.03	$285.03	$285.03		$146.25	105.38%
135	80436	Metyrapone panel	$0.00	$125.05	$69.35	$69.35	$69.35		-$55.70	-44.54%
136	80438	Trh stimulation panel	$0.00	$69.15	$41.59	$41.59	$41.59		-$27.56	-39.86%
137	80439	Trh stimulation panel	$0.00	$92.20	$33.07	$33.07	$33.07		-$59.14	-64.14%

Specific tests listed in the table above facing drastic cuts under CMS' proposed process include CPT Code 80061 Lipid Panel. CMS calculated the weighted median for this test code at $11.23, using this rate as the new payment rates for the code. This would amount to a 38.87 percent reduction when compared to current state and local payment for this code, which is $18.37. Another example is CPT Code 80074 acute

hepatitis panel. CMS calculated the weighted median and proposed a revised payment rate for this test code at $38.79, when the state and local payment for this code is $65.34. This would amount to a 40.63 percent payment reduction, far in excess of statutorily directed payment adjustments of no more than 10 percent per year for three years following reporting.

For tests whose payment rates are calculated using weighted median calculations from reported data, CMS is not permitted under statute to reduce a payment rate by more than 10 percent from "the amount of payment for the test for the preceding year." To do so would be in violation of the statute. NILA/AAB advise that the agency must revisit this issue through notice and comment rulemaking and to also consult the OIG's examination of treatment of tests that are without a NLA before proceeding with any adjustment in payment to tests without a current NLA.

Negative Impact of Transition to Value-Based Payment System and Reduced Medicare Costs

The implications of implementing a revised payment system based on inaccurate data that does not represent the complete marketplace are most grave for patients with chronic disease and comorbidities. The most commonly ordered tests by physicians to treat and manage the care of Medicare beneficiaries (most of the top 25 tests by Medicare spending) would be cut by more than 30 percent if fully phased-in. The following are highlights of some of the commonly ordered tests necessary for patient management that are facing the most serious reductions as proposed:

- Complete blood count: 35 percent cut
- Complete metabolic panel: 35 percent cut
- Glycosylated hemoglobin A1C: 36 percent cut

These cuts are unsustainable for laboratories that work with physicians to manage our most complex Medicare patients, including patients that reside in rural geographic areas or receive their care in the post-acute setting (e.g., skilled nursing facilities, homebound patients). The costs of providing care in these settings is far higher than the reimbursement being proposed, as these labs seek to provide services to complex patients that require emergency testing with quick turnaround times or repeat testing daily. The testing services provided actually reduce over Medicare costs by ensuring that patients can obtain their tests in the community and not be transported to the hospital for more costly testing services. They also reduce costs by ensuring physicians have the diagnostic tools needed to manage care and avoid unnecessary visits to the hospital emergency department. In the post-acute care setting, they ensure physicians can provide needed oversight and care to avoid hospital admissions (or readmissions) of beneficiaries in nursing homes.

As proposed, the reductions in payment for the tests physicians use every day to manage the care of Medicare beneficiaries directly undercut the administration's effort to support MACRA Implementation as the reductions risk the availability of these tests being performed by laboratories that support and provide diagnostic test results and interpretations to physician practices. Without the testing being available to physicians, there is a risk to patient care continuity and patient care coordination, threatening the success of new advance payment and delivery models envisioned under the *Medicare Access and CHIP Reauthorization Act* of 2015. Without the diagnostics available, it is unclear how physicians will meet the requirements envisioned under the law. The same holds true in the post-acute care setting where skilled nursing homes are being held accountable for patient care to avoid costly hospital readmissions. Many

independent laboratories have been working with these facilities to ensure they understand how to appropriately utilize clinical test results to manage patient care and avoid unnecessary hospitalizations.

Other Data and Test Rate Concerns

General Health Panel

The General Health Panel (CPT code 80050) has not previously been on the CLFS and does not have a CY 2017 NLA. However, each component test included on the general health panel (CPT codes 80053, 84443, and 85025) have a CY 2017 NLA, which in sum total $48.20. CMS listed a preliminary payment rate for the general health panel at $23.54. If implemented as proposed by CMS, the reduction in payment for this code would far exceed the 10 percent maximum in adjustment required under statute.

We are not aware of CMS proposing any adjustment in the treatment of the general health panel by adding it to the CLFS. This was not a topic addressed at the annual CLFS public meeting or before the PAMA Advisory Panel. As discussed above concerning other test panels that do not have a current NLA, CMS must limit payment reductions to no more than 10 percent per year based on a reasonable comparison of current payment rates for the test. NILA recommends that this be addressed through notice and comment rulemaking to allow for stakeholder feedback.

Definitive and Presumptive Testing Codes

We are extremely concerned that the toxicology test code rates as proposed were inappropriately derived and will threaten physician access to drugs of abuse tests that are essential to ensure physicians are fully equipped to address the growing drug epidemic.

In 2015, drug overdose became the leading accidental cause of death in the U.S. with 52,404 lethal drug overdoses occurring that year.[9] According to the President's Commission on Combatting Drug Addiction and the Opioid Crisis and the Centers for Disease Control (CDC), 142 Americans die every day from a drug overdose.[10] In fact, drug overdoses are now responsible for more deaths than gun homicides and car accidents combined.[11] As acknowledged by Congress and Administrative agencies alike, we are in the midst of an unprecedented drug abuse crisis, driven primarily by prescription opioids, and health care providers desperately need access to all available resources to curb abuse and put an end to the crisis.

