Summary of Data Reporting for the Medicare Clinical Laboratory Fee Schedule (CLFS) Private Payor Rate-Based Payment System

EXECUTIVE SUMMARY:

Section 216(a) of the Protecting to Access to Medicare Act of 2014 (PAMA) added section 1834A of the Social Security Act (the Act) which significantly revises the Medicare payment methodology for certain clinical diagnostic laboratory tests paid under the Clinical Laboratory Fee Schedule (CLFS). Beginning on January 1, 2018, Medicare will use certain private payor rate information reported by applicable laboratories to calculate Medicare payment rates for most laboratory tests paid under the CLFS. The use of market data to establish CLFS payment rates will strengthen Medicare by paying more appropriately for laboratory services and is expected to save the Medicare program and taxpayers money while maintaining beneficiaries' access to high quality laboratory services.

The preliminary private payor rate-based CLFS payment amounts are estimated to have an impact on Medicare Part B, including the Part B premium effects, of about -$670 million for calendar year 2018. We are seeking public comment on these rates by **October 23, 2017**. Detailed information regarding the private payor rate-based CLFS payment system, including the payment methodology, data reporting requirements, and the data reporting system for submitting private payor data to CMS, is available on the CLFS website at: CLFS PAMA Regulations.

BACKGROUND:

PAMA establishes that the Medicare payment amount for a test on the CLFS generally will be equal to the weighted median of the private payor rates determined for the test, based on the data that is collected during a data collection period and is reported to CMS during a data reporting period. The statute also provides for a phase-in of payment rate reductions for the first six years of the revised payment system. Specifically, for the first three years after implementation (CY 2018 through CY 2020), payment rate reductions for most CLFS tests, cannot be more than 10 percent per year, and, for the next three years (CY 2021 through CY 2023), the reduction cannot be more than 15 percent per year.

Through notice and comment rulemaking, CMS established the requirements for a laboratory to be an applicable laboratory, which is a laboratory that must collect applicable information for reporting to CMS. In order to be an applicable laboratory, a laboratory must meet the CLIA definition of a laboratory in 42 C.F.R. § 493.2 and, by its own billing National Provider Identifier (NPI), must meet the "majority of Medicare revenues" threshold (that is, receive more than 50 percent of its total Medicare revenues from the CLFS and or physician fee schedule (PFS) and the low expenditure threshold (that is, receive at least $12,500 in Medicare revenues for CLFS services) during a data collection period. The determination of "applicable laboratory" is made at the NPI level but the reporting of applicable information is done at the Tax Identification Number (TIN) level (by the "reporting entity").

With regard to hospital outreach laboratories, in response to public comment, CMS defined an applicable laboratory at the NPI level in order to allow hospital outreach laboratories that independently enroll in Medicare to be an applicable laboratory, provided they meet all other aspects of the definition. For example, a hospital outreach laboratory, either currently enrolled in Medicare as an independent laboratory (in which case it would already have its own NPI) 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, could meet the definition of an applicable laboratory if the laboratory meets the majority of Medicare revenue threshold and has more Medicare revenues than the low expenditure threshold.

CMS relies on each laboratory's attestation that the laboratory meets these criteria.

Applicable information means, with respect to each laboratory test for a data collection period: (1) the Healthcare Common Procedure Code System (HCPCS) code for the test; (2) each private payer rate for the test described by that HCPCS code for which final payment has been made and (3) the associated volume of tests performed corresponding to each private payer rate.

The initial data collection period for the new CLFS payment system occurred from January 1, 2016, through June 30, 2016. A 6-month window (in which applicable laboratories reviewed their data for accuracy and completeness) followed the data collection period. The initial data reporting period (in which reporting entities reported applicable information for their applicable laboratories to CMS) began January 1, 2017 and ended March 31, 2017. For most laboratory tests paid on the CLFS, the data collection, data reporting, and payment rate update schedule repeats every 3 years.

