



ASSOCIATION FOR MOLECULAR PATHOLOGY
Education. Innovation & Improved Patient Care. Advocacy.
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September 2, 2014

Ms. Marilyn B. Tavenner
Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-1612-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule; Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B Proposed Rule for CY 2015

Dear Ms. Tavenner:

The Association for Molecular Pathology (AMP) appreciates the opportunity to comment on the CY 2015 Physician Fee Schedule proposed rule. AMP is an international medical professional association representing approximately 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 and commercial clinical laboratories, community hospitals, and the *in vitro* diagnostics industry.

The Association looks forward to working closely with CMS as this proposed rule moves toward implementation and offers the following comments which focus on five areas of particular importance to our members:

1. Using OPSS and ASC Rates in Developing PE RVUs
2. Modifying Process to Establish Values for New, Revised, and Potentially Misvalued Codes
3. Local Coverage Determination Process for Clinical Diagnostic Laboratory Testing
4. Comments on the Palmetto MoDx Program
5. Open Payments Program

Using OPSS and ASC Rates in Developing PE RVUs

CMS is considering using hospital outpatient prospective payment system or ambulatory surgical center (ASC) payment rates in developing practice expense RVUs in future rulemaking. The agency requested comments on potential ways to use Medicare hospital outpatient cost data, not including ambulatory payment classification (APC) payment amounts, to establish practice expense (PE) RVUs. AMP recommends that CMS not use this data in future rulemaking; hospital cost data is not an appropriate proxy that can be used to establish PE RVUs. We believe that this data would result in inaccurate estimates of physician practice expenses.

Hospital cost data allows CMS to estimate facility costs that result in grouping procedures within APCs; some services are paid below cost and others above, allowing hospitals to recoup losses on certain services. The resource based relative value scale (RBRVS) is designed to capture both the direct and indirect costs for physicians to provide individual services. Physicians and independent laboratories who bill under the Physician Fee Schedule (PFS) typically do not provide a range of services as broad as hospitals and would not be able to compensate for negative margins as hospitals do. Also, AMP is concerned about the “charge compression” that occurs within APCs that does not occur in the non-facility setting that would ultimately make APC data a poor proxy for practice expense.

AMP recommends that CMS refine the survey methodology currently used to determine PE RVUs and continue to use survey data to refine these values. CMS should require that there be a minimum number of survey responses to ensure that the results are representative of the costs associated with providing the survey and that the full range of providers who perform the service be required to participate.

Modifying Process to Establish Values for New, Revised, and Potentially Misvalued Codes

CMS is proposing to modify the timing of its review process for new, revised and potentially misvalued codes. If this proposal is implemented, CMS will include the proposed RVUs for these services that the agency receives by January 15 in the proposed PFS rather than creating G-codes to report certain services under Medicare when new or revised CPT codes continue to go through the American Medical Association Current Procedural Terminology (CPT) Editorial and Resource Based Relative Value Update Committee (RUC) processes. This would allow all interested parties regardless of whether they actively participate in the CPT and RUC processes to comment on proposed values before they become final.

AMP is concerned that this proposal will be disruptive to the review process and urges CMS to find an alternate method of ensuring that all interested parties have the opportunity to provide comments on new or revised codes. However, if CMS does implement this proposal, we recommend that the deadline for CMS to receive proposed RVUs be the end of February rather than January 15. This would potentially allow for codes that are RUC reviewed at its late January meeting to be included in the proposed rule.

Local Coverage Determination Process for Clinical Diagnostic Laboratory Testing

AMP appreciates CMS’ intentions to improve the efficiency and prevent delays in coverage in the local coverage determination (LCD) process. The Association and its membership are very familiar with the current LCD process and the Palmetto MoDx pilot project. However, we are very concerned that CMS’ proposed changes to this process will limit the public’s ability to comment and ultimately patient access to these diagnostics may be limited because of the shorter comment period.

While we agree with CMS that technology and electronic commenting has diminished the need for mandatory Carrier Advisory Committee (CAC) meetings, AMP strongly recommends that CMS not reduce the LCD comment period from 45 to 30 days. Even with the ability to submit comments electronically, this will limit public input into the process. Many of the draft LCDs that are part of Palmetto’s MoDx program or are released by other local contractors are complicated proposals both in terms of the science and the policies involved, requiring a thorough review of the scientific literature before comments can be drafted. Shortening the public comment period will put those who wish to respond at a disadvantage.

We support CMS' proposal to publish a final LCD within 45 calendar days of the close of the draft LCD comment period as long as the local Medicare contractors thoroughly review and respond to the comments received. However, we are concerned about the final LCD becoming effective upon publication. When coverage changes are finalized, providers should have time to implement any changes made.

