August 29, 2014

Marilyn B. Tavenner
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Attention: CMS–1612–P

Subject: 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 for CY 2015; Proposed Rule (July 11, 2014)

Dear Administrator Tavenner:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the proposed rule CMS-1612-P entitled “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 for CY 2015.” The CAP is a national medical specialty society representing more than 18,000 physicians who practice anatomic and/or clinical pathology. CAP members practice their specialty in clinical laboratories, academic medical centers, research laboratories, community hospitals and federal and state health facilities.

The CAP’s detailed comments focus on the following subjects included in the proposed rule: 1) opposition to changes to HCPCS prostate biopsy codes; 2) the identification of CPT code 88185 as a potentially misvalued code; 3) opposition for the use of hospital cost data for potential revision or modification of the PFS PE methodology; 4) practice expense equipment change for CPT code 88375; 5) support for AMA revisions to the Centers for Medicare & Medicaid Services (CMS) transparency initiative; 6) proposals regarding local coverage determination processes for clinical diagnostic laboratory testing; and 7) comments regarding CMS’ quality reporting initiatives.

1) **PROSTATE BIOPSY CODES - HCPCS CODES G0416, G0417, G0418 and G0419**

The CAP disagrees with the agency’s conclusion that to establish “straightforward coding and maintain accurate payment”, that it would be appropriate to use only one “G” code to
report prostate biopsy pathology services regardless of the number of specimens. The agency proposes to revise the descriptor for G0416, which is currently used to report the gross and microscopic examination using any method for 10-20 prostate needle biopsy specimens, and to delete codes G0417 - G0419.

In the final 2014 physician fee schedule, CMS implemented a change to HCPCS codes G0416 - G0419 to revise the descriptors by deleting the phrase “saturation biopsy sampling” and replacing it with “biopsies, any method.” This substantive change in reporting the surgical pathology gross and microscopic examination and report of prostate needle biopsies was done in final rulemaking without vetting through the change through a proposed rule which created further confusion regarding the reporting of these services. Prior to 2014, this series of HCPCS prostate G codes were used to report biopsies received when the specimens were obtained through the saturation biopsy sampling technique. The 2014 change required pathologists to use the prostate G codes for 10 or more prostate specimens, regardless of sampling technique.

Since the creation of HCPCS codes G0416 - G0419, CPT code 88305 has been revalued as part of the misvalued code initiative. In 2013, CMS implemented modified recommendations for the 88305 code family based on input from the RUC. Also in the 2013 final physician fee schedule, CMS requested additional data and review of the assumptions used in establishing the 88305 code family direct practice expense (PE) inputs. Subsequently, CAP submitted additional data, which was further reviewed by both the RUC and CMS in validating the PE values.

Pathology services are unique in that the PE for anatomic pathology services does implicitly take into account efficiencies already inherent to pathology services. Specifically, the direct PE inputs for pathology services include reductions in clinical labor, supplies and equipment time to account for batch size, so that there is no duplicative payment for multiple services reported in the same encounter. The reductions incorporated in the PE of physician pathology services to capture efficiency of scale are unique to pathology services. The revaluation of pathology PE direct inputs maintains payment granularity by carefully vetting the medical supplies, equipment and clinical labor associated with each unique service.

The CAP urges CMS to withdraw its 2015 proposal to utilize HCPCS code G0416 for the pathology of all prostate specimens and believe that any valuation with regard to this code family would be premature. The CAP believes that the most accurate coding structure to best define this service and capture accurate payment is to utilize CPT code 88305. We believe that the additional revaluation and scrutiny finalized by the agency in the 2014 final rule for surgical pathology code 88305 together with the greater granularity in payment addresses the agency’s intent to establish straightforward coding and accurate payment for these services.

2) Table 10 - PROPOSED POTENTIALLY MISVALUED CODES IDENTIFIED THROUGH HIGH EXPENDITURE SPECIALTY SOCIETY SCREEN

Table 10 of the proposed rule identifies CPT code 88185 - Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; each additional marker (List separately in addition to code for first marker) as being potentially misvalued through the high expenditure services for codes with Medicare allowed charges of $10,000,000 or more. The CAP notes that following publication of the 2014 Physician Fee Schedule Final Rule, the AMA
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RUC solicited feedback from the specialty societies regarding CPT codes identified in the 2014 proposed rule due to the comparison between payment rates on the physician fee schedule and those paid on either the hospital outpatient department or ambulatory surgery center fee schedule. The RUC recommended the development of practice expense inputs only for the subset of codes identified by specialty societies at the April 2014 RUC meeting. CAP, together with ASC and ASCP, refined the existing direct practice expense inputs for clinical labor, medical supplies and medical equipment for CPT Code 88185. The practice expense data was approved by the RUC and submitted to CMS in May 2014. 88185 has no physician work relative value as this code is used to report only the technical component for flow cytometry. **The CAP recommends that the CPT code 88185 be removed from the list of potentially misvalued services (Table 10) and CMS accept the April 2014 RUC reviewed direct practice expense input recommendations for CY 2015.**