Industry feedback for this initial data reporting period suggested that many reporting entities would not be able to submit a complete set of applicable information to CMS by the March 31, 2017 reporting deadline, and that such entities would require additional time to review collected data, address any issues identified during such review, and compile the data into CMS's required reporting format. On March 30, 2017, CMS announced that it would exercise enforcement discretion until May 30, 2017, with respect to the data reporting period for reporting applicable information under the CLFS and the application of the Secretary's potential assessment of civil monetary penalties (CMPs) for failure to report applicable information. CMS specified that this 60-day enforcement discretion period was the maximum amount of time CMS could allow to still have sufficient time to calculate the CLFS payment rates scheduled to go into effect on January 1, 2018.

CMS is now soliciting comments on the preliminary calendar year 2018 Medicare CLFS rates, until **Monday, October 23, 2017**, and will publish the final rates in November. Comments must be submitted electronically by this date to the following CMS mailbox: CLFS_Annual_Public_Meeting@cms.hhs.gov

SUMMARY OF FINDINGS:

CMS received data from reporting entities in every state, the District of Columbia, and Puerto Rico. This data included 1,942 applicable laboratories with over 4.9 million records of applicable information representing a volume of almost 248 million laboratory tests.

CMS performed additional modeling to determine whether increased participation would significantly affect the payment rates. Through these simulations (discussed in more detail below), CMS confirmed that additional data reporting would not have made a significant impact on the preliminary payment rates.

Characteristics of Applicable Laboratories (NPIs)

CMS received data for 1,942 applicable laboratories as follows:

Type of Laboratory (NPI)	Total Number of NPIs	Percent of NPIs
Total	**1,942**	**100.00%**
Independent Laboratory	658	33.9%
Physician Office Laboratory	1106	57.0%
Hospital Laboratory	21	1.1%
Other (e.g., Urgent Care Center, Hospital Inpatient, FQHC)	157	8.1%

The table below shows the total laboratory test volume reported by laboratory type. Ninety (90) percent of the total laboratory test volume reported in the private payor data was from independent laboratories:

Type of Laboratory (NPI)	Reported Laboratory Test Volume	Percent of Total Reported Laboratory Test Volume
Total	**247,981,005**	**100.00%**
Independent Laboratory	223,586,265	90.1%
Physician Office Laboratory	18,689,597	7.5%
Hospital Laboratory	2,311,564	1.0%
Other (e.g., Urgent Care Center, Hospital Inpatient, FQHC)	3,393,579	1.4%

Our analysis also reviewed applicable information reported from rural regions and we found that 36 applicable laboratories (1.85 percent) are from rural regions. Rural laboratories are not likely

to have the test volume and corresponding revenue to meet the low expenditure threshold, that is, at least $12,500 in CLFS revenue during the data collection period.

Applicable laboratory status is determined by the applicable laboratory itself. When reviewing Medicare claims data for claims paid between January 1, 2016 and June 30, 2016, we found that about 37 percent of the applicable laboratories for which applicable information was reported may not meet the $12,500 low expenditure threshold and, therefore, might not meet the definition of an applicable laboratory.. As all laboratories are required to attest that they meet the definition of an applicable laboratory, we accepted this attestation. Therefore, the data submitted by these laboratories are included in the calculation of the weighted medians of the private payor rates. Similarly, while 21 hospital laboratories submitted applicable information; when reviewing the reported data we found that, 4 of the 21 hospital laboratories did not report applicable information with a distinct non-hospital NPI as required. As all laboratories are required to attest that they meet the definition of an applicable laboratory, we accepted this attestation. Therefore, the data submitted by these laboratories are included in the calculation of the weighted medians of the private payor rates.

Characteristics of Reporting Entities (TINs): 1074 reporting entities had registered to submit data in the CLFS data reporting system. 994 reporting entities submitted certified applicable information for their component applicable laboratories. It is possible that reporting entities that did not submit certified data may have determined during the process that they do not have component laboratories that meet the definition of an applicable laboratory and therefore, are not subject to the reporting requirements.

HCPCS Code Level Analyses

CMS received applicable information for the vast majority (95.7 percent) of HCPCS codes on the clinical laboratory fee schedule. These codes represented 96.1 percent of total spending on the CLFS in 2016.

