COLLEGE of AMERICAN PATHOLOGISTS

November 24, 2015

Acting Administrator Andrew M. Slavitt
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Re: CMS-1621-P/Medicare Program; Medicare Clinical Diagnostics Tests Payment System

Dear Administrator Slavitt:

The College of American Pathologists ("CAP") appreciates the opportunity to comment on the proposed rule CMS 1621-P/Medicare Program: Medicare Clinical Diagnostics Tests Payment System. The CAP is a national medical specialty society representing 18,000 physician members and the global laboratory community. It is the world's largest association composed exclusively of board-certified pathologists and the worldwide leader in quality assurance. The CAP advocates for accountable, high-quality, and cost-effective patient care. The CAP's Laboratory Accreditation Program is responsible for accrediting more than 7,000 clinical laboratories worldwide.

Given the integral roles pathologists play in directing clinical laboratories, overseeing the quality and appropriateness of laboratory testing in their medical communities, and developing laboratory tests, the CAP and its members have a significant stake in the implementation of the Protecting Access to Medicare Act ("PAMA") of 2014. Like CMS, the CAP desires the implementation of PAMA minimize disruption and ensure the ongoing provision of laboratory tests to Medicare beneficiaries. Based on our review of the proposed rule, though, the CAP is concerned about several of its key elements.

The most significant concerns include: (a) the limited scope of those entities required to submit data on which "market" rates and therefore, clinical laboratory fee schedule ("CLFS") rates as of January 1, 2017 will be based, and (b) the reporting requirements overall, particularly the timing and the lack of necessary detail provided in the rule or guidance to ensure compliance and avoidance of civil monetary penalties. The CAP recognizes the need to implement PAMA in a way that minimizes administrative burden, establishes accurate "private payor" rates, ensures statutory compliance, and above all, maintains beneficiary access to testing. In furtherance of these objectives, the CAP provides the agency with these comments focusing first on reporting, followed by coding, and then coverage.

Data Collection. The proposed rule provides little specificity on private payor data to be reported yet rolls forward with a requirement that data submission commence only a few short months after the corresponding final rule. Despite the stated importance CMS placed in the proposed rule on achieving a balance between collecting sufficient data and minimizing the reporting burden to entities that reflect a relatively small amount of revenues under the CLFS in the proposed rule, the net has not been cast broadly enough to calculate a weighted median that adequately reflects the private market rates for a test for the reasons stated in this section. As proposed, the data collection will be based on a retrospective period with which many laboratories will not be able to comply, but which subjects them to potentially steep civil monetary penalties. Furthermore, the premise on which market rates are founded is flawed in that the payment arrangement between a laboratory and a payor does not take into account the cost of reporting on all

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other payers in the market as will be required under PAMA. As CMS concedes, there could be substantial cost to data reporting which is not possible to determine at this point. Clearly, this currently incalculable cost is not taken into account when laboratories extend payment rates to private payors.

1. Majority of Revenues

Whereas CMS in the proposed rule considered it important to define laboratory broadly enough to encompass every laboratory type that is subject to the CLFS, through its definition of applicable laboratory, it has excluded a significant swath of laboratory types. **The statute clearly contemplated that the payment rates established under PAMA would apply to clinical laboratory tests furnished by a hospital laboratory if such test is paid for separately, and not as part of the bundled payment under the prospective payment system for hospital outpatient department services ("OPPS").** As you know, a hospital can provide "outreach" services where the hospital obtains specimens from physicians who see patients in their own offices just as independent clinical laboratories do. In that case, separate payment is issued for these services provided to nonpatients. In fact, in the Department of Health and Human Services Office of Inspector General ("OIG") recently released *Medicare Payments for Clinical Laboratory Tests in 2014: Baseline Data* ("2014 Data"), hospital-based laboratories accounted for about a quarter of the total payments for clinical laboratory services excluding those laboratory services bundled under the OPPS. **It seems clear, therefore, that hospital outreach services should clearly be factored into the calculation of private payor rates.**

Congress clearly contemplated the Medicare rates CMS derives from private payor data apply to laboratory tests furnished by hospital laboratories in the circumstances indicated above. CMS, though, in requiring a majority of Medicare revenue for the **entire organization** to drive the definition of applicable laboratory required to report, essentially excludes all hospital laboratories even when they receive fee-for-service reimbursement. CMS concedes that it excluded hospitals from its overall analysis in the proposed rule of the percentage of laboratories to which the reporting requirements would apply as it felt it unlikely they would meet the definition of applicable laboratory. As a result of this exclusion, CMS will not capture private payor data from an essential segment of laboratory services and will undermine the accuracy of its calculations and future reimbursements for these and all other laboratories providing clinical laboratory services. Since Medicare rates are unquestionably meant to reflect market rates as of 2017, **the full range of pricing data including from hospitals must be included.**

