



## Initial Data Collection and Reporting Periods for Medicare Clinical Laboratory Fee Schedule<sup>1</sup>

CMS has requested feedback on the experience of applicable laboratories collecting and reporting data (each private payer payment for each test) that will be used by the Agency to calculate the rate for each test on the CLFS.<sup>2</sup> CMS is required by PAMA to implement this new payment methodology. **In brief, there were extensive challenges associated with the data collection and data reporting that call into question the accuracy of the payment rates that CMS intends to issue on January 1, 2018.** We emphasize that the lack of data accuracy has been driven by the Agency decision to impose a retrospective data collection period. This was further exacerbated by the sheer detail and volume of data requested for a period covering six months when a shorter period would have reduced the administrative burden and possibly increased accuracy.

We are also very concerned that CMS has not outlined how it will ensure that the final rates accurately reflect the submitted data without corruption once processed by CMS. Our concern is driven by the data errors found in the Open Payment Program in the first year of that program where both CMS and manufacturers alleged that the other party was responsible for the errors. (The situation is even more concerning here because unlike with the Open Payments Program where physicians are able to look at a report and challenge the accuracy, there is no similar process for clinical laboratories to assess whether data that is substantially different from their payment for each test reflects legitimate market variance from other clinical laboratories performing the tests or errors in CMS data processing.)

During PAMA CLFS rulemaking, the AMA urged CMS to provide applicable laboratories adequate time to prepare for and then comply with the reporting obligations. The AMA noted that the reporting requirements are detailed, resource intensive, ambiguous in some areas, and confusing. We underscored that this would be difficult for all clinical laboratories subject to reporting, but to the extent physician office based laboratories (POLs) would be reporting the complexity of the statute, the proposed rule, and the interplay of the various provisions would be overwhelming.

This new law and then proposed rule was the most significant change to occur on the CLFS since 1984 when Medicare began paying for clinical testing services. It was further exacerbated by the fact that there is a general lack of awareness among POLs and the vast majority of national medical specialty societies that POLs receive payment for their clinical test based on the CLFS. The AMA specifically noted that we did not support the start of the initial data collection period until six months after the Agency issued the final rule. Though several stakeholders that were not experienced in implementing large scale changes in payment recommended the initiation of the reporting period potentially before the final rule was issued, the AMA stated in our comments that applicable laboratories may have to hire/train staff and resolve

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<sup>1</sup> Excerpt of AMA comments submitted on September 11, 2017, concerning the Medicare Program: Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program (CMS-1676-P)

<sup>2</sup> The AMA's comments in response to the CMS question and implementation of the PAMA CLFS provisions focus nearly exclusively on clinical diagnostic laboratory tests (CDLT) as the same issues and problems with accurate reporting and transparent calculation by CMS of the final payment rate do not apply to advance diagnostic laboratory tests (ADLTs) or sole source tests that are CDLTs.

software issues in advance to ensure the data is being captured contemporaneous with the data collection period.

The AMA noted that to the extent POLs must report, they are not as likely to have the resources, including the data analytics, to assess whether they will be subject to the reporting requirement the first year of reporting and every third year thereafter. The AMA noted that CMS has claims datasets and the analytics to assess whether a POL meets the reporting requirements based on prior year claims. We strongly urged CMS to provide POLs with advance notice that the POL will be subject to the data collection and reporting requirements. The AMA observed that this was one strategy to enhance the accuracy and reliability of the data that CMS would rely upon to calculate the weighted median of private payer payments and mitigate the risk of civil monetary penalties. CMS rejected both recommendations and effectively created a perfect storm where it has been impossible for many clinical laboratories to accurately report, particularly POLs.

The above was further exacerbated by CMS' decision to require six months of data collection. The AMA strongly urged CMS to reduce the data collection period from a full calendar year every three years to three months of data collection every three years for clinical laboratory developed tests (CDLTS). The AMA stated that the data collection burden of reporting every private payer payment for all tests for a full year would divert already scarce health care resources to administrative tasks instead of to providing clinical care and services. The AMA was aware that other major clinical laboratory stakeholders were recommending six months, but it was very evident that they did not understand the sheer volume of data involved and the strong possibility of errors introduced into the data collection due to the lengthy reporting period. And, the AMA specifically called out that this reporting requirement would fall heavily on POLs—physician practices that are already facing quality reporting, Meaningful Use requirements, and implementation of alternative delivery (and payment) models. A three-month data collection requirement would ensure that the Agency had an enhanced possibility of receiving current and accurate data.