AMP would like to recommend ways that CMS could utilize available technology to further streamline this process. We would like CMS to consider establishing a listserv or web-portal where new draft LCDs would be published. The Association is very familiar with the current searchable database, which can be difficult to navigate. A listserv or web-portal would ensure that those interested would be notified of new drafts upon publication. In place of mandatory CAC meetings, we urge CMS to consider mandating MACs to hold webinars on a regular basis to answer questions and provide clarification on draft LCDs.

Also, the Association urges CMS to consider making other changes to the LCD process. MACs currently bypass the LCD process for "compelling reasons," which can be varied. We recommend that CMS instruct MACs that the only "compelling reason" for which the LCD process can be bypassed are those for which MACs have no discretion to make the coverage policy change. AMP also urges CMS to require MACs to follow the LCD process for any policy that requires edits between the ICD and HCPCS codes and would "restrict coverage."

Further Comments on Palmetto MoIDx Pilot

While AMP supported the PAMA changes to the LCD process to ensure greater transparency and fairness, we, both alone and in cooperation with other organizations, have catalogued numerous concerns about the Palmetto MoIDx program. Its lack of transparency, granularity of coverage decisions, and evidence requirements have been highly problematic -- limiting access to laboratory tests that are often the standard of care - and should not serve as a model for future coverage decisions – molecular or otherwise.

The Agency also cites the "thousands of new clinical diagnostic (particularly molecular) tests developed each year" as a rationale for modernizing the process and removing several of the steps in the current LCD process. AMP notes that the process of assigning CPT codes to new molecular tests has resulted in the creation of a set of codes that adequately identify and categorize these tests by clinical use.

Greater Coordination among MACs: PAMA § 216 mandates that CMS consolidate LCDs to between one and four MACs nationwide. We urge CMS not to use fewer than four MACs for clinical diagnostic laboratory tests and recommend that CMS maintain more than four MACs. Having multiple MACs will best allow for the discovery and adoption of good practices with effective regional input. If CMS were to elect to have only a single MAC, then the national coverage decision (NCD) process should be followed in all determinations; any such decision would be national in scope, requiring the more highly structured processes for solicitation of input and transparency of consideration associated with national coverage determinations. The NPRM states that CMS is "encouraging MACs to collaborate... across jurisdictions" in making LCDs. If the intent or the effect of such collaboration results in a uniform "national LCD," then CMS should require that the NCD process be used instead.

Applicability of New LCD Process to Periodic Review of Existing LCDs: The Agency proposed the process apply to all "new" clinical diagnostic laboratory tests draft LCDs as of January 1, 2015. AMP urges that CMS extend these requirements to all clinical laboratory LCDs going through their mandatory periodic review.

Granularity: CMS states that part of the rationale for updating the LCD process for clinical laboratory tests is to bring greater efficiency in the process given that if CMS “require[s] that MACs follow all steps in the current LCD process, we fear that LCDs will not be able to be finalized quickly enough for even a fraction of the thousands of new clinical diagnostic (particularly molecular) tests developed each year.” CMS also asserts that given “multiple molecular diagnostic tests designated to diagnose the same disease may rely on different underlying technologies and therefore, have significantly different performance characteristics, “that Medicare has an “obligation to consider the evidence at a granular level...”

AMP vigorously disputes this underlying rationale. First, there is no meaningful sense in which the statement that there are “thousands of new clinical diagnostic (particularly molecular) tests are developed each year.” This would be like saying that there is no way to develop LCDs that address E&M services because there are hundreds of thousands of practitioners providing them, each in his or her own fashion; indeed, the ability provided by proficiency testing and alternative methods to validate the accuracy and comparability of laboratory tests exceeds that of any other area in clinical medicine. There is no reason tests should be considered for coverage at a more granular level than CPT with its associated gene identifiers. If CMS and its MACs consider tests by category for each analyte, as is consistent with the remit of the LCD process of assuring alignment of the service with its medical indications, the volume of tests to be reviewed would be entirely manageable. As noted earlier, CLIA and not the coverage process is the best method for addressing the performance characteristics of a given test.

Given the precision of the molecular CPT codes, neither LCD nor NCDs need to be specified beyond the level of the CPT code. The CPT molecular pathology Tier 1, Tier 2 codes with the CPT gene identifiers, and CPT Multianalyte Assays with Algorithmic Analyses (MAAA) codes already cover many of the new tests in current clinical use. These CPT code and CPT gene identifier 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, an official set of 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. These CPT molecular pathology code gene identifiers are to give providers, payers, and coders exactly the clinically-relevant level of granularity to facilitate adjudication of claims for all stakeholders. This should provide the granularity that CMS and other payers quite reasonably seek in making molecular coverage decisions. The list was published online on March 12, 2014.

