



ASSOCIATION FOR MOLECULAR PATHOLOGY

Education. Innovation & Improved Patient Care. Advocacy.

9650 Rockville Pike, Suite 205, Bethesda, Maryland 20814

Tel: 301-634-7939 | Fax: 301-634-7995 | amp@amp.org | www.amp.org

September 10, 2018

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1693-P
P.O. Box 8016
Baltimore, MD 21244-8013

RE: CMS-1693-P

Dear Administrator Verma:

The Association for Molecular Pathology (AMP) appreciates the opportunity to provide comments on the CY2019 Physician Fee Schedule proposed rule. AMP is an international medical and professional association representing approximately 2,400 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from the government, academic medicine, private and hospital-based clinical laboratories, and the in vitro diagnostics industry.

We look forward to working closely with CMS as this proposed rule moves toward implementation and offer the following response to your solicitation of comments on issues directly related to the Protecting Access to Medicare Act (PAMA).

Solicitation of Public Comments on the Protecting Access to Medicare Act (PAMA)

AMP appreciates that CMS is soliciting stakeholder feedback in an attempt to better understand applicable laboratories' experiences during the first reporting period under PAMA, including the data reporting, data collection, and other compliance requirements. AMP welcomes the opportunity to work with the agency to ensure that PAMA is implemented successfully and accurately represents the market rates paid for laboratory tests. However, we have significant concerns about the process of and rates set from the first reporting period, which have resulted in inaccurate and inequitable pricing. AMP believes that the agency needs to revisit the reporting requirements and process, as well as address data integrity concerns.

There is wide recognition and concern across the laboratory, hospital, physician, and patient community that the rates set under PAMA threaten patient access to laboratory testing. While the questions within the CY2019 Physician Fee Schedule Proposed Rule related to PAMA concentrate on the definition of "applicable laboratory," AMP believes that any changes to PAMA must first address and fully resolve the concerns surrounding data

collection and integrity. Moreover, attempting to expand which laboratories qualify as applicable laboratories without addressing data integrity and reporting issues may actually exacerbate the problems with reporting and increase the discrepancies contained within the data. According to the Office of Inspector General's (OIG) July 2018 report, labs reported difficulty determining if they met CMS' criteria to report applicable information. The OIG reported that at least 20 high-volume independent labs did not report in 2017 that likely met the majority criterion.^[1] Further, CMS reported that 37% of reporting labs were exempt from reporting because they did not meet the requirements of the low-expenditure threshold.^[2] The report concluded that these problems may not have had a meaningful impact on the 2018 rates, but pose a risk in future reporting periods.

We believe that one of the reasons for the flaws in the data may have been that the first round of reporting payment rates to CMS required the reporting of retrospective data. The OIG highlighted this as a concern as well. The agency's regulation was finalized just prior to the end of the first 6-month data collection period and applicable laboratories were required to retroactively collect data based upon the final rule's requirements. Laboratories were forced to gather information not readily available in their billing systems in a short amount of time and they reported significant burden in collecting information, including difficulties compiling information from numerous different sources of payment (i.e., primary insurance, secondary insurance, co-pays, etc.) and difficulty dealing with information contained in paper claims. As a result of the delay in the release of the final regulations, large and small laboratories struggled to submit the required data accurately. The OIG also found that CMS provided limited quality assurance during the data collection and reporting periods.

AMP has already communicated to CMS that the first round of PAMA reporting resulted in significantly flawed pricing and remains alarmed by the data reported and submitted for most molecular pathology procedures commonly utilized in the Medicare population. While phased-in reductions and the use of the weighted median calculation to determine rates are touted as safeguards by CMS to extreme outliers and decreases in prices, molecular pathology procedures are more susceptible to potentially faulty data for a number of reasons. Unlike long-established laboratory procedures, the Tier 1 and Tier 2 molecular pathology procedures were established and put on the Clinical Laboratory Fee Schedule (CLFS) in 2012 and underwent gapfill in 2013. In 2014, the first genomic sequencing procedures were placed on the CLFS and gapfilled the following year. The incorporation of molecular pathology procedures onto the CLFS continues to this day, as evidenced by the annual meetings. As new codes are added to the molecular code set, it takes laboratories time to become familiar with them and code these services correctly. Additionally, the volume for many of the codes remains relatively low compared to the more well-established tests on the CLFS. Therefore, submission of inaccurate data impacts the weighted median to a larger degree for these codes.

