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Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: Medicare Program: Medicare Clinical Diagnostic Laboratory Tests Payment System; Proposed Rule

Dear Acting Administrator Slavitt:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments and submit recommendations in response to the proposed Medicare Clinical Diagnostic Laboratory Tests Payment System (proposed rule). The AMA understands the challenges faced by the Centers for Medicare & Medicaid Services (CMS) in crafting regulations and policy consistent with the Protecting Access to Medicare Act of 2014 (PAMA) while striving to minimize disruption to patient access, reduce administrative burdens, and construct a flexible and agile system to accommodate the rapid increase in innovative clinical tests and utilization. We have included a number of recommendations concerning the proposed coding, data collection, and data reporting for applicable laboratories.

PAMA and the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) represent seismic shifts in payment and delivery for health care covered and paid on the Medicare Clinical Laboratory Fee Schedule (CLFS) and the Medicare Physician Fee Schedule (PFS), respectively. As health care stakeholders re-design both delivery and administrative infrastructure to facilitate migration to these new requirements and expectations, strong collaboration and regular communication among stakeholders is essential. In addition, ready access to relevant, accurate, and standardized data along with the associated analytic capabilities are essential building blocks to drive successful change. The AMA welcomes the opportunity to work with CMS and the full continuum of healthcare stakeholders—from the established organizations and providers to new ones, particularly in the emerging technology and genomics arenas—in order to facilitate the implementation of innovative solutions that enjoy broad consensus.

We fully anticipate that adjustments will be needed in Medicare policy and regulations as well as the efforts and initiatives of other health care stakeholders. Ongoing open dialogue and flexibility will be crucial. We welcome this challenge to ensure Medicare beneficiaries have improved health outcomes and the health care system performs optimally and efficiently. The AMA is ready to work closely with CMS and other stakeholders to facilitate a smooth transition to the new coding, data collection, and pricing provisions under PAMA. We urge the Agency to incorporate the recommended changes outlined below to achieve the foregoing goals.

Recommendation: Extend timeline for implementation of the data collection and data reporting requirements.

We applaud CMS' effort to develop the proposed rule, but as a threshold matter we strongly urge the Agency to revise the implementation timeline. We expect that it would be difficult to provide meaningful consideration of the comments and recommendations provided by stakeholders and, where warranted, modify the final rule, and issue subregulatory guidance in time for the January 1, 2016 deadline.

Equally important, the proposed implementation timetable does not provide applicable clinical laboratories adequate time to prepare for and then comply with the reporting obligations—which are detailed, resource intensive, ambiguous in some areas, and confusing. This will be difficult for all clinical laboratories subject to reporting, but to the extent physician office based laboratories (POLs) must report the complexity of the statute, the proposed rule, and the interplay of the various provisions will be overwhelming. This new law and proposed rule is the most significant change to occur on the CLFS since 1984 when Medicare began paying for clinical testing services.

We recommend that CMS provide applicable laboratories at least six months prior to the start date of the data collection period so that applicable laboratories understand the PAMA requirements, are able to develop the digital and administrative infrastructure, and beta test it**.** In light of the Agency's statutory authority to impose $10,000 per day civil monetary penalties for the failure to report or misrepresentation or omission with respect to a clinical diagnostic test, fairness dictates that applicable laboratories have time to scale their reporting capabilities—particularly POLs and their organizations which did not have a role in the passage of PAMA and remain largely unaware of the data collection and reporting requirements. This additional time will also provide CMS with the opportunity to beta test the Agency's registration process for applicable laboratories and data transmission processes and protocols.

Further, we support the recommended allotted length of time for the implementation timetable generated by several stakeholders such as the American Clinical Laboratory Association. However, the AMA does not support the start of the initial data collection period until six months after the Agency issues the final rule. Several stakeholders have recommended the initiation of the reporting period potentially before the final rule is issued, but applicable

laboratories may have to hire/train staff and resolve software issues in advance to ensure the data is being captured contemporaneous with the data collection period.

Recommendation: When the Agency evaluates whether to impose a civil monetary penalty (CMP), consider the size of the clinical laboratory and resources as mitigating factors.

We urge CMS to explicitly include in the final rule mitigation factors that include intent (scienter), size, and resources when the Agency evaluates whether to impose a CMP and the amount. We are concerned that POLs could be penalized for inadvertent errors and Congress clearly intends that CMPs should only be imposed where there is the intent to submit incorrect data. Also, the size of CMP should be commensurate with the size of the applicable laboratory. The impact of the CMP will vary depending on the size and resources of a clinical laboratory and will have a disproportionately negative impact on POLs if an adjustment is not made to ensure that POLs are not crippled by such sanctions.