Evidentiary Standards for Coverage: Palmetto has issued new guidance on the MoIDx coverage process entitled, “ The MoIDx Clinical Test Evaluation Process (CTEP),” (see http://www.palmettogba.com/palmetto/MoIDx.nsf/DocsCat/MoIDx%20Website~MoIDx~Browse%20By%20Topic~General~8PKRZF3404?open&navmenu=Browse%5eBy%5eTopic|_|_|) which provides greater clarity about their process but imposes an evidence bar that very few laboratories can meet. Its high evidentiary bar –based on standards for new prescription drugs– are *inappropriate* for laboratory tests, which serve a different function and have a widely divergent economic model, which would impede access to most molecular tests. Further, a double-blinded randomized control trial is not the gold standard for diagnostics as it is for therapeutics, because both characterizing sufficiently similar patient groups and ensuring sufficiently comparable patient management in a diagnostic (as opposed to a therapeutic) setting is not (and has never been) feasible. Drug trials are generally made against a particular standard of care (placebo or alternate drug), but the clinical utility of

outcomes for diagnostic can range over many approaches to a patient's illness.¹ Additionally, as an article by the Cochrane collaborative notes, "... direct measurements of whether a particular diagnostic test does in fact enhance patient health are currently very rare," and suggests an alternate paradigm for assessments of clinical laboratory tests.²

FDA Guidance: This situation is further complicated by the recent notice from the FDA of their intent to publish draft guidance documents that will establish a framework to oversee LDTs. The public comment period on this guidance will be closing at the end of the calendar year. The FDA is proposing a risk-based, phased-in approach to regulating LDTs to mitigate any consequences of immediately enforcing all applicable requirements such as shortages in the availability of LDTs. Not only does the MoLDx program fail to respect the FDA's legitimate concern to avoid disruption of beneficiary access to medically necessary services but, once these regulations are in place, there will be a need to reconcile the MoLDx program and FDA regulations. It would therefore be gratuitously disruptive to implement the demonstrably flawed MoLDx program in these circumstances.

For example, the FDA may approve Class III LDTs at 5 different labs, presumably each with its own Z-code, which would create confusion. Another scenario is that a Class II LDT may have validated data that shows it's superior to the FDA approved companion diagnostic. This would raise questions about how FDA and MoLDx would address this, and whether they would be in conflict.

It is imperative that the expansion of the MoLDx program be halted until the new FDA regulatory scheme is finalized and implemented. The FDA regulation and MoLDx program will be two parallel programs with the potential to create conflicts, which cannot be minimized unless expansion of the MoLDx program is halted until a system is put in place for harmonization with any FDA decisions.

We vigorously oppose any CMS plans to allow or expand adoption of any such CTEP process for the reasons above, which there was no opportunity to provide to Palmetto, as Palmetto issued CTEP without an opportunity for stakeholder input or comment.

Open Payments Program (Sunshine Act)

CMS is proposing to revoke the Sunshine Act reporting exclusion for continuing medical education (CME) activities. The proposal would exempt third party transfers for CME only in circumstances where the industry donor is unaware of the recipients before and after the funds are transferred. We believe that this proposal is not only unworkable, but will have a detrimental impact on AMP's continuing education activities and those of other specialty societies.

We believe that it will be next to impossible for industry not to learn the identities of speakers, other faculty and potentially participants after the funds have been transferred through brochures, programs, other publications and even physician-employees who participate. This will directly impact AMP and ultimately the public whose providers will not be educated on state of the art technology. AMP's annual meeting is a CME accredited event. Without support, AMP would not be able to provide the CME events that our membership requires to maintain

¹ Personalized Medicine Coalition, "*The Future of Coverage and Payment for Personalized Medicine Diagnostics*," 2014. Downloaded from http://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/pmc_the_future_coverage_payment_personalized_medicine_diagnostics.pdf

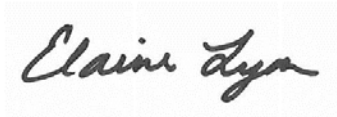
² L. Di Ruffano et al, "How do tests impact on patient health? Development of an explanatory Framework," *Cochrane Methods*. *Cochrane DB Syst Rev* 2011 Suppl 1: 1–40

their licensure and certifications and to stay on the cutting edge of our field. Under this proposal, AMP will be forced to limit members' access to these educational sessions because there is no way to prevent industry supporters to learn of the CME faculty after the fact.

We urge CMS not to implement this provision as written. If CMS feels that some action must be taken with respect to CME, we recommend that the proposal be revised so that the exemption will still apply when a manufacturer provides funding for CME but does not select or pay the speaker or faculty directly or provide the continuing education provider with a distinct, identifiable set of cover recipients to be considered as faculty. Most importantly, CMS must specify that the exemption is satisfied as long as the industry supporter is unaware of the CME faculty prior to committing to fund the course.

Thank you again for the opportunity to submit comments on this proposed rule, and we look forward to working with you as they are finalized. If you have any questions about these comments, please contact Mary Williams at mwilliams@amp.org.

Sincerely,

A handwritten signature in black ink that reads "Elaine Lyon". The signature is written in a cursive style and is placed on a light gray rectangular background.

Elaine Lyon, PhD
President