PAMA defines the term "applicable laboratory" to mean **a laboratory** that receives a majority of its Medicare revenues from CLFS payments or physician fee schedule ("PFS") payments or the new 1384A of the Social Security Act added by PAMA. Despite the statutory definition, CMS has proposed an applicable laboratory be determined based on the Medicare revenues from the aforementioned sources of the **entire organization**. As proposed, the majority would be determined based on services provided across the entity rather than just laboratory services. Further, CMS has indicated "if an entity is not a laboratory itself, it must have at least one component that is a laboratory." The CAP is perplexed how an "applicable laboratory" which statutorily and logically is a laboratory now encompasses an organization that potentially provides the full complement of services along the continuum of care of which laboratory may be a minor component. Basing the majority of Medicare revenues on the collective amount

of an entire organization's Medicare revenues received during the data collection period will not serve to meaningfully reflect market rates for clinical laboratory services. This approach will instead inherently deny CMS access to data from laboratories whose rates should be factored into the calculation of true market rates. If the applicable laboratory as indicated in CMS's proposal is the "entity that would be reporting applicable information," that information should be from a laboratory and should be based on the majority of that **laboratory's** Medicare revenues received under the CLFS, PFS and Section 1834A of the Social Security Act. To consider laboratory services as a percentage of the overall organization's Medicare revenues from the CLFS, PFS and Section 1834A dilutes the capture of applicable information that is representative of the market rates intended under PAMA. We question CMS's interpretation of PAMA in arriving at its definition of applicable laboratory and posit that **an applicable laboratory means a CLIA designated laboratory as defined under the proposed rule that receives a majority of the laboratory's Medicare revenues from payments made under the CLFS, PFS, or the new section 1834A of the Society Security Act added by PAMA.**

2. Low Expenditure Threshold

In the interest of setting forth reporting requirements that reflect the intended market, the CAP supports the Secretary not exercising discretion granted under PAMA to propose a low volume threshold, as deemed appropriate. **The CAP, though, disagrees that excluding all laboratories paid less than $50,000 a year on the CLFS does not materially affect the quality and sufficiency of data needed to set rates.** CMS expects that any entities that meet the low expenditure threshold will be physician offices. At the same time, of the top 25 laboratory tests in 2014, laboratories based in physicians' offices accounted for 20% of Medicare laboratory test payments per the OIG 2014 Data. Excluding physician office laboratories by applying the low expenditure threshold could substantially alter the weighted median payment rate of individual codes and does not achieve the need to broadly define applicable laboratories that CMS sought to achieve under its proposal. The CAP acknowledges the burden on all laboratories subject to the reporting requirement as well as CMS's need to establish a low expenditure threshold to ease the impact on smaller operations**, but feels that the threshold needs be significantly lower** so that private payor data from this entire category of laboratories is not excluded from weighted median calculations.

In the proposed rule, CMS provides a percentage of CLFS spending for which it could account with those laboratories subject to reporting when the low expenditure threshold is applied. It appears this percentage assumes all laboratories above the low volume expenditure threshold would indeed be subject to the reporting requirement and not statutorily excluded for other reasons under PAMA such as the exception for payments made on a capitated or other similar payment basis. Without knowledge of laboratory contractual arrangements with payors, the percent of CLFS spending CMS asserts it will be collecting even after applying the low volume expenditure threshold is undoubtedly overstated. The quality and sufficiency of data needed to set rates is therefore, an unknown rather than a factor CMS can reliably calculate when it imposes a $50,000 low volume expenditure.

Finally, should the definition of applicable laboratory and low expenditure threshold remain as proposed, the CAP encourages CMS to publicly report the weighted average payment for each test stratified by the size of the laboratory (as measured by volume of Medicare billing per test). The purpose of this effort would

be to enable CMS to validate and document a likely trend toward lower payments correlated with higher volumes and adjust requirements as needed prospectively so that data collected mirrors true market rates that potentially includes smaller laboratories should this trend be validated.