Recommendation: Retain the proposed POL low expenditure threshold exclusion.

While the AMA originally advocated the exclusion of all POLs from the reporting requirement, we appreciate and support CMS' proposal to establish a POL low expenditure threshold exclusion. The Agency has proposed that any entity that would otherwise be an applicable laboratory, but that receives less than $50,000 in Medicare revenues under section 1834A and section 1833(h) of the Act for laboratory tests furnished during a data collection period, would not be an applicable laboratory for the subsequent data reporting period.[1] The Agency has indicated that excluding certain entities with CLFS revenues below a $50,000 threshold would not have a significant impact on the weighted median private payor rates. With this threshold, using Medicare utilization data, CMS estimates that there are only 17 tests whose utilization is completely attributed to laboratories that would not be reporting because they fell below a $50,000 threshold.

CMS has stated that, with a $50,000 revenue threshold, the exclusion of data from POLs and independent laboratories with total CLFS revenues below that threshold did not materially affect the quality and sufficiency of the data needed to set rates. The Agency indicates that it is able to substantially reduce the number of entities that would be required to report (94 percent of physician office laboratories and 52 percent of independent laboratories) while retaining a high percentage of Medicare utilization (96 percent of CLFS spending on physician office laboratories

[1] CMS provided in the PAMA proposed rule that an entity would need to determine whether its Medicare revenues from laboratory tests billed on Form CMS 1500 (or its electronic equivalent) and paid under the current CLFS (under section 1833(h) of the Act) and the revised CLFS (under section 1834A of the Act) are at least $50,000. The Agency is proposing that if an applicable laboratory receives, collectively with its associated National Provider Identifier (NPI) entities (which would include all types of NPI entities, not just laboratories), less than $50,000 in Medicare revenues for CLFS services paid on Form CMS 1500 (or its electronic equivalent), the entity would not be an applicable laboratory.

and more than 99 percent of CLFS spending on independent laboratories) from applicable laboratories that would be required to report.

The low threshold exclusion is appropriate given the negative impact the data collection and data reporting requirement (and associated risk of civil monetary penalties) would have on POLs. The data collection obligations require access to expensive back office software and powerful data analytics. Mastering new software and reporting requirements will re-allocate staff time and practice resources away from other CMS priority areas such as quality reporting, meaningful use, and alternative delivery and payment practice transformation. We are concerned that the complexity and risk of the data collection and reporting requirement will cause many POLs to reduce or forgo offering clinical testing services given the rapidly compounding demands of other federal regulatory, quality, and delivery reform programs. The AMA strongly supports the decision to exclude the overwhelming majority of POLs from the reporting requirement.

Recommendation: Permit any clinical laboratory to voluntarily engage in data collection and report private payor rates including otherwise excluded hospital-based clinical laboratories or POLs.

Improved care coordination and promoting patient centered care often means ensuring services are delivered efficiently, at the point-of-care, and coordinated and communicated quickly to the patient, caregivers, and the medical team. POL testing supports these goals. Patients who must seek test services at another location incur added expense and may delay or forgo testing altogether. In addition, there is added administrative expense when clinical testing is performed outside of a POL as results must be tracked down and additional steps taken to ensure patients receive results and information is distributed to the health care team. Low compliance, higher acuity, and increased administrative burdens take a toll on patient health outcomes, undermine migration to new delivery models, and cost the health care system.

In light of the foregoing, we have concerns that the weighted median price generated from the independent laboratories' and a subset of POLs' data alone will depress the pricing to the point that POLs are no longer able to provide rapid and accurate testing when a patient is at their physician's office. We would welcome the opportunity to work closely with the Agency to undertake both data modeling and forecasting to evaluate these issues in greater detail. In addition, we strongly urge CMS to permit all clinical laboratories that are not otherwise required to engage in data collection and reporting to voluntarily do so.

Recommendation: When a POL is subject to the data collection and reporting requirements, CMS should notify the POL at least six months prior to the start of the data collection period.

Even with limitations on the number of POLs that will be responsible for reporting, the POLs that must report may not 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. CMS has claims datasets and the analytics to assess whether a POL meets the reporting requirements based on prior year claims. We strongly urge CMS to provide POLs with advance notice that the POL will be subject to the data collection and reporting requirements. This will enhance the accuracy and reliability of the data that CMS will rely upon to calculate the weighted median of private payor prices and mitigate the risk of civil monetary penalties.