In 2016, we published a list of Applicable Information HCPCS Codes (on the CLFS Web site at CLFS PAMA Regulations) which included 1,347 existing HCPCS codes. In addition, there are 13 new codes that were implemented on January 1, 2017 and 59 new codes to be implemented on January 1, 2018 for which there is no applicable information because the codes were not available during the January 1, 2016 through June 30, 2016 data collection period. For these new codes we are posting preliminary CMS determinations of crosswalking or gapfilling as the payment methods for CY 2018.

Additionally, CMS received no applicable information (either the private payor rates or volumes were zero or both were zero) for 58[1] HCPCS codes that existed during the January 1, 2016 through June 30, 2016 data collection period. For the majority of these codes there was little or no Medicare utilization in the 2016 claims data. We will also use crosswalking or gapfilling to set the rates for these codes for CY 2018. These codes will be subject to discussion at the September 25, 2017 meeting of the Advisory Panel on Clinical Diagnostic Laboratory Tests

[1] The file of the 60 codes that is posted on the CLFS Web site includes 2 erroneous codes (81504 and 0111T); hence the number of existing codes for which we received no applicable information is actually 58.

(https://www.gpo.gov/fdsys/pkg/FR-2017-09-14/pdf/2017-19539.pdf). We are also posting preliminary CMS determinations of crosswalking or gapfilling for these codes for CY 2018.

All HCPCS codes for which CMS has made preliminary determinations of crosswalking or gapfilling for CY 2018 are posted on the CLFS Web site at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings.html, *CY 2018 – Clinical Laboratory Fee Schedule Test Codes Preliminary Determinations*. Information on submitting comments for these codes are also included on this Web site; the deadline for submitting comments is also **October 23, 2017**.

Below is a table that shows the number of HCPCS codes reported by reporting entities (TINs).

Reporting Entities (TINs)	Number of HCPCS Codes	Percent of Total HCPCS Codes	Total Spending in 2016
1	48	4%	$140,640,036
2-10	199	15%	$103,445,948
11-50	319	25%	$133,124,131
51-100	178	14%	$109,271,704
101-300	419	32%	$1,261,207,411
301-611	127	10%	$3,912,625,645

- 48 HCPCS codes had applicable information reported by only one (1) reporting entity. The 48 codes accounted for 2% of total CLFS spending in CY 2016.

- 247 HCPCS codes had applicable information reported by 10 or fewer reporting entities. The 247 codes accounted for 3.8% of total CLFS spending in CY 2016.

The overwhelming majority of CLFS spending is represented by HCPCS codes that had more than 10 reporting entities, with 56 percent of codes having over 50 reporting entities (TINs). The codes with only one reporting entity are likely to be tests that are offered by only a single laboratory.

Outliers

CMS identified 4 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 4 reporting entities were contacted, 3 confirmed they misunderstood 'payment rate' and reported inaccurate data. Two (2) of the reporting entities submitted corrected data, which we included in calculating the weighted medians of the private payor rates); the 3rd reporting entity stated 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 rates). The 4th reporting entity we contacted did not provide us feedback on the accuracy its data; therefore, we removed this reporting entity's data from the calculation of

the weighted medians of the private payor rates. As an example, for one (1) laboratory test code, including the data from this reporting entity would have resulted in a private payor rate-based CLFS payment rate that was 42,637 percent greater than the 2017 NLA for the code.

In addition, for 12 reporting entities, 50 percent or more of their records had data that resulted in rates lower than the 5th percentile of the weighted median of the private payor rates. For an additional 57 reporting entities, 60 percent or more of their records had data that resulted in rates greater than the 95th percentile of the weighted median of the private payor rates.

We did not remove the data associated with these statistical outliers from the calculation of the weighted median of the private payer rates. Their impact on the weighted median should be minimal.

Preliminary CLFS Payment Amounts

The preliminary private payor rate-based CLFS payment amounts are estimated to have an impact on Medicare Part B, including the Part B premium effects, of about -$670 million for calendar year 2018.