3. Other "Applicable Laboratory" Consideration

In response to the request from CMS for input on defining applicable laboratories by tax identification number ("TIN") rather than by national provider identification number ("NPI"), the **CAP recommends that the definition, and therefore, reporting be set at the NPI level**. As mentioned above, the CAP feels that the proposed rule incorrectly excludes too many types of laboratories. Defining applicable laboratories by NPI will include a far more representative sample of laboratories. Furthermore, the more granular reporting that occurs at the NPI level is needed to cleanly capture private payor data and to calculate an accurate weighted median. As noted in the proposed rule, laboratory business models vary throughout the industry. Defining applicable laboratories by NPI would increase the representation of that variability in the types of information that is reported and create naturally correct comparisons in the data collected. The CAP, therefore, recommends that while exemptions are calculated at the NPI level, **data certification and submission would still occur at the TIN level, but would individually identify all NPIs under the TIN.**

4. Applicable Information

The CAP appreciates the inclusion of all patient cost sharing amounts (e.g. patient deductible and coinsurance) in determining private payor rates and concurs that doing so is necessary to calculate a market CLFS amount. Not only does including patient responsibility in the definition of private payor rate have a material effect on the private payor rate and ultimately, the payment amount determined by CMS, but also reduces the accounting and reporting burden on applicable laboratories.

As you know, Section 1384A(a)(3)(a) of PAMA defines "applicable information" as the payment rate that was paid by each private payor for each clinical laboratory diagnostic test ("CDLT") and the volume of such tests for each such payor for the data collection period. The CAP is especially concerned with a submission date just around the corner that not much additional specificity on "applicable information" to be submitted was provided in the proposed rule. As indicated in the proposed rule, generally CMS would expect laboratories to report the specific HCPCS code associated with each laboratory test, the private payor rate or rates associated with the HCPCS code, and the volume of laboratory tests performed by the laboratory at each private payor rate. Beyond this general information, **CMS has indicated it will specify the form and manner for reporting applicable information in guidance prior to the first data reporting period. This is amongst the deepest concerns for the CAP's members as it leaves them unable to assess administrative burden, cost and frankly, their ability to comply yet exposes all applicable laboratories to potentially costly civil monetary penalties.**

The reporting of private payor rates is a complex matter. That it was not addressed with any specificity in the proposed rule and is therefore, not subject to notice and comment is a material omission. A sampling of those items that need to be considered and addressed with clarity in further defining "applicable information" are:

- *Reimbursement by Product* – Reporting is to be by each private payor as defined under PAMA yet within their private payor rates, laboratories may have varying rates with the same private payor by product (e.g. the same payor's HMO, point-of-service plan, PPO products).

- *Participation Status* – Clarity on CMS's methodology and reporting requirements to account for the differences in payment rates for applicable in network and out of network laboratories is also needed. Not only might a laboratory not participate with a given health plan, it may participate only in some products and not others within a private payor's offerings.

- *Partial or No Payment* – While a contracted rate exists, private payors may issue partial payment or in some instances, no payment for a service they may believe is not covered, not authorized, or for which notification has not been provided. To include claims that are partially paid or for which no payment has been issued would only serve to inaccurately drive down the weighted median. As under PAMA applicable laboratories are required to report the "payment rate that was paid" by each private payor during the data collection period, information would not be submitted if no payment was made. We recommend that partial payments also not be reported in order to maintain the accuracy and integrity of the weighted median.

- *Final Payment* – A claim may be in appeal or under further review/consideration for technical reasons including, but not limited to ICD10 or other coding issues such that the payment issued is quite possibly not the final payment. Again, to include claims that do not reflect actual final payment from the private payor artificially reduces the weighted median payment rate.

- *Global Payment* – Reporting should be of global payments only. We are aware of private payor variations in contracting methodology that are generally geographic under which a rate for the professional component ("PC") of clinical pathology is negotiated and paid to the contracted pathologist's professional services. This methodology differs from Medicare under which the pathologist/laboratory would be paid to the pathologist from the hospital for such services that are factored into the hospital's DRG rate. To ensure comparable services are being factored into the private payor rate for these services and accuracy of the weighted median not negatively affected, only **global** payments, rather than PC only or potentially technical component only payments should be reported.

- *Payments Not Itemized* – The CAP's members have conveyed that laboratories do not always receive insurer explanations of payment that itemize reimbursement on a test-by-test or code-by-code basis, particularly where a large number of individual tests were provided. Guidance on how to allocate payment per-patient or per-visit and/or whether to include such payments in reporting will be needed.

The above is not an exhaustive list, but is illustrative of some the **nuances of private payor payment issues that will need to be addressed with clarity and specificity well in advance of any reporting by applicable laboratories commencing**.

