ASSOCIATION FOR MOLECULAR PATHOLOGY
Education. Innovation & Improved Patient Care. Advocacy.
9650 Rockville Pike. Bethesda, Maryland 20814
Tel: 301-634-7939 | Fax: 301-634-7995 | amp@amp.org | www.amp.org

November 24, 2015

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Clinical Diagnostic Laboratory Tests Payment System Proposed Rule; CMS-1621-P

Dear Mr. Slavitt:

Thank you for the opportunity to comment on the Medicare Clinical Diagnostic Laboratory Tests Payment System proposed rule, implementing the provisions of the Protecting Access to Medicare Act (PAMA) to reform the payment system for clinical diagnostic laboratory tests (CDLTs). The Association for Molecular Pathology (AMP) is an international medical and professional association representing over 2,300 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. Below, we expand on specific sections of the proposed rule that AMP feels require some further consideration before the rule is finalized.

Definition of Applicable Laboratories

CMS proposes that Applicable Laboratories be defined to include only those labs that receive more than 50 percent of their Medicare payments from services billed under the current Clinical Laboratory Fee Schedule (CLFS) and the Physician Fee Schedule. Based on the information provided in the proposal, the definition will exclude most hospitals and large healthcare providers. We thank CMS for this decision, and for recognizing that requiring reporting would be unduly burdensome to hospitals. The addition of complicated reporting requirements, in conjunction with the statutory penalty for failure or incorrect reporting, would potentially discourage hospitals from providing molecular pathology testing and other reportable testing in-house, resulting in a substantial decrease in access to testing for Medicare beneficiaries and a decrease in patient choice over critical healthcare decisions. Further, while we support the exclusion of most hospital and large healthcare providers from the definition of applicable laboratories, we are concerned that their exclusion will create a bias that will drive prices for molecular pathology procedures down.

Advanced Diagnostic Laboratory Tests (ADLTs)

The narrow definition of ADLTs proposed by CMS will unduly limit the number of tests that qualify as ADLTs. CMS proposed that an ADLT meet the following criteria: 1) must be a molecular pathology analysis of multiple biomarkers of DNA, or RNA; 2) when combined with an empirically derived algorithm, yields a result that predicts the probability a specific individual patient will develop a certain condition(s) or respond to particular therapy(ies); 3) provides new clinical diagnostic information that cannot be obtained from any other tests or combinations of tests; 4) may include other assays; 5) is designed, marketed, performed, and sold by a single laboratory; and 6) is cleared or approved by the FDA.

We note that this definition does not meet the criteria outlined in PAMA itself. The statute states the following: "The test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined in a unique algorithm to yield a single patient specific result." Based on the statutory provision, **AMP requests CMS include in the criteria defining ADLTs the same criteria used in the statute, namely requiring that it be a molecular pathology analysis of multiple biomarkers of DNA, RNA, or proteins.**

Unique Identifiers

AMP has long advocated that whenever possible existing CPT codes be used to identify these diagnostic tests and support the Agency's proposal not to create a new coding structure to meet PAMA's unique identifier requirement. AMP is concerned that potential proliferation of temporary G-codes would create complexity for PAMA data collection and reporting efforts where private payers are using a different code from Medicare. Further, switching from temporary G codes to a permanent CPT code structure creates uncertainty in pricing and may trigger a second round of coverage and pricing determinations, which raises significant concern for AMP members as multiple rounds of coverage and pricing determinations require extensive resources. Therefore, **AMP requests that CMS use the new clinical laboratory test section of the CPT code set approved by the American Medical Association (AMA) CPT Editorial Panel to fulfill the PAMA codification requirements.**

The AMA CPT panel recently authorized the establishment of a new section in the CPT code set. AMP believes that this new infrastructure will allow CMS to limit its reliance on temporary G-codes. CPT has created an infrastructure whereby a clinical laboratory or manufacturer that meets certain criteria may request a code to more specifically identify their test. This new section will be separate from the Category I Pathology and Laboratory section and will include ADLTs and CDLTs that are cleared or approved by FDA. Codes in this new section will be issued on a quarterly bases and be effective the following quarter. The Panel would be responsible for verification of the information submitted and codification of tests in this section. This new section provides a sustainable coding infrastructure utilizing an established, transparent process that will ensure consistent national coding across Medicare and other public and private payers. We encourage CMS to adopt codes from this new section whenever possible, rather than assigning G-codes or any other code set for these services.