Recommendation: Reduce the data collection period from 12 months to 3 months.

We strongly urge the Agency to reduce the data collection period from a full calendar year, every three years for clinical diagnostic tests to three months of data collection every three years ("3-3"). The data collection burden of reporting every private payor price for all tests for a full year will divert already scarce health care resources to administrative tasks instead of to providing clinical care and services. This reporting requirement will fall heavily on POLs—physician practices that are already facing quality reporting, meaningful use requirements, and implementation of alternative delivery (and payment) models. The 3-3 data collection requirement will ensure that the Agency has current and accurate data. It will also reduce the likelihood that well-intentioned clinical laboratories—particularly POLs—are not faced with serious civil monetary penalties due to data errors precipitated by the overwhelming volume of data that they must track, verify, and report.

Recommendation: Utilize the new clinical laboratory test section of the Current Procedural Terminology (CPT) code set approved by the CPT Editorial Panel to fulfill the PAMA codification requirements.

CMS has proposed the creation of G codes to identify new and existing advanced diagnostic laboratory tests (ADLTs) and new and existing clinical diagnostic laboratory tests (CDLTs) that are cleared or approved by the Food and Drug Administration (FDA), if a specific Healthcare Common Procedure Coding System (HCPCS) code does not already exist. As noted by the Agency, G codes are temporary HCPCS Level II codes used by CMS to identify professional health care procedures and services, including laboratory tests, that would otherwise be identified by a CPT code but for which there is no CPT code. The AMA is urging CMS to utilize the CPT code set instead, including the newly established clinical laboratory test section approved by the CPT Editorial Panel to fulfill the PAMA HCPCS specificity requirements as well as broader coding needs. The CPT code set is developed with broad stakeholder input and will continue to ensure consistent, uniform, national coding. In addition, the CPT Editorial Panel has the infrastructure and capacity to process code requests on a quarterly basis, provide transparency, and offer a public forum at regular intervals several times a year to convene interested and impacted stakeholders. The foregoing will facilitate scaling and modifying this new section of the CPT code set, as needed, and ensure consistency with the larger CPT coding framework for other health care services and procedures.

Transparency and Stakeholder Engagement

The CPT Editorial Panel has and will continue to employ a transparent and stakeholder-driven process to develop a new code section that is consistent with the PAMA coding requirements. In light of PAMA's mandate that CMS must ensure the availability of specific HCPCS codes or identifiers for ADLTs and CDLTs that are cleared or approved by the FDA, the Molecular Pathology Coding Workgroup (MPCW) of the CPT Editorial Panel hosted numerous public meetings over the past year with a broad cross-section of stakeholders from private payors, industry, national medical specialty societies, the clinical laboratory community, Medicare, and Medicare contractors to discuss potential CPT coding solutions that could meet the statutory coding requirements in PAMA. Following the publication of the proposed rule, the MPCW held a public meeting during the regularly scheduled CPT Editorial Panel meeting in order to solicit additional input and feedback on an appropriate PAMA coding solution that would ensure consistent and accurate coding across payors, providers, and clearinghouses. A number of common comments and recommendations emerged including:

- Codes should be issued on a quarterly basis.
- Switching code sets—from temporary G codes to permanent CPT codes—may trigger a second round of coverage and pricing determinations which raises significant concern among stakeholders in light of the resource intensive nature of these activities and the uncertainty it generates.
- The use of different code sets for the same services, for even a short period of time, creates administrative confusion and additional complexity for PAMA data collection and reporting efforts where private payors are using a different code from Medicare.
- Administrative efficiency is essential.

In light of the foregoing as well as broad considerations around the need for consistent and clear coding options within the CPT code set for clinical laboratory testing, in early November, 2015, the CPT Editorial Panel authorized the establishment of a new section in the CPT code set.

The new section established by the CPT Editorial Panel provides an infrastructure whereby a clinical laboratory or manufacturer that meets certain criteria may request a code to identify more specifically their test. This section will include ADLTs and CDLTs as defined under PAMA.

Parameters and criteria of this section include:

- The test is or will be paid on the CLFS.
- The test must be performed on a patient population.
- The clinical laboratory or manufacturer that offers the test must request the code.

- The codes in this new section will be issued on a quarterly basis (and effective the following quarter to allow payors time to load them into their systems).