3) **USE OF HOSPITAL COST DATA FOR PFS PE METHODOLOGY**

The CAP and CMS agree that “the comparison of OPPS (or ASC) payment amounts to PFS payment amounts for particular procedures is not the most appropriate or effective approach to ensuring that that PFS payment rates are based on accurate cost assumptions.” However, your proposal also states that CMS continues “to believe that there are various possibilities for leveraging the use of available hospital cost data in the PERVU methodology to ensure that the relative costs for PFS services are developed using data that is auditable and comprehensively and regularly updated.” The agency is therefore exploring ways of collecting better and updated resource data from physician practices and is “seeking comment on the possible uses of the Medicare hospital outpatient cost data (not the APC payment amount) in potential revisions of the PFS PE methodology.” **The CAP opposes the use of hospital cost data for potential revision or modification of the PFS PE methodology.**

The hospital and the Resource Based Relative Value Scale (RBRVS) are vastly different payment systems and any comparison of costs between the two represents a fundamental misunderstanding of the differences in how resource costs are generated in each payment system. Below are several reasons why hospital cost information should not be used for any potential revision or modification of the PFS PE methodology:

1) Hospital data is based on not-for-profit accounting principles associated with each hospital’s separate patient charges, chargemaster, groupings of services, and charge ratio, whereas the fully resource-based non-facility PERVUs employ granular cost accounting principles utilized by the majority of physician offices and independent laboratories. The RUC deploys a code-by-code, batch-based review of the clinical labor, medical supplies and equipment typically used in the non-facility and facility settings, as appropriate to value laboratory services. A batch-based review is a means to prorate practice expenses and helps ensure that each service is distinct and that no overlap in practice expenses occurs.

2) Although hospital cost data is auditable and regularly updated, its estimated costs are derived from hospital charges adjusted to costs using each hospital’s cost-to-charge ratio. Rather than estimating the costs of each resource on a per line item basis, this charge ratio is a gross average of costs at the hospital department level. Hospital data does not reflect the necessary granularity associated with the direct resource costs of
physicians in their offices or in laboratories. It reflects average costs of “buckets” of services rather than resource costs for individual services performed by physicians. Failure to fully separate the packaged costs of multiple medical services in the buckets can lead to a distortion of the costs. The RUC’s practice expense review process minimizes the potential for any distortion of costs.

3) The hospital cost data is static, a snapshot of one particular year of audited Medicare cost reports. It also reflects gross averages of charges that are mathematically manipulated into costs. Hospital accounting is designed to capture the average cost of providing care for a broad range of somewhat comparable services by the many departments of a hospital, rather than the actual cost of individual services provided by a physician in an office or laboratory.

4) Since the creation of the OPPS, this averaging mechanism has consistently resulted in charge compression. CMS defines charge compression as the “practice of applying a lower charge markup to higher cost services and a higher charge markup to lower cost services.” As a result, the cost-based weights may reflect some aggregation bias, undervaluing high-cost items and overvaluing low-cost items when an estimate of average markup, embodied in a single cost to charge ratio, is applied to items of widely varying costs in the same cost center.

5) The expertise and knowledge behind the current RUC review of the non-facility direct practice expense inputs is currently the best available method to accurately account for the direct resource inputs necessary to perform a specific service. It is infinitely more reliable than any data sampling techniques used by auditors to develop their reasonable basis for an opinion made about the accuracy of hospital cost data. In addition, in the RBRVS, direct resource costs have over 16 years of clinical and medical expert review that are calculated on a line item specific costing type basis.

6) Direct practice expense resource costs in the Medicare physician payment schedule are developed through an extremely thorough “bottom-up” methodology in which all the necessary resource costs (clinical labor, medical supplies, and equipment) are reviewed and researched by numerous clinical experts and added line by line to achieve the highly accurate granular resource costs for the physician to provide the care. In contrast, payment to facilities under the OPPS is calculated using the geometric mean of the costs of services in the same APC.

7) The AMA RUC’s practice expense input review process provides for an itemized costing process that is under continuous review by hundreds of experts, medical professionals, and CMS representatives. Itemized costing methods, such as those used in the RUC process to measure resource cost components, help improve the validity and reliability of total cost estimates for physician services and for diagnostic or treatment interventions where costs are not available or evolving.