The extreme difficulties experienced by even the largest reference laboratories (that were involved in crafting the PAMA legislation, knew the statutory requirements, contract with sophisticated clearinghouses for claims management, and followed the rulemaking process) underscores that retrospective data collection constituted an impossibility for many clinical laboratories, particularly the small, regional independent clinical laboratories and the physician office-based laboratories. The physician community was not engaged in the development of the legislation and most physician office-based laboratories have still not received effective outreach from the Agency on whether or not they are an applicable laboratory.

It is notable that the largest reference laboratories sought extensions for the data reporting because of the challenges associated with paper claims reporting, in particular. Many POLs and regional, rural, small independent clinical laboratories serving underserved areas are more likely to have a larger number of paper claims and less likely to have resources to hire additional staff and vendors to assist with the claims tracking and validation. This data collection and reporting obligation was designed for sole source clinical tests and the large reference clinical laboratories, but not even the large clinical laboratories could report on time and there remain many questions as to the methods used to collect data after the fact given the sheer volume and the complexity of the reporting requirement. We emphasize that the AMA is not

asserting that applicable laboratories failed to utilize best efforts to submit accurate data. Instead, based on what we have learned it appears that for most, if not all, applicable laboratories the retrospective, six-month data collection requirement constituted an impossibility.

There are two additional examples that raise questions vis-à-vis whether accurate reporting was possible.

First, the difficulties with accurate reporting have been exacerbated by the practice of Medicare contractors, in particular the molecular diagnostic (MoIDX) program administered by Palmetto GBA requiring clinical laboratories to use codes other than the applicable CPT codes to report a clinical test in that jurisdiction. Because private payers require clinical laboratories to utilize the applicable CPT codes consistent with the mandate of the Health Insurance Portability and Privacy Act, there is a mismatch between the codes used to report the clinical test in the Medicare program and among private payers. This practice must be curtailed as it is in conflict with the clear requirements of PAMA. If Palmetto GBA requires differential identification, it must either direct clinical laboratories to assign a modifier to the applicable CPT code or direct clinical laboratories to obtain a proprietary CPT code (which were created to accommodate PAMA requirements).

Second, CMS noted earlier this summer that it had not received any data and/or insufficient data to calculate a weighted median private payer rate for sixty codes (clinical tests). As noted during the AMA's public comments as part of the Annual CLFS meeting, our concern with the lack of data accuracy have been reinforced by the late notice provided by CMS that no data was produced for 60 codes. CMS requested comments on whether sixty codes should be included on the CLFS. On the one hand the 60 codes may no longer be offered by applicable laboratories, on the other hand these tests may still be offered. We do not know.

We are extremely concerned that patient access will be harmed in early 2018 which would be challenging and difficult, but will undermine nascent and important efforts to implement payment and delivery reform under the Medicare Access and CHIP Reauthorization. Reasonable and measured policy adjustments are needed so that the most frail and vulnerable are not required to shoulder the consequences of poor implementation. This will also ripple across the health care infrastructure and impose additional pressure that is not necessary because there are reasonable and sensible alternatives that will provide CMS with essential facts to guide policy decision-making. Furthermore, we are very concerned that implementation of inaccurate and excessively low payment for clinical tests will lead to many POLs and small, independent clinical laboratories around the country to stop offering testing for patients for rapid, near patient testing for infectious disease. This will degrade the necessary clinical laboratory infrastructure that ensures accurate detection of infectious disease outbreaks. Many rural regions will be especially vulnerable where coverage from the large national reference clinical laboratories is more limited.

**The AMA strongly urges CMS to conduct a market segment survey (to include consideration of the market for reference laboratories, physician office-based laboratories, independent laboratories, and hospital laboratories) in order to assess the accuracy of the data collected as part of the data collection exercise.** The foregoing is needed in order to validate and adjust the final amount calculated based on the data collection to ensure it accurately reflects private payer payments—which CMS has the authority to do under a general grant of authority in the Social Security Act to administer the Medicare

program and to ensure the integrity of the Medicare program.<sup>3</sup> At a time when relief from overly burdensome regulation has become a top priority of the current administration, we urge CMS to ensure that implementation of PAMA results in as little administrative burden and disruption as possible.

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<sup>3</sup> We urge CMS to exclude from the interim final rule sole source clinical tests including those that could be considered advanced diagnostic laboratory tests (ADLTS) and other clinical tests with a limited number of laboratories that perform such clinical tests. Laboratories with such tests had little to no difficulty, reportedly, preparing to report accurate data given their small test menu and overall awareness of the PAMA provisions. Furthermore, if the final weighted median is inaccurate, it will be easier to assess by such clinical laboratories given the limited universe of data sources.