American
Clinical Laboratory
Association

October 23, 2017

Ms. Seema Verma, Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Submitted electronically to CLFS_Annual_Public_Meeting@cms.hhs.gov

Dear Administrator Verma,

The American Clinical Laboratory Association (ACLA) respectfully submits these comments on the CY 2018 Clinical Laboratory Fee Schedule (CLFS) Preliminary Payment Determinations and accompanying documents released on September 22, 2017.[1] ACLA is a not-for-profit association representing the nation's leading clinical and anatomic pathology laboratories, including national, regional, specialty, ESRD, and nursing home laboratories. The clinical laboratory industry is at the forefront of personalized medicine, driving diagnostic innovation and contributing more than $100 billion to the nation's economy annually. As providers of millions of clinical diagnostic laboratory services for Medicare beneficiaries each year, ACLA member companies have a direct stake in ensuring that prices for laboratory testing services are determined openly and rationally and that the pricing levels represent reasonable compensation for developing and providing the services.

We note at the outset that ACLA has objected to the Centers for Medicare & Medicaid Services' (CMS's) failure to implement the data reporting obligations that Congress included in Sec. 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA). Unless CMS corrects its implementation of the data reporting obligation, it cannot take the next step of establishing payment rates under Sec. 216(b) of PAMA. Although we hope that our comments will assist CMS with evaluating the preliminary payment rates, we continue to believe that CMS's definition of "applicable laboratory" does not comport with the definition of that term that Congress included in subsection (a) of Sec. 216 of PAMA.

ACLA remains committed to ensuring that all sectors of the laboratory market are represented adequately in the calculation of any new CLFS rates, consistent with Congressional intent. We have voiced our concerns to the agency repeatedly that the CY 2018 CLFS rates likely would not be market-based, that the rate-setting exercise would result in unsustainable cuts to Medicare rates for many tests, and that the integrity of the data used to calculate those rates was likely to be questionable. The preliminary rates that CMS released last month confirm that our concerns were not unfounded. Indeed, CMS calculated the preliminary rates using data from an extremely small number of labs that are not representative of the entire laboratory market serving Medicare beneficiaries. The quality of some of the data is poor, and aspects of CMS's administration of the data collection concern us.

[1] CY 2018 CLFS - Preliminary Payment Rates and Crosswalking/Gapfilling Determinations, *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html.

In short, CMS's approach to collecting applicable information did not work. The deficiencies in the number and types of entities that reported data and in the data CMS used to develop weighted medians are far too significant for the agency to proceed according to its planned schedule. **CMS must delay implementation of any new CLFS rates until it has collected data and calculated rates that accurately reflect all segments of the laboratory market (independent labs, physician office labs, and hospital outreach labs), and until it addresses data integrity concerns.**

Among others, our comments address the following issues:

- The lack of representation of the full laboratory market in data reported to CMS and the miniscule number of laboratories that reported data;
- Obvious problems with some data that was reported;
- CMS's questionable treatment of certain reporting entities and data;
- The enormity of the cuts to many tests, going far beyond what Congress intended;
- CMS's treatment of codes without CY 2017 National Limitation Amounts (NLAs); and
- Problems with CMS's approach to pricing other specific codes.

I. The preliminary rates CMS released may not accurately reflect private payor rates paid in the full laboratory market serving Medicare beneficiaries.

The preliminary rates that CMS released do not include inputs from the full laboratory market serving Medicare beneficiaries. More than 99 percent of laboratories that were paid for laboratory services under Medicare Part B in 2015 reported no data to CMS – a mere 0.7 percent of all labs paid by Medicare reported applicable information to the agency.

Far fewer labs reported data than the Department of Health and Human Services Office of the Inspector General (OIG) estimated would be required to report their private payor data.[2] The OIG estimated that just five percent of all labs paid under Medicare Part B in 2015, or 12,547 labs, would qualify as applicable laboratories and would be required to report applicable information to CMS. In reality, only 0.7 percent of labs paid under Medicare Part B in 2015 – 1,942 out of 261,524 – reported applicable information to CMS.[3] Just 658 independent labs reported applicable information – only twenty percent of all independent labs paid under Medicare Part B and less than half of the labs the OIG estimated would report. Only 1,106 physician office labs (POLs) reported applicable information to CMS – only one tenth of the POLs the OIG estimated would

[2] Office of Inspector General, Medicare Payments for Lab Tests in 2015: Year 2 of Baseline Data (OEI-09-16-00040) at 7, *available at* https://oig.hhs.gov/oei/reports/oei-09-16-00040.pdf.
[3] Summary of Data Reporting for the Medicare Clinical Laboratory Fee Schedule Private Payor Rate-Based System ("Summary") at 3, *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf.

report information and just one half of one percent of all POLs paid for lab services under Medicare Part B in 2015. And just 21 hospital outreach labs reported data – representing one percent of all reporting entities and less than one half of one percent of all hospital labs paid under Medicare Part B for lab services in 2015. Rural laboratories comprised just two percent of laboratories reporting applicable information.

Additionally, as shown below, the volume of applicable information CMS received from independent laboratories, POLs, and hospital laboratories is far out of proportion to their respective shares of CLFS volume.