8) Using activity based costing and micro-costing methods, as the RUC does, helps improve the validity and reliability of total cost estimates for hospital and physician services and for diagnostic or treatment interventions where costs are not available or evolving. Detailed itemized costing findings reflect the true costs to the healthcare
system and account for the clinical intricacies of each service. Gross-costing methods, which estimate average levels of costs, (i.e. for Medicare cost reporting) are unable to provide transparent and consistent estimates and misrepresent the true costs to the healthcare system.

9) CMS has previously stated that comparisons between the PFS and OPPS payments for services are not appropriate because of the different nature of the cost inputs and has explicitly refused to impose one payment system on the other in other rulemakings.¹

10) The use of hospital data for any other purpose other than for what it is intended undermines not only the fundamental concept behind the RBRVS, but also the significant time and resources spent by medical specialty societies who provide expert analysis to recommend accurate resource data for each service reviewed by the RUC.

11) Decisions made with inadequate hospital cost data could lead to the unintended consequences, of misaligned Medicare funds allocation. The unintended consequences may include the loss of patient-specific care, beneficiary access to critical cancer diagnostic services, and increased costs elsewhere in the Medicare program.

12) CMS has also stated that the RUC process is the most accurate available and these data were the basis for CMS’ decision to change from the top-down to its bottom up practice expense methodology.² CMS has been involved from inception and has been a significant voice in the refinement of these inputs. CAP, as well as other specialty societies, welcomes the opportunity to continue to provide guidance to the agency to improve the accuracy of its data. However, arbitrarily accepting hospital outpatient rates in lieu of the carefully reviewed inputs is a step away from improving the relativity of the physician fee schedule.

13) There is no other organized mechanism of medical service cost data collection or methodology which can provide for the necessarily detailed itemized costing of physician services as efficiently or as effectively than the RUC process. CMS has established this vetted process through the RUC to review and provide greater scrutiny of the direct practice expense inputs. CMS can adjust or reject these recommendations and also request further review at any time. There is no such process for hospital cost data.

14) The RUC’s practice expense review process provides CMS with paid invoices for thousands of medical supplies and equipment items. These items are reviewed by the

¹ See, e.g., HHS, CMS, Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates; the Hospital Inpatient Prospective Payment System and FY 2008 Payment Rates; Interim and Final Rule with Comment Period, 72 Fed. Reg. 66580, 66697-98, 66722, 66726 (Nov. 27, 2007).

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RUC participants for accuracy and appropriateness. Hospital cost data has no mechanism or process to review paid invoice costs to such detail.

15) Although the direct costs to furnish a service in the non-facility setting are not always lower than in the facility setting, there are significantly greater indirect resource costs that are carried by facilities even in the event that direct costs involved in furnishing a service in the office and facility settings are comparable. The non-facility setting is thus the most cost-effective location for services.³

CAP supports the existing RUC process for valuing physician service codes and welcomes the opportunity to continue to provide guidance to the agency to improve the accuracy of its data. This process involves many stakeholders across the payer community, government, and medicine, including CAP. The AMA-RUC has shown itself to be the most accurate and fair expert medical professional body available for valuing physician services.

Pathology’s Role in Itemized Direct Practice Expense Input Costs
The practice expense inputs that CAP and its partner associations, American Society of Cytopathology (ASC) and American Society for Clinical Pathologists (ASCP), provide to the AMA RUC and the agency have always been extremely detailed and accurate. These direct input recommendations are developed through extensive laboratory workflow research that is painstakingly analyzed and perfected by numerous experts. The recommendations take into account the typical pathology laboratory arrangement related to each of the following:
- Clinical labor work flows, efficiencies, multi-tasking, and detailed tasks
- Medical supplies used and exact quantities per service
- Modern equipment used and number of minutes used
All recommendations by pathology associations are adjusted for the typical batch size and apportioned specifically to the unit of service. In addition, CAP continues to foster open collaboration with the agency on all coding, physician work, practice expense, and unit of service issues related to pathology.

The CAP has been both proactive and responsive to all RUC and CMS requests and concerns with physician work and practice expense. In fact, all of pathology’s frequently performed services have gone through rigorous pathology specialty review, RUC review, and CMS review over the past few years. Most recently, the RUC provided a forum for specialty societies to provide practice expense recommendations for codes identified in the 2014 proposed rule as potentially misvalued due to the comparison between payment rates on the physician fee schedule and those paid in either the hospital outpatient department or in the ambulatory surgery center. As a result, CAP, ASC, and ASCP provided information that 16 of the services had recently been revalued, and provided updated practice expense direct input data on the remaining 22 codes. Pathology provided more recommendations than any other specialty at the meeting. The RUC and CMS representatives at the meeting carefully reviewed the direct practice expense inputs. The RUC approved updated data in April of this year and subsequently submitted the information to CMS. CAP also frequently follows up on additional questions raised by the agency.