Through its established, public, and transparent processes, the CPT Editorial Panel will verify and codify tests in the new section. The Panel will not determine whether or not the test meets the ADLT criteria.[2]

In addition to the foregoing, the existing CPT Category I Pathology and Laboratory and Category III sections provide the specified unique HCPCS codes for existing CDLTs that are cleared or approved by FDA and for which payment is made by Medicare. To the extent that a manufacturer or laboratory seeks additional specificity, they would be eligible to seek a code in the new clinical laboratory test section. The CPT Editorial Panel is able to establish guidance on the appropriate use of each section so there is consistent and accurate coding and identification. The CPT Editorial Panel will benefit from the input of stakeholders on this new section and is positioned to make appropriate adjustments, as needed.

Uniform, Specific, Transparent Coding in the Digital Age: Essential Tool for Electronic Transactions as well as Delivery and Payment Transformation

The existing CPT code set, as well as the new clinical laboratory test section approved by the CPT Editorial Panel, ensures consistent national coding across Medicare and other public and private payors. First and foremost, HCPCS codes should facilitate electronic transactions. The CPT code set is subject to ongoing change and update to achieve this primary objective. The new section, in particular, is intended to provide a sustainable infrastructure and is responsive to increased demand for specificity. This new code section represents the longstanding commitment of the CPT Editorial Panel to ensure the CPT code set remains consistent, predictable, and meets the needs of a broad cross-section of stakeholders.

In 1996, Congress passed the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to advance several goals including administrative simplification through consistent and uniform coding for electronic transactions across health insurance payors, clearinghouses, and providers. The need for administrative simplification through the use of a standard code set to transmit electronic claims is no less important today than in 1996. Indeed, the need for consistent national standardized coding has increased with the advent of big data and the need for semantic and syntactic interoperability to advance important—data intensive—goals including alternative payment model analytics and improved patient care.

[2] To the extent that CMS and stakeholders conclude it would be beneficial for the CPT Editorial Panel to have a role in the determination of ADLT status—separate and distinct from the codification process—there is willingness to develop such a collaboration. However, the new section does not make distinctions between what could be ADLTs, CDLTs, or FDA cleared or approved CDLTs.

As required by HIPAA, providers, clearinghouses, and payors all use the CPT code set for outpatient services. CPT is a listing of descriptive terms and identifying codes for reporting medical services and procedures. The purpose of the CPT code set is to provide a uniform language that accurately describes medical, surgical and diagnostic services provided by physicians and other qualified healthcare professionals. The CPT code set offers healthcare stakeholders across the nation a reliable system that streamlines the reporting process and increases efficiency. For more than four decades, physicians and other qualified healthcare professionals have used the CPT code set to communicate concisely with colleagues, patients, hospitals and insurers about procedures performed.

In addition to processing reimbursement claims, CPT codes are used in developing guidelines for medical care and reporting on health outcomes. To ensure the CPT code set fairly and accurately reflects the medical care provided to patients, the CPT Editorial Panel maintains an open, transparent process. The CPT Editorial Panel−with assistance from physicians and other qualified healthcare professionals representing all specialties of medicine, and with important contributions from many third-party payors and governmental agencies − has public meetings several times a year to discuss and act on proposed changes to the CPT code set to reflect current medical practice.

We urge CMS to employ the CPT code set, including the new clinical laboratory test section established by the CPT Editorial Panel, as the appropriate coding solution to meet the PAMA coding requirements.

Recommendation: Retain the existing HCPCS system to provide specificity and retain prohibition on the use of unlisted and not otherwise classified (NOC) codes to report private payor rate.

Consistent and uniform identification is maintained when payors, providers, and clearinghouses utilize the same code set. The proposed rule provides that the existing HCPCS system—comprised of CMS HCPCS Level II codes and HCPCS Level I CPT codes—does not require additional unique identifiers. The AMA concurs that the Agency is able to utilize the existing HCPCS system to provide the requisite specificity required by PAMA.

Further, the Agency proposes to expressly prohibit the use of unlisted and NOC codes to report private payor rates. The AMA strongly supports the proposal to prohibit the use of unlisted and NOC codes to report private payor rates for the reasons outlined by CMS and because hybrid coding using such codes impacts consistent, uniform coding across payors. In addition, the use of such codes will generate unnecessary complexity for PAMA data collection and reporting if private payors require CPT codes and Medicare uses another coding regime. It also impacts the ability to track the use of tests across time and across payors for sentinel purposes and comparisons. To the extent there is a desire and need for additional specificity, the new CPT code section will allow for enhanced specificity to meet the requirements of PAMA as well as broader coding needs.