Of the over 230 molecular tests (including oncology, inherited diseases, and infectious diseases) on the CLFS, 57% decreased in value while 20% increased from their 2017 National Limitation Amount (NLA). Ninety molecular tests (or roughly 40%) decreased by 30% or more. Moreover, there are many instances within the

^[1] "Setting Medicare Payment Rates for Clinical Diagnostic Laboratory Tests- Strategies To Ensure Data Quality." OIG, July 2018, <https://oig.hhs.gov/oei/reports/oei-09-17-00050.pdf>

^[2] "Summary of Data Reporting for the Medicare Clinical Laboratory Fee Schedule (CLFS) Private Payor Rate-Based Payment System." CMS, 22 Sept. 2017, <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf>

molecular code set where a high volume of reported payments and their corresponding price amounts do not cover the cost of providing a service. In addition to the underlying data integrity issues regarding the payment amounts reported, CMS did not release the raw data that was reported for fewer than 10 TINs. This is especially significant for molecular pathology procedures as there are over 50 molecular service codes on the list of services where fewer than 10 TINs reported data, depriving AMP of the opportunity to review the raw data for outliers or other inaccuracies that may impact pricing. Without an opportunity to review this data, stakeholders cannot accurately assess the values. CMS must take steps to address the data accuracy, integrity, and transparency issues such as these in future price setting under PAMA. To help improve data integrity, we believe that the data should be reviewed to confirm that the reported payments are reasonable before they are used to calculate the weighted median to set the service's price.

AMP recognizes that many stakeholders believe that hospital outreach laboratories should not have been excluded from the definition of applicable laboratory and that their inclusion would significantly raise the weighted median of the reported data, despite CMS' analysis showing otherwise. However, AMP remains concerned that it is difficult for hospital and other laboratories to accurately extract payer information from their records. While laboratories will be better prepared to report during the next reporting period, we anticipate they will remain relatively overwhelmed by the process and report with varying degrees of success. Many laboratories still do not have the systems in place to determine the private payor payment rates for each test and the associated volume of those tests and do not have the resources to significantly change their systems as reimbursement levels decrease under PAMA. Thus, expanding the definition of an applicable laboratory would likely result in further inaccuracies and reporting errors present in the first data collection and reporting period. AMP does not recommend that CMS revise the definition of applicable laboratories unless and until the reporting process is refined.

Instead, AMP urges CMS to implement measures to safeguard data integrity in future reporting periods to address the concerns the OIG and AMP have articulated. Also, the agency should consider implementing a data aggregation system in future reporting periods. The statute grants CMS this authority after the first reporting period:

“In the case where an applicable laboratory has more than one payment rate for the same payor for the same test or more than one payment rate for different payors for the same test, the applicable laboratory shall report each such payment rate and the volume for the test at each such rate under this subsection. Beginning with January 1, 2019, the Secretary may establish rules to aggregate reporting with respect to the situations described in the preceding sentence.”^[3]

While the statute explicitly grants CMS this authority, no steps have been taken to implement it. We believe that data aggregation may guarantee more complete reporting and may expand the ability of laboratories to report more accurate data.

^[3] Protecting Access to Medicare Act of 2014, H.R. 4302, 113th Congress. (2014).