	Proportion of CLFS Volume[4]	**Proportion of Applicable Information by Volume[5]**	**Potential Over- or Under-Representation**
Independent Labs	50 %	90.1 %	**40.1 % over**
POLs	23 %	7.5 %	**15.5 % under**
Hospitals	27 %	1.0 %	**26.0 % under**

Clearly, independent laboratories submitted a far larger proportion of applicable information than their share of CLFS volume. Hospital laboratories and POLs submitted significantly less applicable information by volume than their share of CLFS volume. Simply put, the preliminary rates cannot be characterized as "market-based" when the data does not reflect the market.

CMS reports that 1,074 TIN-level entities registered to submit applicable information, but only 994 TIN-level entities reported applicable information. The agency dismisses the fact that 80 registered TIN-level entities reported no applicable information by saying that the reporting entities "may have determined during the process that they do not have component laboratories that meet the definition of applicable laboratory and therefore, are not subject to reporting requirements."[6] The agency offered no support for its supposition. It is just as likely that some or all of these 80 missing TIN-level entities are or had component laboratories that meet the definition of applicable laboratory and were subject to the reporting requirement – yet failed to report.

Seemingly in order to avoid addressing the low number of applicable laboratories that reported data, CMS suggests that its modeling shows that more labs reporting would not make a material difference in the eventual payment rates. As a threshold issue, Congress did not require applicable laboratories to report applicable information only when that information would make a difference in payment rates; Congress required applicable labs to report applicable information, period. Regardless, CMS's modeling exercise was fatally flawed for two reasons. First, the agency simulated the difference in the weighted medians if twice as many POLs reported or ten times as many hospitals reported, but apparently it did not do any simulation to determine the

[4] 2016 Physician/Supplier Procedure Summary file; 2015 Outpatient Standard Analytic file.
[5] Summary at 3.
[6] *Id*. at 4.

impact if POLs or hospital laboratories reported in proportion to their share of CLFS payment volume. In 2016, hospital labs received about 26 percent of payments under the CLFS, but in CMS's model they would have only a 10 percent share.[7] Second, CMS's model also mistakenly assumed that all hospital labs would report the same prices, which is not the case. CMS's simulations significantly underrepresent the impact of additional laboratories reporting applicable information.

It is incumbent upon CMS to let the public know what enforcement actions it has taken against non-reporting laboratories. There is a large discrepancy between the number of applicable laboratories that the OIG estimated would be required to report applicable information to CMS and the number of laboratories that actually reported. CMS does not say if it investigated whether any of the 80 registered TIN-level entities that failed to report applicable information were under an obligation to do so, or if it made any efforts to identify the 10,000 laboratories that the OIG included in its estimate of applicable laboratories but that did not report information to CMS. CMS's receipt of applicable information from those 10,000 laboratories could have had a material impact on the weighted medians CMS calculated, especially for the highest-volume test codes.

The agency's data is woefully inadequate to calculate truly market-based rates, when such a miniscule portion of the market is represented and when some sectors of the laboratory market reported very little data to CMS. CMS should determine why so few applicable labs registered to report applicable information during the data reporting period, and why so many of those that registered to report failed to do so – and it must do so before finalizing the preliminary rates.

II. There are obvious problems with the data reported to CMS that call into question the integrity of the weighted medians.

The quality of the applicable information that CMS did receive from some reporting laboratories is questionable, as is CMS's treatment of some of the data. This raises serious concerns about the integrity of the weighted medians calculated from the data.

A. The quality of data reported by some laboratories raises serious concerns about the preliminary rates.

CMS published the final rule to implement Sec. 216 of PAMA on June 23, 2016.[8] In the Final Rule, CMS announced that the first data collection period would span January 1, 2016 to June 30, 2016, ending just one week after the Final Rule was published. Until the Final Rule was published and certain other subregulatory guidance was issued, laboratories were unable to build systems to extract information from their billing systems – not least because they did not know how long or when the first data collection period would be, what private payor rates would be included in applicable information, and whether manual remittances and secondary payor rates would be included. Each laboratory had to create a system for extracting data from its billing system, tailored to the specifics of the Final Rule. It was not until August 4, 2016 that CMS released the list of codes for which applicable laboratories were to report applicable information,

[7] Medicare Payments for Lab Tests in 2016: Year 3 of Baseline Data (OEI-09-17-00140) at 2.
[8] 81 Fed. Reg. 41035 (Jun. 23, 2016) ("Final Rule").

and it was in mid-September 2016 that CMS released the corrected template for reporting applicable information. CMS shared information with applicable laboratories in a variety of ways throughout the summer and fall of 2016, for a data reporting period that started on January 1, 2017.

We do not believe that laboratories reported inaccurate and incomplete data intentionally. But a review of the complete data file and statements that CMS included in its own summary underscore that many of the labs that did report applicable information did not understand what was to be included or excluded from the data, or found that it was impossible to access the information in their systems retroactively.