Data Collection and Reporting Timeline

The proposed rule requires applicable labs to report the volume of tests at each payment rate received during the data collection period. For data collections purposes, the proposal is not clear if the lab is to report per the date the test is performed or the date the payment is received. We urge CMS to clarify this in the final rule because it is possible that the two dates may not fall within the same data collection period.

CMS proposed that final payment rates will be published in November and new rates will take effect on the first of the year. **We are concerned that this will not provide sufficient time to validate and appeal these rates and urge CMS to publish these rates earlier in the year, giving interested parties more time to review the new payment rates.**

AMP is also concerned with the proposed rule's data collection and reporting timeline. While PAMA required the new payment system to be in place January 1, 2017, the legislation also required CMS to implement a final rule by June 30, 2015, providing an 18 months for applicable laboratories to understand and comply with the reporting requirements. These labs will not have experience with or the infrastructure to collect and report private payor data and will need time to build the necessary systems to collect and report data to CMS. Because there was a significant delay by CMS in formulating the proposal, a final rule will not be in place by January 1, 2016. In the proposed rule, the data reporting period is scheduled to begin on January 1, 2016. **We urge CMS to postpone the effective date of the new rates to provide applicable labs the 18 months contemplated by the statute to prepare for this significant change in process and payment.**

The Gapfill Process

CMS proposes to use the gapfill and crosswalk processes for new tests until prices are established and the new reporting process can be used. The Agency also proposes to provide explanations for gapfill determinations; currently, explanations are provided for crosswalking, but not gapfill. For Tier1 Molecular Pathology and Genomic Sequencing Procedure CPT codes, AMP recommends crosswalk rationales but asks that if CMS prescribes gapfill for any CPT code present on the clinical lab fee schedule, that the process be implemented properly and with transparency. **Therefore, AMP supports the Agency's proposal to provide explanations for prices determined by gapfill, but urges CMS to make further improvements to the gapfill process.**

While the Agency has confidence in the gapfill process, AMP believes there are concrete steps to augment not only the process, but the prices that result from it. In 42 CFR 414.508(b), the requirements for the process are outlined as follows:

> Gapfilling is used when no comparable existing test is available.
>
> (1) In the first year, carrier-specific amounts are established for the new test code using the following sources of information to determine gapfill amounts, if available:
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> (i) Charges for the test and routine discounts to charges;
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> (ii) Resources required to perform the test;
>
> (iii) Payment amounts determined by other payers; and
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> (iv) Charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant.
>
> (2) In the second year, the test code is paid at the national limitation amount, which is the median of the carrier-specific amounts.

(3) For a new test for which a new or substantially revised HCPCS code was assigned on or before December 31, 2007, after the first year of gapfilling, CMS determines whether the carrier-specific amounts will pay for the test appropriately.

To ensure the process functions in accordance with these regulations, AMP requests that CMS clearly articulate what data sources can and must be used in the process to the Medicare Administrative Contractors (MACs). Also, both MACs and labs should be educated on what is expected of them for the gapfill process to work as intended. Most importantly, AMP requests that the process become more transparent, so that interested parties can better understand how the preliminary and final gapfill determinations were reached. We believe that implementing these changes will significantly improve the gapfill process functions and its results.