CMS's proposed rates for toxicology tests would have drastic negative ramifications on efforts to monitor and ensure physicians can address the rising drug epidemic.

Definitive Drug Testing

Laboratories that perform toxicology or drugs of abuse testing are on the front-lines supporting physicians in their work to monitor patient use of prescribed opioids. Specifically, definitive drug testing is ordered by a physician when it is medically necessary to identify specific medications, illicit substances, and metabolites present in patients who are receiving medical treatment. This type of testing is medically

[9] https://www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf
[10] https://www.whitehouse.gov/sites/whitehouse.gov/files/ondcp/commission-interim-report.pdf
[11] Id.

indicated for patients who are receiving chronic opioid therapy and for the diagnosis and treatment of substance use disorders.

Beginning in July 2015, CMS proposed significant changes in Medicare's coding and pricing for toxicology testing. Finalized for 2016, these changes resulted in significantly low payment rates that went beyond industry and the PAMA advisory panel recommendations. In response, we and many other industry stakeholders expressed our concerns that the final pricing determinations made by CMS did not reflect the methods and justifications for these tests or the costs associated. CMS acknowledged and agreed with stakeholders that the rates implemented for 2016 were insufficient. Beginning in 2017, the erroneous rates were corrected and re-priced by CMS with adjustments ranging from an 18 percent to 47 percent increases from 2016 rates.

Despite CMS's correction of these rates for 2017, private payors had unfortunately adjusted 2016 rates for toxicology tests based on the 2016 CLFS, and because of the retrospective reporting process required by CMS that relied upon 2016 private payor rates, the proposed 2018 CLFS rates for these tests are now being evaluated based on reported data that reflects the erroneous 2016 rates that CMS acknowledged as too low and subsequently corrected. As CMS has previously recognized, these payments are inadequate to sustain the costs of performing these tests, and given the critical nature of these tests, we urge CMS to reconsider their calculation of these new rates for 2018 and adjust them based on the corrections made to rates in 2017. If implemented as proposed, the new rates will disproportionately cut payments for definitive drug tests, reducing or possibly eliminating physician and beneficiary access to these critical test services.

Presumptive Drug Testing Codes

As part of CMS's coding and re-pricing of toxicology testing, new codes were implemented in 2017 that replaced existing G-codes for presumptive drug testing (drug screening). HCPCS codes G0477, G0478, and G0479 were replaced with new codes 80305, 80306 and 80307, respectively. However, because CMS again required laboratories to retrospectively report 2016 rates and their associated test codes, there were no rates to report for the new codes since the Medicare codes did not exist in the private market.

CMS did not receive any data for the new presumptive drug testing codes. In response, the agency is proposing to crosswalk the new preliminary drug testing codes to the previous G-Codes. In doing so, the agency is proposing cuts that far exceed the statutory maximum of 10 percent as outlined in the table below.

HCPCS Code	**2017 NLA**	**PAMA Weighted Median**	**Pct. Change in Payment**
80305 (G0477)	$14.96	$12.60	15.7%
80306 (G0478)	$19.95	$17.14	14%
80307 (G0479)	$79.81	$62.14	22%

Because the codes did not exist on the CLFS during the first data collection period from January-June 2016 and no data was reported, CMS cannot calculate a weighted median. CMS has instead proposed crosswalking these codes to codes that no longer exist on the CLFS.[12] We do not believe or agree that these codes may be crosswalked to non-existent G-codes, as current regulations clearly state that crosswalking is comparable to existing test codes.[13] We recommend that the presumptive test codes should remain at the 2017 CLFS prices and be re-evaluated through subsequent reporting under PAMA.

CMS Rate Setting Process Requires Transparency and Methods to Validate Data

In its report issued in September 2016, the OIG notably stated that the chance of errors in the laboratory reported data is high based on the compressed timeline created by agency and delays in finalizing the PAMA regulations and issuing guidance to laboratories. NILA/AAB believe the OIG was accurate in this statement as is confirmed through a review of the data issued by CMS and the errors and inaccuracies noted, coupled with the absence of statistically meaningful data from all segments of the laboratory market.

CMS's regulation did not outline any process to ensure transparency in how CMS derived its rates or any method for validation of the data. It has not been stated as to whether the HHS Office of the Actuary reviewed the data received by market segment or the agency's approach and calculation of the weighted medians or proposed payment rates. It seems from the data provided that CMS alone conducted its assessment and that there was no review or validation to the methodologies outlined or calculations made.

Conclusion

While NILA/AAB has worked closely with our members and sought to actively engage CMS toward PAMA implementation, we believe that as it currently stands, the proposed weighted medians and preliminary payment rates do not reflect accurate market rates for clinical laboratory services as required by statute. Given the significance of our concerns regarding the severe lack of market representation in the data and major data inaccuracies, we continue to respectfully request that CMS suspend implementation of the CLFS reforms under PAMA while it resolves these significant issues. The risk of eliminating a competitive laboratory marketplace and ensuring fair pricing under Medicare and significantly reducing Medicare beneficiary access to clinical laboratory services is far too grave if this flawed system proceeds without adjustment.

Sincerely yours,

Mark S. Birenbaum, Ph.D.

Administrator

[12] CY 2017 Clinical Laboratory Fee Schedule Final Determinations.
[13] 42 CFR 414.508(b)(1).