The weighted median distribution table that CMS released with the preliminary rates reveals truly bizarre data that some laboratories reported – and that CMS used to calculate weighted medians. A review of the table shows that laboratories reported that private payors paid:

- From **$.01** on the low end to **$27,356.01** on the high end for a metabolic panel (CPT code 80048)
- From **$.01** on the low end to **$92,702.94** on the high end for a general health panel (CPT code 80050)
- From **$.01** on the low end to **$65,081.33** on the high end for a comprehensive metabolic panel (CPT code 80053)
- From **$.01** on the low end to **$94,234.12** on the high end for a lipid panel (CPT code 80061)
- From **$.01** on the low end to **$51,061.49** on the high end for a renal function panel (CPT code 80069)

A lab also reported having received **$99,999.99** for a thyroid stimulating hormone assay (CPT code 84443) – which is the highest price that was possible to report for any test, and it also could be a place-holder value, but in either case, this data clearly is erroneous. Additionally, a price of **$0.00 was reported for 2.4 million tests**, which is fully one percent of the test volume reported by applicable laboratories.[9] CMS's guidance in the Final Rule was very clear: "Laboratories should not report zero dollars for CDLTs where a private payor has denied payment within a data collection period."[10] Despite this unequivocal statement by the agency, many laboratories apparently were not aware of this or mistakenly included these "zero payments."

The examples above are obvious and easily detectable errors in data reporting. Our concern lies not only with these examples, but also with all of the other data reporting errors that are not as easy to detect but that are just as likely to have occurred. We also are concerned about the impact

[9] We understand that these "zero payments" were not used in calculations of weighted medians but that the $.01 rates were used.
[10] 81 Fed. Reg. 41054.

these errors had on the preliminary payment rates that CMS released. When CMS relies on clearly erroneous information, it is not possible to have confidence in the data set as a whole.

B. CMS selectively corrected or omitted data that would have resulted in higher than expected weighted medians.

CMS acknowledges that it made its own judgment about what would be an acceptable amount by which a weighted median could exceed a 2017 CLFS National Limitation Amount (NLA). In its Summary, it states:

> CMS identified four reporting entities that submitted data which resulted in weighted medians that were significantly high compared to the 2017 CLFS payment amounts (that is, greater than 150 percent of the 2017 CLFS national limitation amount (NLA)). All four reporting entities were contacted, 3 confirmed they misunderstood the "payment rate" and reported inaccurate data. Two of the reporting entities reported corrected data, which we included in calculating the weighted medians of the private payor rates; the third reporting entity stated that it would submit corrected data but did not (we removed the reporting entity's data from the calculation of the weighted medians of the private payor rate). The fourth reporting entity we contacted did not provide us feedback on the accuracy of its data; therefore, we removed this reporting entity's data from the calculation of the weighted medians of the private payor rates.[11]

In the same section of the summary, CMS states that it did not remove data associated with "statistical outliers" from the calculation of the weighted median of the private payor rates – when it assumed the impact on the weighted median would be minimal.[12]

CMS's selective editing of data does not comply with the law. Section 216 of PAMA does not prohibit the weighted median for a test from being higher than the 2017 NLA – by one percent or by 50 percent – and Congress did not give CMS the authority to decide that a 2018 rate that is 150 percent of a 2017 rate is "too much." Furthermore, the statute and the regulations do not allow CMS to "correct" data that have been submitted and certified by an officer of an applicable laboratory or his or her designee.[13] And nothing in the statute or the regulations allows CMS to pick and choose among the data it received, excluding certain data and including other data, based on how it would affect the weighted median.

While CMS did not accept at face value the questionable but certified data of some labs, it chose to accept at face value the attestations of other laboratories that reported questionable data.

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[11] Summary at 5-6.
[12] *Id*. at 6.
[13] *See* 42 U.S.C. § 1395m-1(b)(2) ("For each laboratory test with respect to which information is reported under subsection (a) for a data collection period, the Secretary shall calculate a weighted median for the test for the period, by arraying the distribution of *all* payment rates reported for the period for each test…") (emphasis added); 42 C.F.R. § 414.507(b).

For example, four of 21 hospital laboratories that reported applicable information "did not report applicable information with a distinct non-hospital NPI as required."[14] CMS's own current policy, as articulated in the Final Rule, is that a hospital enrolled in Medicare as an independent laboratory "or that obtains a unique NPI (separate from the hospital) and bills for its hospital outreach services (that is, services furnished to patients other than inpatients or outpatients of the hospital) using its unique NPI" can meet the definition of an applicable laboratory and report applicable information.[15] Regardless of its policy and its underpinnings, CMS inexplicably looked the other way, noting that "all laboratories are required to attest that they meet the definition of an applicable laboratory," and blindly accepted this attestation to include this data. These hospitals were not "applicable laboratories" under CMS's current regulations and were prohibited from reporting applicable information, unless they had an extremely unusual mix of Medicare CLFS and Physician Fee Schedule payments and bundled payments under the Inpatient Prospective Payment System and Outpatient Prospective Payment System.[16] CMS believed that these laboratories were not permitted to report applicable information, so the agency's acceptance of the hospitals' attestations is not reasonable. Furthermore, more hospital laboratories may have reported applicable information if they knew that CMS would accept their data, regardless of whether they met the definition of an "applicable laboratory" – even though the regulations are clear that "applicable information may not be reported for an entity that does not meet the definition of an applicable laboratory."[17]

Given the low quality of much of the data that CMS received – and given that CMS has acted beyond its authority in selectively including and excluding certain data reported to it – it is not possible to have confidence in the accuracy of the weighted medians that the agency calculated and in the resulting preliminary rates.