5. Data Collection Period

In determining what the data collection and data reporting periods should be, CMS considered several objectives outlined in the proposed rule. The CAP's assessment is that at least two of those key objectives: 1) providing applicable laboratories with sufficient notice of their obligation to collect and report applicable information to CMS, and 2) allowing applicable laboratories enough time to collect and report applicable information were not met. By no stretch does the March 31, 2015 submission deadline provide applicable laboratories with sufficient notice nor allow them enough time to collect applicable information. As such, **CMS must extend the submission deadline and also reassess the reporting period** that, by the time a final rule is released, will be entirely retrospective.

As you know, applicable laboratories are faced with an exceedingly tight time frame on which to execute due to the agency's inability to meet the June 30, 2015 deadline for a final PAMA rule. As a result of this significant delay, with a proposed rule not released until September 25, 2015, CMS has proposed a reporting period from July 1, 2015 – December 31, 2015. That CMS believes as indicated in the proposed rule, the statute contemplates the first data collection period beginning prior to rule publication is unsettling and seemingly an ex post facto justification related to the release of the proposed rule well past the statutorily required final rule date. Year-end reporting falling within the reporting period and not long before the proposed submission deadline only serves to make the proposed time frames less possible to achieve. CMS acknowledges the amount of applicable information could be voluminous for applicable laboratories particularly that offer a large number of tests. This is an understatement particularly given the number of private payors from which an applicable laboratory may receive payment. There are massive information technology issues and other operational challenges that will be faced by each laboratory that must collect, organize, validate, and transmit data to CMS. In some instances, laboratories will need to engage outside support to fulfill the requirement yet at this point, under the proposed rule, they have no specificity on what must be reported if they want to begin preparing their data. Regardless, their failure to comply potentially subjects them to significant civil monetary penalties.

In addition to lack of specificity as to reporting elements, very minimal information has been released on the data collection system itself. We understand a web-based data collection system will be available to applicable laboratories for submission of applicable information. We are also told that system will require registration and that laboratories are encouraged to register early on a system that has not yet been launched. We appreciate that when registration is available CMS intends to provide manuals and other instructional materials on how to utilize the system. While this will be their first time submitting private payor data, hurdles members were not able to clear in attempting to register for other CMS reporting portals leave them concerned about the CMS enterprise identity management and data collection system for PAMA reporting.

The meaning of the reporting period itself, at this point, remains unclear. Applicable laboratories must report applicable information to CMS for the period of July 1, 2015 through December 31, 2015. Whether dates of service, dates of payment, posted payments, or some other factor determines the reporting period will need clarification. In order for applicable laboratories to be able to implement the change, the

CAP recommends the reporting period cover payments made and posted as of the end of the reporting period.

The CAP would also urge that the submission deadline take into account a more realistic lag time. Under the proposed rule, CMS pointed to the value of starting data reporting immediately after the data collection period limiting the lag time between reporting applicable information and the use of that applicable information to determine Medicare CLFS payments, thus ensuring that CMS is using the most recent data available to set CLFS payment rates. While this is a valid consideration the more important lag time that should drive the submission deadline takes into account requirements for timely filing for laboratories and timely payment to laboratories for payors under applicable contract(s) and law.

As CMS believes applicable laboratories should have three months during which to submit applicable information from the corresponding data collection period, the CAP interprets the reporting period as including posted payments as of December 31, 2015 rather than dates of service through December 31, 2015. Even assuming this interpretation reflects CMS's intent, **applicable laboratories would need a minimum of six months, not three to be able to determine whether they are applicable laboratories for the reporting period** and if so, to collect, format, organize, validate and submit their data on a recurring basis. **Without applicable information specifications available and as a result, systems not programmed to collect data in the required format, the CAP recommends an even longer time period for initial submission.**

If the reporting period is determined by dates of service contrary to the CAP's recommendation, the recommended time frames would need to be lengthened significantly to take into account timely filing (which can vary from 90 to 180 days and in some instances, a year) and final payment including completion of any pending appeals. Alternatively, if guidance specifies date of service determines the reporting period, it would need to acknowledge that final adjudication may fall outside the reporting period and even beyond the submission date. Such an approach, however, could very much interfere with the weighted median accurately representing private payor rates unless the contracted or non-participating rate is used as a default for payments that are not final.