Recommendation: Utilize the Advisory Panel on Clinical Diagnostic Laboratory Tests (Advisory Panel) to determine whether a test qualifies as an ADLT and strike the proposed novelty requirement.

The AMA strongly urges CMS to simplify the proposed definition of an ADLT and conform it to the statutory requirements and criteria. The CLFS provision of PAMA is complicated and establishes an expansive new coding and pricing regime. Additional complexity is not desirable, particularly as it is expected that ADLTs will constitute a relatively small universe of tests in the short-term. (Even if the Agency were to expand ADLTs to include next generation genetic and genomic testing, it is not clear how many clinical laboratories will avail themselves of this option given the annual reporting requirement and the limited benefit—three quarters at list price subject to recoupment if it exceeds a subsequently determined threshold.) The proposed regulation increases the complexity of adjudicating eligibility for this provision—which we expect will consume an inordinate amount of Agency and stakeholder resources to resolve. The statutory specification of ADLTs under criterion A includes proteins. To ensure consistency with the statutory language, it is recommended that proteins be an independent basis for qualifying for ADLT status. In addition, the Agency has proposed a novelty requirement under criterion A—it appears in order to establish whether an algorithm is unique. We recommend that the Agency establish a mechanism to consult with the Advisory Panel on Clinical Diagnostic Laboratory Tests to ascertain whether a test qualifies as an ADLT under criterion A.

Recommendation: Maintain the current number of Medicare Administrative Contractors (MAC), ensure MAC transparency and training on the gap-fill method for pricing new codes, and ensure each MAC complies with the established Local Coverage Determination (LCD) process.

While there are efficiencies associated with a single, national MAC for the claims on the CLFS, there are significant drawbacks that over time will undermine access to medically necessary and reasonable clinical testing services. Significant MAC consolidation inexorably moves coverage into *de facto* National Coverage Determinations (NCDs) without the benefit of several MACs considering the medical necessity and reasonableness of such services. The AMA agrees with other stakeholders that the local coverage determination process (LCD)—when adhered to—provides transparency and opportunity for input from a cross section of stakeholders, particularly physician subject matter experts. We also urge CMS to utilize the Advisory Panel on Clinical Diagnostic Laboratory Tests and stakeholders to augment the subject matter expertise of MACs on coverage matters.

In addition to the foregoing, the AMA welcomes the opportunity to work collaboratively with MACs that have developed expertise with regard to services on the CLFS and believes such expertise and communication with the physician community is essential to ensuring Medicare beneficiaries have access to important clinical testing services that are transforming medical care. A priority area for the AMA will be supporting and promoting regular communication between MACs, private payors, physicians, and other care providers and stakeholders during the

PAMA transition and to the extent there are new regulatory requirements vis-à-vis laboratory developed testing services and procedures.

We also urge CMS to maintain or establish ongoing MAC support, guidance, and resources on the gap-fill method and processes for pricing new codes. There were reports that MACs were not prepared to use the gap-fill method to price the approximately 100 new molecular pathology codes. This generated widespread confusion, delays, and inconsistent data sources and requirements across MACs. It also interrupted patient access to services in Medicaid programs that rely on the Medicare fee schedules and put clinical laboratories under financial stress as claims were not processed or adjudicated for many months. We understand that CMS recently provided MACs with additional guidance on the gap fill method. We applaud this action and urge CMS to expand on this training and publicize the expectations for how the gap-fill method should be conducted and the appropriate data sources so that providers are able to meet this expectations. We also urge CMS to provide an explanation of the gap-fill final determinations.

Conclusion

CMS must clear many hurdles on the road to implementing PAMA and MACRA—essentially within the same timeframe. The difficulties and controversies would have been taxing with a major overhaul of payment and delivery reform on the PFS or the CLFS, yet the Agency is tasked with both at the same time. Similarly, patients, physician, other health care providers, industry, private payors, and new stakeholders from the technology and telecommunication community must master the existing requirements and the new ones over the next several years. Transparency, regular communication, ongoing collaboration amongst stakeholders, and willingness to adapt and modify will be essential to a successful transition that minimizes disruption to patient care and drives patient-centered care and improves health outcomes. The AMA is ready to play a central role in convening stakeholders on a regular basis in order to facilitate consensus driven solutions across these issues. We appreciate the opportunity to work with CMS and are ready to assist.

Sincerely,

James L. Madara, MD