III. The enormous cuts to tests commonly performed for Medicare beneficiaries would go far beyond what Congress and the Office of Management and Budget anticipated and would be unsustainable for many labs.

If CMS were to proceed with finalizing the preliminary rates, the resulting cuts would be unsustainable for many laboratories furnishing services to Medicare beneficiaries and would threaten access to laboratory services in some areas. The cuts go far beyond what Congress and the Office of Management and Budget anticipated, calling into question CMS's approach to implementing the law. Further, some of the cuts violate the statutory limit on how much a rate can be reduced from year to year.

A. The preliminary rates include enormous cuts to tests furnished to thousands of Medicare beneficiaries each day.

If the preliminary rates were to be implemented, nine of the top 10 laboratory tests (by CLFS spending) would be cut by more than 30 percent if fully phased-in. Moreover, 18 of the top

[14] Summary at 4.
[15] 81 Fed. Reg. 41046.
[16] 42 C.F.R. § 414.504(g).
[17] *See* 81 Fed. Reg. 41048.

25 lab tests (by CLFS spending) would be cut by more than 30 percent, and another three of the top 25 tests would be cut by between 20 and 30 percent. For example:

- Comprehensive metabolic panel would be cut by 35 percent (41.6 million tests performed in 2016)
- Complete blood count would be cut by 35 percent (42 million tests performed in 2016)
- Vitamin D test would be cut by 35 percent (9 million tests performed in 2016)
- Glycosylated hemoglobin A1c test would be cut by 36 percent (19.3 million tests performed in 2016)
- Thyroid stimulating hormone test would be cut by 35 percent (21.5 million tests performed in 2016)

Collectively, laboratories performed more than 133 million of the foregoing five tests for Medicare beneficiaries in 2016. The top 25 tests by CLFS spending represented fully 63 percent of all Medicare payments for lab tests in 2016, or $4.3 billion.[18] But the deep cuts are in no way limited to the highest volume test codes. The majority of test codes would be cut by more than 10 percent, if the preliminary rates were to be fully phased-in.[19]

Cuts of this magnitude would be unsustainable for many laboratories serving beneficiaries in rural areas, physician office labs in many locations, and nursing homes, and they would threaten beneficiary access to even basic laboratory testing. The costs of providing laboratory testing to Medicare beneficiaries in these labs is higher than costs in other types of labs. It is likely that the cost could exceed the return for some bread-and-butter tests, meaning some labs will close down and some physician offices no longer will offer routine lab testing to their patients to inform treatment and enable diagnosis at the time of a patient's visit. It is not at all the case that other laboratories will rush in and fill the void, once these laboratories stop operating.

B. The cuts go far beyond what Congress or the Office of Management and Budget anticipated.

The cuts that CMS has estimated would take place if the preliminary rates were to be finalized would go well beyond what the non-partisan Congressional Budget Office (CBO) or the Office of Management and Budget (OMB) anticipated. This indicates a fundamental disconnect between the way the law has been implemented and the way it was intended to be implemented. Following is a comparison of CBO's estimates of the effect of PAMA Sec. 216 on CLFS spending (when Congress passed the law), OMB's estimate of the Final Rule's effect on CLFS spending

[18] Medicare Payments for Lab Tests in 2016: Year 3 of Baseline Data (OEI-09-17-00140) at 3.
[19] Summary at 6. CMS itself said that "about 58 percent of HCPCS codes will receive a phased-in payment reduction in CYs 2018, 2019, and 2020, rather than a full private payor rate-based payment amount in CY 2018 because the total payment decrease" will exceed 10 percent.

(when the Final Rule was promulgated), and CMS's recently-released estimate of the effect of the preliminary rates on CLFS spending.

	Year 1	Year 2	Year 3	3-Year Total
CBO[20]	- $100 million	- $400 million	- $500 million	**- $1.0 billion**
OMB[21]	- $390 million	- $700 million	- $620 million	**- $1.7 billion**
CMS[22]	- $670 million	- $1.2 billion	- $1.7 billion	**- $3.6 billion**

The way CMS has implemented Sec. 216 of PAMA, the cuts to the CLFS in the first three years would be more than two and a half times what the CBO anticipated, and more than twice what OMB estimated when the Final Rule was promulgated in June of 2016. If the preliminary rates were implemented, the overall cut to the CLFS in the first three years would be a staggering $3.6 billion. The CY 2018 cut would be 10 percent in the aggregate, the CY 2019 rates would cut another 17 percent from the CLFS, and the CY 2020 rates would add another 23 percent cut on top of the previous years' cuts. We are not aware of another Medicare provider or supplier type that has been required to absorb such deep cuts in reimbursement in such a short period of time, and it is difficult to imagine a scenario in which Congress would legislate such a cut. Congress certainly did not do so in this instance.