Due to the lack of defined applicable information that precludes collecting data in the required format at this point and in order to avoid a reporting period that is entirely retroactive to a final rule, **the CAP recommends the initial reporting period be from January 1, 2016 through June 30, 2016 with submission by September 30, 2016**. Assuming applicable information is more concretely defined by January 2016, this would enable laboratories to begin to collect their data in the required format and more timely receipt of information by CMS. It will also afford applicable laboratories more sufficient time to register to submit data to CMS through whatever secure process is established.

Weighted Median. While what is being deployed appears to be more of a straight median of the array of volume and reimbursements rather than a true weighted median, the CAP understands its basis in statute and its application. What sort of reporting CMS will issue about how it derived the weighted median, though, remains unclear and of potential concern. If independent review of CMS's weighted median calculations is not contemplated, the CAP believes such a review and the publication of findings emerging from such review are necessary.

In addition, the CAP recommends CMS, through applicable information, identify Medicaid managed care organizations, calculate a weighted median both with and without Medicaid managed care organizations based on such information, and publicly report its findings. With managed Medicaid enrollment steadily on the rise since the enactment of the Affordable Care Act and projected to continue to increase by millions of beneficiaries, the effect of the inclusion of managed Medicaid plans as private payors under PAMA and their corresponding payment rates in the calculation of the weighted median is not yet fully known. While PAMA includes Medicaid managed care organizations under its private payor definition, some state Medicaid agencies even after the enactment of PAMA have begun setting their Medicaid schedules to a percent of the Medicare fee schedules, including the CLFS. While Medicaid managed care organizations are typically not required to apply the Medicaid fee schedule with their contracted providers doing so is standard practice in our members' experience. Determining the weighted median with and without Medicaid managed care plans will help assess the effect over time should this practice of setting Medicaid rates at a percentage of Medicare expand and then serve as a significant private sector payment rate deflator contrary to statutory intent and not reflective of the state of affairs at the time PAMA was enacted.

Civil Monetary Penalties. As with the additional forthcoming guidance on applicable information, the CAP is concerned with reporting imminent that additional information on civil monetary penalties ("CMPs") has not been released, but is forthcoming under separate guidance. CMS's expectation that civil monetary collections will be a rare event is not of sufficient comfort to applicable laboratories that have never been required to submit applicable information. Despite expectations, in reality, if the Secretary determines an applicable laboratory has failed to report or made a misrepresentation or omission, a civil monetary of up to $10,000 per day for each such failure to report, misrepresentation or omission may be applied. As written, the penalties do not have a materiality threshold such that penalties would only be applied if the failure to report, misrepresentation, or omission is material.

With data collection an entirely new concept for applicable laboratories under PAMA, we suggest that CMPs only be assessed for material and/or willful violations. As no laboratory has been subject to the reporting requirement and the specifics of applicable information have not yet been provided, **we urge CMS to exercise leniency particularly for the initial reporting period**. Furthermore, **we ask that CMS makes some allowance for correction of reported data and opportunity to address disputed information before CMPs are applied**. We also ask CMS to calibrate the amount of any penalty to the complexity and impact of the applicable laboratory reporting. We note that while CMS proposes to adopt a provision similar to the regulation governing manufacturer's reporting of Part B drug prices, the economics and other characteristics of the laboratory industry differ greatly from the pharmaceutical industry.

We look forward to publication of the forthcoming CMP guidance and are hopeful that amongst the issues it addresses is the opportunity to correct information once submitted where the need could arise for a variety of reasons.

Coding. The CAP was pleased with requirement under PAMA that in determining the payment amount under crosswalking or gapfilling processes, the Secretary must

consider recommendations from the PAMA advisory panel ("Panel"). The CAP was also pleased the Secretary shall make available to the public an explanation of the payment rate for the new test, including an explanation of how the gapfilling criteria and panel recommendations are applied. We look forward to a transparent explanation with specificity as to the application by CMS of the recommendations of the vast group of experts on the Panel made.

While we recognize PAMA permits the Secretary to extend temporary HCPCS codes for new advanced diagnostic laboratory tests ("ADLTs") or establish a permanent HCPCS code as the Secretary deems appropriate should Medicare continue to have a need to pay for a test, **we strongly recommend the establishment of a permanent code**, as follows. Our recommendation is for CMS to issue a formal temporary code sunset list at the conclusion of the two year period. Such a sunset is in sync with CMS's desire to add greater transparency to the coding process. The CAP believes that before the end of the two-year temporary HCPCS code period, laboratories that have received temporary HCPCS codes should have applied for permanent successor CPT codes to ensure broad stakeholder input into the development process particularly if there is an ongoing need for Medicare to pay for the test(s) in question.