- For approximately 10 percent of the HCPCS codes on the CLFS, the weighted median of the private payor rates is an increase over the CY 2017 CLFS NLA.
- For approximately 75 percent of the HCPCS codes on the CLFS, the weighted median of the private payor rates is a decrease from the CY 2017 CLFS NLA.
- About 58 percent of HCPCS codes will receive a phased-in payment reduction in CYs 2018, 2019, and 2020 rather than the full private payor rate-based payment amount in CY 2018 because the total payment decrease would be greater than the 10 percent floor.
- The Top 25 HCPCS codes, by 2016 CLFS spending, account for 63 percent of total CLFS spending. (See Appendix A)

The statute provides for a phase-in of payment rate reductions for the first six years of the revised payment system. Specifically, for the first three years after implementation (CY 2018 through CY 2020), payment rate reductions for most CLFS tests, cannot be more than 10 percent per year, and, for the next three years (CY 2021 through CY 2023), the reduction cannot be more than 15 percent per year.

Participation Simulations

Based on the applicable information collected during the data reporting period, the total spending for the CLFS for CY 2018, using the weighted median of private payor rates compared to the current CLFS rates (the 2017 NLAs), is expected to be a decrease of approximately 21.9 percent.[2]

[2] For purposes of the simulations, CMS calculated the 21.9% decrease which was based on the applicable information collected during the data reporting period and serves as a baseline comparison for the simulations. The 21.9% decrease does not account for the statutory phase in of payment rate reductions that will be incorporated in the CY 2018 CLFS.

We ran multiple simulations of the data to estimate the impact of increasing laboratory participation (i.e., increasing the data reporting) on the weighted median of the private payor rates and projected laboratory spending for CY 2018. The following summarizes the simulations and analysis:

- Increasing the volume of hospital laboratories reporting applicable information by 10 times (21 hospital laboratories times 10 equals 210).
- Increasing the volume of physician office laboratories reporting applicable information by 2 times (1106 physician office laboratories times 2 equals 2212).
- Increasing participation for all laboratories (independent, physician office, and hospital) using as weights the volume of CLFS HCPCS codes for each type of laboratory as represented in the 2016 professional and outpatient hospital (14x TOB) claims data. This analysis is an attempt to simulate what the results may have been had all providers receiving Medicare payment for CLFS services in CY 2016 reported applicable information to CMS, assuming their Medicare share of business would reflect their overall share.

Overall, as noted in the simulations below, there would be no significant impact on projected CLFS spending when reporting is increased by a multiple for hospital, office, and independent laboratories, although, increasing the reporting would make the reduction in spending somewhat less compared to the actual reporting.

We simulated the same three scenarios on the top 25 laboratory tests (based on Medicare spending) and found a similar pattern (see Appendix A for an analysis of the top 25 tests). A comparison of the simulation findings are below:

	Estimated Percent Difference in Total CLFS Spending for CY 2018 (Weighted Median of Private Payor Rates versus 2017 NLA)	
Simulation	**All Codes**	**Top 25 HCPCS Codes**
Baseline (actual reporting)	-21.9%	-24.6%
Increase hospital laboratory reporting by 10 times	-20.8%	-23.5%
Increase physician office laboratory reporting by 2 times	-20.4%	-22.9%
Increase hospital, physician office, and independent laboratory reporting	-19.9%	-23.0%

based on the volume of CLFS HCPCS codes for each laboratory type in the claims data		

NEXT STEPS:

- October 23, 2017: Public comment period closes for the preliminary determinations (codes to be crosswalked or gapfilled) and the preliminary CLFS rates and data files regarding applicable information for CY 2018.
- Early November 2017: CMS makes final CY 2018 CLFS rates available on the CMS website.
- January 1, 2018: Implementation date of new CLFS.

REQUEST FOR INFORMATION:

Additionally, in the Medicare Physician Fee Schedule proposed rule for calendar year 2018, CMS sought comment from applicable laboratories and reporting entities regarding their experience with the first data collection and reporting periods under the new private payer rate-based CLFS. Comments received will be used to inform CMS regarding potential refinement to the CLFS for future data collection and data reporting periods.

CMS is committed to the successful implementation of the new private payor rate-based CLFS and looks forward to continuing to work with the laboratory industry to help ensure accurate payment rates. CMS also appreciates the stakeholder participation and feedback we have received, and look forward to hearing comment on the preliminary CLFS rates.