C. CMS must change its approach to payment for test codes with no CY 2017 National Limitation Amount.

In the event that CMS moves forward with implementation of the weighted median rates in CY 2018, it must change its approach to pricing test codes that had no CY 2017 NLA, because its current approach violates the statute. A section of the statute titled "Phase-in of Reductions from Private Payor Rate Implementation" states that "payment amounts determined [based on the weighted median of private payor rates] may not result in a reduction in payments for a clinical diagnostic laboratory test for a year of greater than the applicable percent…*of the amount of payment* for the test for the preceding year."[23] For 2018, the applicable percent is 10 percent. In the Final Rule, CMS limited a payment cut in 2018 to "10 percent of the national limitation amount

[20] CBO Cost Estimate for the Protecting Access to Medicare Act of 2014 (Mar. 26, 2014), *available at* https://www.cbo.gov/sites/default/files/113th-congress-2013-2014/costestimate/house-introduced-protecting-access-medicare-act-2014-march-26-20140.pdf. The CBO estimate shows $1 billion in savings from 2014-2019, assuming the new rates would go into effect in 2017, as was called for in the law.
[21] 81 Fed. Reg. 41097.
[22] CY 2018 – Preliminary Private Payor Rate-Based CLFS Payment Rates and Analytics, *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html.
[23] 42 U.S.C. § 1395m-1(b)(3)(A) (emphasis added).

for the test in 2017," but it was silent on a cut for a code without an NLA.[24] A number of tests had no NLA for CY 2017. For example, the lipid panel (CPT code 80061) has not had an NLA because it includes two automated multi-channel chemistry (AMCC) tests that have been bundled and paid at the ATP02 price (triglycerides and cholesterol) and one test that is not a bundled AMCC test (HDL).

The document that CMS released entitled "Preliminary Payment Rates in 2018, 2019, and 2020 (with 10% Reduction Cap – where applicable)" shows a 2018 rate for the lipid panel of $11.23, a 39 percent cut from the most prevalent local fee schedule amount for the test. The chart also states that the entire reduction for this test would be taken in 2018. Applying a 39 percent reduction in payment for this test in 2018 would violate the plain language of the statute. The "10 percent reduction cap" is applicable to this test and to every other test that was paid for by Medicare in 2017 and whose rate is based on a weighted median of private payor rates, regardless of whether a test had an NLA, because the statute limits a reduction in payment in 2018 to 10 percent of "the amount of payment for the test for the preceding year." When establishing the phased-in reductions, Congress did not distinguish between tests that had an NLA in CY 2017 and those that did not – it limited the payment reduction for any test that had an "amount of payment" in the preceding year.

CMS can comply with the plain language of the statute by recognizing a *de facto* CY 2017 NLA for each test that does not have one. For panel codes comprised of tests represented by codes that do have CY 2017 NLAs, the *de facto* NLA should be the sum of those codes' NLAs. The maximum payment reduction in 2018 would be 10 percent of this *de facto* NLA. The 2019 payment reduction would be no more than 10 percent of the 2018 rate, and the 2020 payment reduction would be no more than 10 percent of the 2019 rate. Using this methodology, CMS would comply with the statutory limit on the year-to-year payment reduction without maintaining a system of different payment amounts in different localities. Using the lipid panel as an example, the CY 2017 NLA for HDL (CPT code 83718) is $11.24, and the CY 2017 NLA for ATP02 is $7.15. Their sum is $18.39. The 10 percent payment reduction limit would be applied as follows:

Lipid Panel (CPT code 80061)	
De facto CY 2017 NLA for lipid panel (sum of NLAs for 83718 and ATP02)	$18.39
Maximum 10 percent payment reduction (10 percent of *de facto* CY 2017 NLA)	$1.84
2018 rate (*De facto* CY 2017 NLA – maximum 10 percent payment reduction)	$16.55
2019 rate (2018 rate – 10 percent of 2018 rate)	$14.89
2020 rate (2019 rate – 10 percent of 2020 rate)	$13.40

The acute hepatitis panel (CPT code 80074) is another organ and disease panel without a CY 2017 NLA. CMS's preliminary 2018 rate for the acute hepatitis panel is $38.79. In 2017, it was paid most often at a price of $65.34, which is the sum of the CY 2017 NLAs for its constituent tests: Hepatitis A antibody (CPT code 86709), Hepatitis B core antibody (CPT code 86705),

[24] *See* 42 C.F.R. § 414.507(d); 81 Fed. Reg. 41079.

Hepatitis B surface antigen (CPT code 87340), and Hepatitis C antibody (CPT code 86803). The 10 percent payment reduction limit would be applied to the acute hepatitis panel this way:

Acute Hepatitis Panel (CPT code 80074)	
De facto CY 2017 NLA for acute hepatitis panel (sum of NLAs for 86709, 86705, 87340, 86803)	$65.34
Maximum 10 percent payment reduction (10 percent of *de facto* CY 2017 NLA)	$6.53
2018 rate (*De facto* CY 2017 NLA – maximum 10 percent payment reduction)	$58.81
2019 rate (2018 rate – 10 percent of 2018 rate)	$52.93
2020 rate (2019 rate – 10 percent of 2020 rate)	$47.64

Other test codes like this are:

- ACTH stimulation panels (CPT codes 80400 - 80406)
- Aldosterone suppression evaluation (CPT code 80408)
- Testosterone response panel (CPT code 80414)
- Estradiol response panel (CPT code 80415)
- Peripheral vein renin stimulation panel (CPT code 80417)
- Glucagon tolerance panel (insulinoma) (CPT code 80422)
- Glucagon tolerance panel (pheochromocytoma) (CPT code 80424)
- Gonadotrophin hormone panel (CPT code 80426)
- Growth hormone stimulation panel (CPT code 80428)
- Metyrapone panel (CPT code 80436)
- TRH simulation panels (CPT codes 80438 – 80439)

For other tests with a $0 NLA whose component codes do not have CY 2017 NLAs, the *de facto* NLA should be the highest local rate on the 2017 CLFS. CMS should apply the 10 percent payment reduction limit to this *de facto* NLA in CY 2018, as well.