CMS proposes to use its current coding process to meet its statutory obligation to assign codes to certain new tests. **For clarity's sake, in implementing the new temporary coding provisions, the CAP would like to ensure CMS use HCPCS level I (CPT) codes, whenever available**. The CAP notes that the CPT molecular pathology Tier 1, Tier 2 codes with the CPT gene identifiers, and CPT Multianalyte Assays with Algorithmic Analyses (MAAA) codes already specifically cover many new tests in current clinical use. These CPT code and CPT gene identifiers lists are updated throughout the calendar year and continue to accommodate an expanding list of new tests offered for clinical use that demonstrate a need for new codes. In addition to the resources that are already available in CPT, a set of official gene abbreviation/identifiers have been created for use in the narrative field of the claims form for Tier 2 molecular pathology test codes 81400 – 81408. The new CPT molecular pathology code gene identifier will inform providers, payors, and coders during the claims submission process. These official abbreviation/identifiers distinguish the specific analyte tested, which will facilitate adjudication of claims for all stakeholders. This advancement is intended to maximize the utility and directly address concerns of some CPT users of the need for increased granularity in the more than 600 tests that are associated with these nine codes. Furthermore, this will enable the CPT code set to be used for reporting purposes by applicable laboratories for Tier 2 codes and analytes recognized for coverage and payment by the Medicare Administrative Contractors ("MACs") and CMS.

CMS notes in the proposed rule that it likely expects to assign different codes to the Food and Drug Administration ("FDA")-approved and the non-FDA approved versions of an existing CDLT with each having a unique identifier although they are currently under a single HCPCS code. We agree with the agency's verbal explanation that issuance of Level II HCPCS codes for this circumstance should only be by specific request. We believe, however, there may be unintended consequences of generating these codes ahead of any further actions from the FDA with regard to oversight of laboratory tests. It is also not apparent that an FDA-cleared or approved CDLT may not share its code with clinical equivalent non-FDA approved tests nor that doing so would be inconsistent with requirements under PAMA and good laboratory practice. **The CAP does not believe there is a clinical or an economic rationale for CMS to use the coding process to differentiate between FDA-approved or cleared and laboratory**

developed tests ("LDTs"). Some contractors are distinguishing services not on the basis of any recognized system of nomenclature. We believe that only in unusual circumstances should Level II HCPCS codes be issued and used instead of CPT codes so that the median prices that are being used to establish payments under the new system are not distorted. The use of non-HIPAA designated code sets, identifiers or modifiers also may result in distorting the weighted median. Coding in this fashion at the very least is non-standard and will not be uniformly reported.

If CMS nonetheless believes it necessary to capture tests using HCPCS Level II for reasons *other* than to create payment or coverage distinctions between FDA approved or cleared and CLIA categorized tests, then CMS should establish the HCPCS temporary code or modifier through public notice and comment rulemaking to allow for transparency and multi-stakeholder input.

With respect to new tests that are not ADLTs, **the CAP remains concerned with the lack of transparency and full disclosure associated with the use of gapfill methodology**. The use of the gapfill process for molecular pathology services has already demonstrated to the CAP the difficulty of gathering accurate information. In particular, the CAP noted widely disparate pricing among MACs as well as failure to report gapfill pricing at all in the material CMS has published for some codes designated for the 2015 CLFS. The lack of transparency and full disclosure involved in the gapfill process has left it unclear what data was utilized and how each MAC determined its prices. This inconsistency in carrier pricing methodology and result is disruptive to providers, patients, and health care institutions. We are hopeful that through focusing the Panel and working with the Panel on this issue, improvements in gapfill transparency and disclosure can be made.

Finally, we are aware of the recent announcement from the American Medical Association that the CPT® Editorial Panel authorized the establishment of a new section in the CPT code set intended to provide an infrastructure whereby a clinical laboratory or manufacturer that meets certain criteria may request a code to more specifically identify their test under PAMA. Based on our initial review of the information available, we believe this process presents a potential CPT coding solution that could fulfill PAMA requirements using an established transparent process that will ensure consistent national coding across private payors and therefore, Medicare post-PAMA implementation. We look forward to engaging in what we understand will be an ongoing stakeholder process as this concept becomes operational as early as the first quarter of 2016.