Local Coverage Determination (LCD) Process

PAMA provides that appeal and review of LCDs for CDLTs must be consistent with the existing LCD appeal and review rules. **AMP agrees that the existing LCD process can and should remain in place, but urges CMS to ensure that MACs follow the process as articulated in the guidance and make the following improvements.**

AMP urges CMS to reduce both CMS and the MAC's reliance on any single contractor's policies when making coverage determinations. As long as the current number of contractors is maintained, each MAC should independently evaluate each service and promulgate a policy in accordance with the Agency's LCD guidance. MACs represent different areas of the country, which vary in population diversity and testing needs. MACs should only adopt another jurisdiction's policies after thorough review, scrutiny and input from the local MAC's Carrier Advisory Committees (CACs). As testing is performed in diverse areas of the country, this will ensure that the diversity of expertise is considered in this process.

Also, CMS must ensure that MACs follow the guidance on LCDs and require MACs to consider comments received through the public comment process. On more than one occasion, final LCDs have been posted a day after the close of the public comment period. Subject matter experts within the MAC jurisdictions as well as professional societies spend an enormous amount of time reviewing each coverage policy and expect that each response to draft LCDs be given serious consideration by the MACs before LCDs are finalized. Therefore, MACs should be required to thoroughly respond to the comments received on their policies during the public comment period.

Finally, AMP requests that CMS increases the transparency in the LCD process. By doing this, stakeholders will have more confidence in the process, especially if it makes it clear that their input is thoroughly considered during the determination of the final policies.

MAC Consolidation

PAMA provided CMS with the authority to consolidate the number of MACs so there would be between 1 and 4 MACs. In the proposed rule, the Agency says that the medical complexity and volume of these tests requires them to seriously consider the consolidation and seeks feedback on consolidating the MACs for both policy and claims processing functions.

AMP strongly opposes consolidating the MACs for both claims processing and policy purposes and asks that CMS preserve the current system that utilizes multiple contractors to determine coverage policies and process claims for diagnostic laboratory tests. Having a single MAC for policy purposes would create a *de facto* national coverage determination (NCD), losing the varied approach to coverage determinations the current scheme is

intended to foster. Competition and varied input is critical to the coverage process employed by the MACs, ensuring a full complement of evidence and experience is considered in coverage determinations. Losing this variety would be particularly harmful in the field of molecular diagnostics where the technology is constantly evolving.

However, AMP would support a uniform appeals adjudication process across the MACs. This process would include input from the relevant specialty societies and utilize the best available evidence. This type of process would ensure that appeals were subject to a uniform process and were based on most current science.

Advisory Panel on Clinical Diagnostic Laboratory Tests

AMP is pleased that the Secretary of the Department of Health and Human Services established this Advisory Panel to provide input on the many important issues related to clinical diagnostic laboratory testing. AMP has been actively engaged in the first two meetings of this panel and will continue to monitor the Advisory Panel's activity and participate whenever possible. During the first two Advisory Panel meetings, we noticed that there were certain technical topics discussed by the panel for which it did not have a subject matter expert. AMP recommends that in instances when the panel members lack subject matter expertise that CMS and the Advisory Panel invite subject matter experts in advance to participate in the meetings and provide relevant information to the panel to inform its deliberations. **Further, AMP requests that CMS follow more closely the recommendations of the Advisory Committee on Clinical Diagnostic Laboratory Tests, as that body exists to provide input from experts who are broadly representative of the laboratory community so that CMS actively engages in an open, transparent public decision-making process.**

According to the Federal Advisory Committee Act, agencies are required to give only 15 days notice of the meetings. This time window is too short to allow medical professionals time to plan travel and adjust their schedules to attend. Participation by subject matter experts is essential for the Advisory Panel to receive valuable input and thus provide comprehensive, informed recommendations to the Agency. **We encourage CMS to give at least 30 days notice of Advisory Panel meetings and to explore options to allow public comment via teleconference or webinar.** Providing reasonable notice as well as alternative participation methods would allow stakeholders to actively participate in the process while addressing scheduling and cost issues.

Thank you for the opportunity to provide these comments. If you have any questions, please contact Mary Steele Williams, Executive Director, at mwilliams@amp.org.

Sincerely,

Charles E. Hill, MD, PhD
AMP President