In sum, for tests whose rates are calculated using the weighted median of private payor rates reported by applicable laboratories, as all of the above tests were, CMS cannot cut more than 10 percent from "the amount of payment for the test for the preceding year" (2017) without violating the statute. For each such test, CMS must determine "the amount of payment for the test for the preceding year" and limit any cuts to 10 percent of that amount.

IV. Other Issues

A. Automated Multi-channel Chemistry Tests

We wish to confirm that the 23 AMCC tests and the organ and disease panels that consist of AMCC tests will be paid based on the weighted medians of private payor rates received for each individual CPT code and that they will not be paid as bundles under the codes currently listed on the CLFS as "automated test panel" or "ATP" codes. These codes all are on the CLFS and CMS included them on its list of HCPCS codes about which applicable laboratories were required to submit applicable information. Consistent with this, reimbursement for each code is to be the weighted median of private payor rates reported by applicable laboratories.

The law sets forth clear instructions for when and how CMS is to develop new rates based on weighted medians of private payor rates. It does not permit CMS to determine which tests on the CLFS will be priced based on the weighted median of reported prices and which will be priced in some other fashion. Not paying for each of the AMCC codes individually would be contrary to both the letter and spirit of the law. CMS received private payor data from applicable laboratories for the AMCC tests and is required by Sec. 216 of PAMA and by CMS's own regulations to pay for the codes at the weighted medians of private payor rates.

B. Presumptive Drug Testing Codes

ACLA believes that the presumptive drug testing codes that first appeared on the CLFS in 2017 should maintain their current prices, as permitted under the statute. CMS did not receive any applicable information about CPT codes 80305, 80306, or 80307 during the first data reporting period under PAMA. This is because the codes did not exist on the CLFS during the first data collection period, which was the first six months of 2016. As a result, CMS could not calculate a weighted median for any of the codes for CY 2018. CMS has suggested re-crosswalking these codes to codes that no longer exist on the CLFS.[25] We do not believe that these codes may be crosswalked to non-existent G-codes. The crosswalking regulation says "Crosswalking is used if it is determined that a new CDLT is comparable to an *existing test, multiple existing test codes, or a portion of an existing test code.*"[26] The G-codes to which CMS has recommended re-crosswalking these codes no longer appear on the CLFS. However, we believe that the statute allows CMS to leave in place the current prices for these codes until after the next data reporting period.

As CMS acknowledged in the final rule implementing Sec. 216 of PAMA, the statute does not address how CMS is to price tests for which no applicable information was reported.[27] However, the statute does provide guidance to CMS on how it is to treat tests that received new codes on or after April 1, 2014. It says that in the case of a clinical diagnostic laboratory test that

[25] *See* Calendar Year (CY) 2017 Clinical Laboratory Fee Schedule (CLFS) Final Determinations, *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2017-CLFS-Codes-Final-Determinations.pdf.
[26] 42 C.F.R. § 414.508(b)(1) (emphasis added).
[27] 81 Fed. Reg. 41086

is assigned a new or substantially revised HCPCS code on or after the date of enactment of PAMA, "during an initial period until a payment rate under subsection (b) is established for the test, payment for the test shall be determined—(A) using crosswalking to the most appropriate existing test under the fee schedule under this section during that period" or through gapfilling.[28]

In late November 2016, CMS finalized its crosswalks for CPT codes 80305, 80306, and 80307 to then-existing test codes. Under the terms of the statute, "until a payment rate under subsection (b)[29] is established for the test," that crosswalked rate stays in place. The statute does not specify a minimum or a maximum number of years that a crosswalked rate may stay in effect—only that it is to remain in place until a weighted median of private payor rates can be calculated for that test. The "initial period" during which the crosswalked payment rate is to stay in effect is until after CMS calculates a weighted median for the new test, not the test to which it was crosswalked. Thus, the CY 2017 NLAs for these codes should remain in place until after the next data reporting period, when new payment rates will be calculated for them.

If CMS does not leave in place the CY 2017 NLAs for CPT codes 80305, 80306, and 80307, CMS must take into account the CY 2017 NLAs for each of these codes to calculate maximum rate reductions for CY 2018. For example, the CY 2018 rate reduction for CPT code 80307 should not be more than 10 percent of the CY 2017 NLA of $79.81, resulting in a CY 2018 rate of $71.83.

C. Definitive Drug Testing Codes

CMS cannot use the applicable information reported by applicable laboratories for HCPCS codes G0480 through G0483 to develop weighted medians for the CY 2018 rates because CMS materially revised the code descriptors for those codes as of January 1, 2017. As such, the applicable information that was reported for G0480 through G0483 is not relevant to the new codes. They must be treated as codes for which no applicable information was reported.