Advisory Panel. We support CMS's proposal that the public consultation process regarding payment for new CDLTs on or after January 1, 2017 must include the Panel's recommendations. We also support the proposal to explicitly indicate via regulation how CMS took into account the Panel's recommendation and look forward to learning more about how this will be implemented and seeing it come to pass as part of future panel meetings. **We expect that with the vast expertise of the Panel members, CMS will give serious consideration to the Panel's advice and make very clear to the public how it will be using the panel to develop coverage and payment policies beyond what we witnessed at the Panel's initial two meetings.**

ADLT Definition. The CAP was pleased that under the proposed rule, discretionary authority was not exercised to establish additional criteria for defining ADLTs. While the CAP has encouraged narrow construction of the ADLT definition, it is

concerned that CMS seems to have altered the statutory definition of ADLTs and interpreted and incorporated "key statutory terms and phrases" differently than their express statutory definition. Under statute, one of the criteria is that the test is an analysis of multiple biomarkers of DNA, RNA, **or proteins** combined with a unique algorithm to yield a single patient-specific result." CMS "interprets" this provision to require that the test analyze, at a minimum, biomarkers of DNA or RNA. In CMS's interpretation, tests that analyze nucleic acids (DNA or RNA) are molecular pathology analyses. Therefore, CMS proposes that under the above criterion of the ADLT definition, the test must be a molecular pathology analysis of DNA or RNA to the exclusion of "proteins" in a manner seemingly inconsistent with the statutory definition. There are certainly other areas of the statute we would also like to have narrowed. Doing so, though, by regulation, seems to exceed statutory authority.

We also wanted to clarify the meaning of the proposed rule's statement that a new ADLT or CDLT that is FDA cleared or approved is not already assigned a CPT code or HCPCS level II code, CMS would assign a G code to the test. Our understanding is that CMS does intend to sua sponte issue codes for all FDA cleared or approved tests, but instead expects that those codes be requested by providers of such tests.

Additionally, we highlight that guidelines for laboratories to apply for ADLT status and submit documentation to support their application are not yet available. This is another reflection that CMS readiness for PAMA implementation might not be on track by the statutorily required implementation date.

Coverage. The CAP was pleased CMS did not exercise its authority to consolidate coverage polices and/or claims processing for clinical laboratory tests to between one and four Medicare Administrative Contactors ("MACs"), but instead requested comment. In response to the express request from CMS to comment on the benefits and disadvantages of exercising its MAC consolidation authority, we provide the following background and highlight many of the disadvantages of consolidation based on our recent experiences.

While PAMA emphasized that MACs releasing coverage policies for CDLTs issued on or after January 1, 2015 are required to comply with the local coverage determination ("LCD") process outlined in Chapter 13 of the Medicare Program Integrity Manual, several MACs have fulfilled this requirement in letter only, but not in spirit.

One MAC within the last year held carrier advisory committee ("CAC") meetings in each of its jurisdictional states during which the draft LCD was on the agenda. No meaningful discussion of the draft LCD by the MAC medical director or solicitation of input was allowed. Contrary to the CAC process, CAC representatives were explicitly told that only general questions about the draft would be allowed and that their comments or concerns should be submitted in writing to the MAC during the public comment period. In contrast, several other LCDs not related to laboratory services were presented and discussed at these same CAC meetings.

On this draft LCD, the CAP provided extensive comments developed by over 40 pathologist experts in the areas covered by the draft. The CAP's comments included 28 evidentiary challenges, many containing sub-points and were supported by over 53 citations from published scientific literature including generally accepted guidelines of national organizations. Despite the extensive feedback from the CAP's board-certified

pathologists, the MAC made only three trivial revisions in its final LCD. The MAC's published response to comments on the draft LCD did not address many of the issues the CAP raised and where it did address one of the CAP's comments, it failed to address the substantive issues presented.

Amongst those substantive issues, the draft relied upon highly selective and partial literature citation, took references out of context, overlooked fine points, misrepresented the opinions of national organizations and contained several key premises that are unsubstantiated. In addition, the CAP's experts identified published evidence and generally accepted guidelines that directly contradicted the draft LCD. The draft also left both providers and beneficiaries unable to determine prospectively if a service is covered. In some instances, services deemed not necessary under the draft LCD are performed to improve diagnostic turnaround time which may be lifesaving. In other instances, the draft LCD's provisions could direct pathologists to practices that predispose to misdiagnosis, denying patients services from which they may benefit or subjecting them to harmful and unnecessary interventions, particularly regarding some difficult-to-diagnose malignancies.