Appendix A

Top 25 HCPCS Codes by 2016 CLFS Spending

HCPCS Code	HCPCS Code Description	Total 2016 Claim Lines	Total 2016 Payment	% of Total Spending	2017 NLA	Weighted Median	2018 Payment w/Cap	2019 Payment w/Cap	2020 Payment w/Cap
Total		**242,885,700**	**$4,072,744,372.55**	**63%**					
84443	Assay thyroid stim hormone	21,328,890	$478,201,900.40	7%	$23.05	$14.87	$20.75	$18.67	$16.80
80053	Comprehen metabolic panel	41,058,385	$464,050,570.56	7%	$14.49	$9.08	$13.04	$11.74	$10.56
85025	Complete cbc w/auto diff wbc	41,063,717	$425,439,439.40	7%	$10.66	$6.88	$9.59	$8.63	$7.77
80061	Lipid panel	28,716,199	$407,636,228.63	6%	$0.00	$11.23	$11.23	$11.23	$11.23
82306	Vitamin d 25 hydroxy	8,922,296	$347,582,955.60	5%	$40.61	$26.37	$36.55	$32.89	$29.60
83036	Glycosylated hemoglobin test	19,141,107	$248,747,306.97	4%	$13.32	$8.50	$11.99	$10.79	$9.71
G0483	Drug test def 22+ classes	1,183,239	$240,503,211.90	4%	$253.87	$193.71	$228.48	$205.63	$193.71
80048	Metabolic panel total ca	13,130,016	$128,574,438.03	2%	$11.60	$8.06	$10.44	$9.40	$8.46
G0482	Drug test def 15-21 classes	784,920	$126,254,803.37	2%	$204.34	$132.00	$183.91	$165.52	$148.96
83970	Assay of parathormone	2,176,845	$119,472,877.14	2%	$56.62	$36.76	$50.96	$45.86	$41.28
82607	Vitamin b-12	5,553,620	$111,752,421.91	2%	$20.68	$13.43	$18.61	$16.75	$15.08
85610	Prothrombin time	19,180,431	$102,955,635.98	2%	$5.39	$4.29	$4.85	$4.37	$4.29
84153	Assay of psa total	4,182,938	$102,655,551.38	2%	$25.23	$16.38	$22.71	$20.44	$18.39
84439	Assay of free thyroxine	7,001,009	$84,030,813.18	1%	$12.37	$8.03	$11.13	$10.02	$9.02

HCPCS Code	HCPCS Code Description	Total 2016 Claim Lines	Total 2016 Payment	% of Total Spending	2017 NLA	Weighted Median	2018 Payment w/Cap	2019 Payment w/Cap	2020 Payment w/Cap
87086	Urine culture/colony count	7,466,946	$81,233,769.73	1%	$11.07	$7.19	$9.96	$8.97	$8.07
G0481	Drug test def 8-14 classes	615,161	$72,905,808.62	1%	$160.99	$94.07	$144.89	$130.40	$117.36
G0480	Drug test def 1-7 classes	922,783	$68,205,583.28	1%	$117.65	$47.96	$105.89	$95.30	$85.77
82728	Assay of ferritin	3,663,893	$66,633,636.06	1%	$18.70	$12.13	$16.83	$15.15	$13.63
83880	Assay of natriuretic peptide	1,473,604	$66,286,148.81	1%	$46.56	$39.26	$41.90	$39.26	$39.26
81528	Oncology colorectal scr	122,759	$61,218,169.80	1%	$512.43	$508.87	$508.87	$508.87	$508.87
81519	Oncology breast mrna	17,892	$59,979,233.35	1%	$3,443.36	$3,873.00	$3,873.00	$3,873.00	$3,873.00
85027	Complete cbc automated	6,499,731	$55,439,625.60	1%	$8.87	$5.91	$7.98	$7.18	$6.47
82746	Assay of folic acid serum	2,835,646	$55,278,196.24	1%	$20.17	$12.88	$18.15	$16.34	$14.70
87186	Microbe susceptible mic	3,893,666	$49,897,154.33	1%	$11.86	$7.70	$10.67	$9.61	$8.65
G0103	Psa screening	1,950,007	$47,808,892.29	1%	$25.23	$19.31	$22.71	$20.44	$19.31