CMS substantially revised the code descriptors for the definitive drug tests represented by HCPCS codes G0480 through G0483 so that the codes could be used only by laboratories that employ highly complex mass spectrometry methods and several newly-added quality controls.[30] A new fifth code, G0659, was created to be used for lower quality and less expensive drug testing methodologies. In recognition of the material increase in resources required for the more complex methods and quality controls associated with the codes, reimbursement rates for these codes also were changed substantially. Reimbursement rates for codes G0480 through G0483 were increased by approximately 17 to 46 percent apiece. The lowest tier code (G0480) was priced about 50 percent higher than the lower quality test represented by G0659. These new codes and the new reimbursement rates became effective January 1, 2017. The old code descriptors that existed

[28] 42 U.S.C. § 1395m-1(c)(1).
[29] Subsection (b) of Sec. 216 of PAMA describes the methodology for calculating a weighted median from applicable information reported about a test.
[30] Under the Social Security Act, "a code shall be considered to be 'substantially revised' if there is a substantive change to the definition of the test or procedure to which the code applies (such as a new analyte or a new methodology for measuring an existing analyte-specific test)." 42 U.S.C. § 1395l(h)(8)(E)(ii).

during the data collection period are compared below to the code descriptors that were implemented on January 1, 2017 and that exist now:

HCPCS	Pre-2017 Code Descriptor	2017 Code Descriptor
G0480	Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 1-7 drug class(es), including metabolite(s) if performed	Drug test(s), definitive, utilizing: (1) drug identification methods able to identify individuals drugs and distinguish between structural isomers (but not necessarily stereoisomers), including but not limited to GC/MS (any type, single or tandem), and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing; 1-7

		drug class(es), including metabolite(s) if performed
G0481	8-14 drug classes	8-14 drug classes
G0482	15-21 drug classes	15-21 drug classes
G0483	22 or more drug classes	22 or more drug classes
G0659	*Did not exist.*	Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem), excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase), performed without method or drug-specific calibration, without matrix-matched quality control material, or without use of stable isotope or other universally recognized internal standard(s) for each drug, drug metabolite or drug class per specimen; qualitative or quantitative, all sources, includes specimen validity testing, per day, any number of drug classes)

HCPCS codes G0480 through G0483 were "assigned a new or substantially revised HCPCS code on or after the date of enactment" of Sec. 216 of PAMA. Accordingly, "payment for the test shall be determined…using cross-walking (as described in section 414.508(a) of title 42, Code of Federal Regulations, or any successor regulation) to the most appropriate existing test under the fee schedule under this section during that period."[31] These codes should be crosswalked to multiples of CPT code 82542, which remains on the CLFS and has a weighted median for CY 2018. CMS already has done the work and determined the proper crosswalks for these codes, given their methods and resources, and it should apply the same crosswalks as it did in November 2016 as follows:[32]

G0480	4 * 82542 + (3 * (.25 * 82542))
G0481	4 * 82542 + (10 * (.25 * 82542))
G0482	4 * 82542 + (17 * (.25 * 82542))
G0483	4 * 82542 + (25 * (.25 * 82542))

.

Alternatively, the CY 2017 NLAs for these codes could remain in place until after the next data reporting period, when new payment rate are calculated for them.

[31] 42 U.S.C. § 1395m-1(c)(1).
[32] *See* Calendar Year (CY) 2017 Clinical Laboratory Fee Schedule (CLFS) Final Determinations.

D. General Health Panel

The general health panel (CPT code 80050) is a bundled code composed of a comprehensive metabolic panel (CPT code 80053), thyroid stimulating hormone test (CPT code 84443), and complete blood count (CPT code 85025), when ordered and performed together. It has not been listed on the CLFS historically or used for Medicare claims. We are not aware that CMS has changed its policy or that it has directed any laboratory to use CPT code 80050 going forward.

CMS released a preliminary rate for the general health panel of $23.54. Not having been on the CLFS in the past, the general health panel does not have a CY 2017 NLA. However, each of the constituent tests of the general health panel does have a CY 2017 NLA, which sum to $48.20.

We know of no reason why CMS would add CPT code 80050 to the CLFS now, when its policy for many years has been that the code is not payable by Medicare. Whether or not applicable information was reported for a code has no bearing on whether it appears on the CLFS or whether it is payable by Medicare. If CMS were to develop a policy justification for starting to pay for CPT code 80050 and were to include it on the CY 2018 CLFS, then like the lipid panel and the acute hepatic panel discussed above, the agency should develop a *de facto* CY 2017 NLA for the general health panel and limit any payment rate reduction to no more than 10 percent from the *de facto* CY 2017 NLA. Based on this, the CY 2018 rate would not be lower than $43.38. The CY 2019 rate would not be lower than $39.04, and the CY 2020 rate would not be lower than $35.14.