Since this MAC's LCD was finalized, it has expanded to several other MAC jurisdictions without the benefit of stakeholder input by regional CAC representatives and others or responsive feedback to public comments. As a result, the fundamentally defective LCD is now in effect in twenty states. This experience is not dissimilar from what would be a disadvantageous output of MAC consolidation: the adoption of an LCD significantly limiting/precluding coverage that is of such geographic magnitude it in practical terms approaches becoming a national coverage policy without ever being subjected to the appropriately rigorous national coverage determination requirements.

Exacerbating the problem and magnifying the potential negative impact of MAC consolidation, under current rules, MAC LCDs are essentially unreviewable once they become final. In order to have an LCD reconsidered new evidence must be presented to the very MAC that issued the LCD. In the case described above, the CAP provided a comprehensive set of objections that were then disregarded leaving the CAP unable to seek reconsideration. The CAP's objective was to prepare a thorough response supported by accepted evidence rather than to hold back evidence so that it could present new evidence subsequently in order to have the LCD meaningfully reconsidered.

The CAP would not only discourage MAC consolidation, it would encourage improvement of the current process. This would include greater oversight by CMS to allow for meaningful exchange with CAC representatives and other subject experts during the draft LCD process, response to and consideration of stakeholder comments, and a meaningful reconsideration process for providers, where the need arises once the LCD is finalized. Consolidation could further amplify the problems as demonstrated in our examples above, as could failure to pursue process reform. Most concerning is the implication on future coverage decisions on laboratory services for both patients and pathologists. LCDs such as those seen recently from some MACs not only interfere with physician judgment and the practice of pathology and laboratory medicine absent any compelling evidence base, but also do not serve the public good nor ensure Medicare beneficiaries receive appropriate access to medically necessary diagnostic services.

The issues CMS raises that would arise under consolidation where a MAC has to implement and defend policies it did not author are tremendously important. Their effect is perfectly illustrated in the instance we highlight above whereby subsequent MACs are attempting to respond to stakeholder comments for the LCD authored by another MAC. The overall result is a process that hinders meaningful stakeholder exchange and renders the MAC's decision to deny coverage to beneficiaries a fait accompli. Consolidating claims processing functions only worsens the problem by having a MAC processing claims for laboratory services when the ordering physician is in another MAC.

Moreover, CMS has acknowledged that no savings are to be gained by claims processing consolidation, and the above circumstances illustrate clearly the risks of any further incentives to consolidate coverage determinations. **Taken in conjunction with the complexity of attempting to consolidate claims processing without coverage consolidation leads very definitely to the conclusion the disadvantages of consolidation far outweigh any advantages that could accrue.**

The CAP would enthusiastically welcome the opportunity to discuss and/or provide additional information as needed.

Conclusion. In closing, the CAP reiterates the most significant areas of concern its member pathologists identified in the proposed rule (presented in the order arrayed in these comments) and underscores its key recommendations for effectively addressing them.

Reporting. The limited scope of entities required to submit data must be broadened to improve the accuracy of private payor/market rates and the resulting weighted median. To capture a more representative sample of the laboratory market, the CAP urges (a) adherence to the statutory definition of an applicable laboratory as a **laboratory** that receives a majority of its Medicare revenues from the CLFS, PFS or new section 1834A of the Social Security Act as added by PAMA, and (b) significant decrease in the low expenditure threshold. To achieve compliance with reporting requirements, timely and clear guidance on the specifics of applicable information to be reported that reflects private payor contracting and claims/adjustment processes is essential as is an extension of both the data submission deadline and data collection period.

Coding. Critical to the success of PAMA implementation and ongoing operation is the transparency and integrity of the coding process. In support of this objective, we emphasize the importance of the use of HIPAA-designated code sets, identifiers, and modifiers particularly in assigning codes for new tests. Further, the CPT Code Set (HCPCS Level I) should be used when possible to capture a single test with a single code regardless of payor, and to ensure that payment rates that are established for the CLFS that truly represent private payor market rates. Lastly, the CAP recommends a formal temporary code sunset list be established and temporary codes be replaced with permanent codes at the conclusion of the two year period. By this time, laboratories that received a temporary HCPCS Level II code(s) should have applied for a permanent successor CPT code should a coding need still exist to capture services provided to Medicare beneficiaries.

Coverage. Based on the clear disadvantages identified, we urge CMS not to pursue MAC consolidation of coverage policies and/or claims process for clinical laboratory tests.

We are pleased to have the opportunity to respond to CMS on its proposed rule and appreciate your consideration of the CAP's comments. Should you have any questions regarding the CAP's comments, please do not hesitate to contact us through to Sharon West at swest@cap.org or 202-354-7112.

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