Solicitation of Public Comment on the Proposed Change to the Majority of Medicare Revenues Threshold in Definition of Applicable Laboratory

PAMA states that “with respect to its revenues under this title, a majority of such revenues are from” the CLFS and the PFS in a data collection period when defining a majority of Medicare revenues. In the PAMA final rule, CMS stated that “revenues under this title” are payments received from the Medicare program, which includes fee-for-service payments under Medicare Parts A and B, as well as Medicare Advantage (MA) payments under Medicare Part C, and prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance amounts for Medicare services furnished during the data collection period. This total Medicare revenues amount (the denominator of the majority of Medicare revenues threshold calculation) is compared to the total of Medicare revenues received from the CLFS and/or PFS (the numerator in the majority of Medicare revenues threshold calculation). If the numerator is greater than 50 percent of the denominator for a data collection period, the entity has met the majority of Medicare revenues threshold criterion.” The agency believes the current definition may exclude laboratories that deliver services to significant numbers of beneficiaries enrolled in MA from meeting the majority of revenues threshold criterion and is requesting comment on whether MA plan revenues should only be considered private payer payments rather than both Medicare revenues and private payer payments.

AMP supports the removal of Medicare Advantage plan payments under Medicare Part C from the total revenues when calculating the majority of Medicare revenues and only considering these plans to be private payers. We believe that this is consistent with what Congress intended when they defined MA plans as private payers in the statute.

Solicitation of Public Comments on Other Approaches to Defining Applicable Laboratory

We understand that CMS is exploring ways to increase the number of hospital outreach laboratories reporting data and meet the definition of applicable laboratory despite Congress’ apparent intent to exclude them based on their definition of applicable laboratory that required an entity’s revenues from the CLFS and PFS to constitute a majority of its total payments received from the Medicare program for a data collection period. As such, we provide the following comments on the alternatives CMS outlines that have been suggested by stakeholders.

CMS-1450 14x Bill Type

AMP has significant concerns about using the CMS-1450 14x bill type to define applicable labs. As the agency correctly recognizes, this bill type captures Medicare Part B revenues only and would essentially make every hospital laboratory an applicable one. We share CMS’ interpretation of the statute, as discussed above, that Congress did not intend for hospital laboratories to shoulder this reporting burden.

AMP is also concerned that by using the CMS-1450 14x bill type, the form will only capture Part B spending and payment documentation. Private payer rates will not be captured and this contradicts the legislative intent in establishing a rate setting methodology based on private payer rates.

Not only do we believe that using this bill type will violate Congressional intent, it will also place an unnecessary administrative burden on these laboratories. The bill will correctly identify Medicare Part B revenues, but the laboratories would then be responsible for correctly identifying and collecting private payer rates. The billing systems for these laboratories are not arranged such that this information can be easily extracted. It would require a whole new system to be developed at potentially considerable cost to the laboratories. Again, AMP is

not confident nor has it seen any data that the burden associated with reporting this data would change the reported rates to significantly raise the weighted median. If the rates were calculated based on a weighted mean, this might not be the case. However, that would take an act of Congress to change.

Furthermore, if CMS were to implement a requirement of hospital laboratories to report, it would potentially exacerbate existing data integrity issues for the second rate setting exercise. The data collection period begins on January 1, 2019. This would not provide hospital laboratories with sufficient time to put the needed systems in place to collect this data for the first 6 months of 2019. The agency would be running the risk of having inaccurate data reported again.

Using CLIA Certificate to Define Applicable Laboratories

In response to stakeholder comments, CMS is requesting comment on defining applicable laboratories by CLIA certificate. AMP agrees with the agency's assessment of the potential problems with this definition, namely that this definition would be overly inclusive and include all hospital laboratories, not just hospital outreach laboratories. We do not recommend that the agency define applicable laboratories in this manner. In short, using this method would be overly inclusive and a laboratory's CLIA certificate has no relationship to its billing, potentially creating other unintended consequences if implemented.

Thank you for the opportunity to provide these comments. If you require any further information or require additional information, please contact Tara Burke, PhD, AMP Director of Public Policy and Advocacy, at tburke@amp.org.

Sincerely,

Kojo S.J. Elenitoba-Johnson, MD
President, Association for Molecular Pathology