E. CLFS Codes v. Codes for which CMS Collected Applicable Information

We ask CMS to confirm that its collection of applicable information for a code that is not on the CLFS does not indicate that the code will be included on the CY 2018 CLFS or on future years' fee schedules. When CMS first released the list of codes on which applicable laboratories were to report applicable information, ACLA noted to the agency that the list included a number of codes that are not on the CLFS. They include codes that are not payable by Medicare for one reason or another (*e.g.*, general health panel), codes that were on the CLFS during the data collection period but that since have been removed from the CLFS (*e.g.*, G0479), and codes that do not describe a specific test (*e.g.*, Tier II molecular pathology procedure codes). In the Final Rule, CMS had said that for purposes of reporting applicable information, "only private payor rates for CDLTs paid for under the CLFS are considered private payor rates."[33]

If the agency seeks to add a code to the CLFS or change its policy on payment for a code, it should continue to do so through the public consultation process described in Sec. 1833(l)(8) of the Social Security Act or through rulemaking. CMS should not include a code on the CY 2018 CLFS or subsequent fee schedules simply because it received applicable information for the code and calculated a weighted median. Furthermore, for codes that never were on the CLFS, CMS had no basis to collect applicable information in the first place. The agency should remove from its

[33] 81 Fed. Reg. 41055.

website weighted medians it calculated for each of these codes, as well as the raw data files and weighted median distributions for the codes, and it should not distribute this information.

F. Codes Gapfilled in CY 2017

Like the presumptive drug testing codes, CMS did not collect any applicable information on the codes that were gapfilled by Medicare contractors in 2017. CMS should follow its normal procedure for these codes and determine the median gapfill rate for each of them, which will be the CY 2018 rate. Then, "during an initial period until a payment rate under subsection (b) is established" for the test codes, the median gapfill rate should stay in place until after the next data reporting period, because these codes are new after the date of enactment of PAMA, and because CMS has not yet collected any applicable information for them.[34]

G. New Codes Crosswalked for CY 2018

A test code that is new in CY 2018 does not have a CY 2017 NLA, but it may be crosswalked to a code that does have a CY 2017 NLA. In most instances, the code to which it is crosswalked will have had a weighted median calculated from private payor rates reported by applicable labs. Under the language of the statute and CMS's own regulations, the maximum reduction from the CY 2017 NLA for that existing code will be 10 percent. When CMS crosswalks a new CY 2018 code to an existing code, it also should apply the existing code's payment rate reduction limitation, if applicable, to the new code. The purpose of using the crosswalk payment determination ultimately is to arrive at a CLFS rate for the new code, and the weighted median in these cases is not a fee schedule value in the years when CMS is phasing in a payment reduction, so it is not available to use as the fee schedule value for the new code.

For example, an existing test code "A" has a CY 2017 NLA of $100, and the weighted median that CMS has calculated is $70. A test code that is new in CY 2018 - test code "B" – is crosswalked to test code A. In CY 2018, test code A would be paid at a rate of $90, taking into account the first year 10 percent reduction limit. In CY 2019, test code A would be paid at a rate of $81, and in CY 2020, it would be paid at $72.90. In CY 2018, 2019, and 2020, CMS should pay for test code B at the same rates as it pays for test code A (rather than apply the weighted median for three years beginning in CY 2018) and treat the payment rates for the two codes the same, as it has in the past with codes that are crosswalked.

H. Calculation Errors

There are six HCPCS codes in the preliminary rate file whose CY 2020 rates are lower than the indicated weighted median rate. These CY 2020 rates should be corrected as follows before CMS finalizes the 2018-2020 rates:

- 82274 (Assay test for blood fecal): The weighted median rate is $15.92, but the CY 2020 preliminary rate is listed erroneously as $15.91. This should be $15.92.

[34] *See* 42 U.S.C. § 1395m-1(c)(1).

- 83630 (Lactoferrin fecal (qual)): The weighted median rate is $19.70, but the CY 2020 preliminary rate is listed erroneously as $19.63. This should be $19.70.

- 85347 (Coagulation time activated): The weighted median rate is $4.28, but the CY 2020 preliminary rate is listed erroneously as $4.26. This should be $4.28.

- 87169 (Macroscopic exam parasite): The weighted median rate is $4.31, but the CY 2020 preliminary rate is listed erroneously as $4.27. This should be $4.31.

- 88175 (Cytopath c/v auto fluid redo): The weighted median rate is $26.61, but the CY 2020 preliminary rate is listed erroneously as $26.49. This should be $26.61.

- 88262 (Chromosome analysis 15-20): The weighted median rate is $125.49, but the CY 2020 preliminary rate is listed erroneously as $124.64. This should be $125.49.

V. Conclusion

We very much appreciate that along with the preliminary rates, CMS released its raw data file and a summary of its approach to calculating new CLFS rates. The information has been extremely helpful to ACLA and other stakeholders reviewing the preliminary rates in order to provide feedback to the agency. We also appreciate your willingness to meet with ACLA representatives in person to discuss our concerns.

ACLA's position is that CMS must not implement any final rates until it has collected private payor data from all sectors of the laboratory market in proportion to their share of the laboratory market and in a manner that is not burdensome to laboratories, until there is reasonable certainty about the quality and integrity of the data used to develop those rates, and until those rates fairly reflect the significant private payor pricing differentials among different sectors of the laboratory market.

Thank you for your consideration of ACLA's comments.

Sincerely,

Julie Khani, President
American Clinical Laboratory Association