Direct Input Information Used in Developing PE RVUs

The CAP agrees with the agency’s goal to provide for periodic maintenance of supply and equipment prices, as well as greater transparency to the process. The agency has expressed “serious concerns” regarding the accuracy of some of the information used in developing PE RVUs.

The practice of pathology is constantly changing as new technologies and laboratory techniques are developed. In order to provide for proper rank order of the technical component reimbursement for pathology services within the physician fee schedule, it is critically important to have the best available market prices for our typically utilized clinical labor, medical supplies, and equipment. To the best of its abilities, the CAP provides CMS with market price invoices, net of rebates or discounts. Invoices are gathered from mid-sized laboratories (viewed by the RUC as more representative than very small laboratories that only run an occasional test, or very large laboratories that run many tests at once) that regularly provide the service under review. We have also addressed any and all concerns or questions expressed by the agency regarding the direct practice expense inputs for pathology services.

Again, we oppose CMS’ proposal to utilize hospital cost data in developing physician fee schedule services. Pathology has strove to ensure that the direct inputs represent the most accurate data available and strongly believe that utilizing hospital cost data would base payment for pathology services on inferior data.

4) PRACTICE EXPENSE EQUIPMENT ITEM CHANGE AND REAFFIRMATION OF RUC RECOMMENDATIONS FOR CPT CODE 88375

Although it was not part of this proposed rule the CAP would like to bring to CMS’ attention an error in the practice expense for CPT code 88375 Optical endomicroscopic image(s), interpretation and report, real-time or referred, each endoscopic session, which is typically performed by a pathologist in the facility setting while a gastroenterologist performs specific endoscopic procedures such as CPT codes 43206 and 43253.

In January 2013 the RUC reviewed the PE inputs of 88375 and discussed the ownership of the equipment and the associated clinical labor time for preparing the equipment for use, turning it off, and storing it after completion of the service. The CAP and PE Subcommittee agreed that the clinical labor time for those tasks should be deleted (8 minutes) as the equipment is owned and maintained by the gastroenterologist who performs the endoscopic procedures. However, the extraction of the equipment item and its minutes of use from this pathology service were inadvertently overlooked by the CAP and the Subcommittee. The recommendation, in error, was subsequently approved by the RUC and sent to CMS in May 2013.

The CAP and the RUC recommend that the equipment item “Surgical Pathology Optical Image Processing and Review Station” and the 25 minutes of time assigned to it be extracted from the RUC recommended direct PE inputs for 88375. In addition, CMS has assigned a Medicare procedure status of “I” (Not valid for Medicare purposes. Medicare uses another code for the reporting of and the payment for these services) for CY2014. CPT code 88375 was established specifically to distinguish between the work done by a physician interpreting referred images by the endoscopist and work performed directly by the endoscopist for optical...
endomicroscopy. CAP and the RUC disagree that there are other codes more appropriate to report the service. CAP and RUC request that CMS assign a Medicare Status of A for CY2015 and immediately publish all of the relative value units for this service.

5) TRANSPARENCY INITIATIVE

We would like to reiterate our support for the American Medical Association’s (AMA) recommended improvements to CMS’ transparency initiative included in the proposed rule. On August 13, CAP joined the AMA and 69 other medical specialty societies expressing support for additional transparency and comment opportunity in the valuation of physician services and offered alternatives to both the initiation year and CPT/RUC timeline from what was outlined in the proposed rule.

CMS proposes to shift the consideration of all new, revised and potentially misvalued services starting in 2016 to the proposed rule rather than the current process of publishing the values in the interim final rule. CAP supports the AMA recommendation to begin implementing the new timeline and procedures for the CPT2017 cycle and the 2017 physician fee schedule to provide appropriate notification to those submitting code change applications by the first deadline for CPT2017, which is February 13, 2015. We also support adopting the AMA proposal to modify the CPT/RUC workflow to accommodate publication in the proposed rule. Adopting the AMA proposal will eliminate the need for CMS to create G codes which essentially duplicate the CPT codes. CMS’ proposal to create identical G codes is unworkable and would create severe administrative burdens on providers. Again, we urge the agency to adopt the AMA’s recommended improvements when finalizing CMS transparency initiative.

6) LOCAL COVERAGE DETERMINATION PROCESS FOR CLINICAL DIAGNOSTIC LABORATORY TESTING

The Purpose of Local Coverage Decisions
The CAP supports that requirement in P.L. 113-93, “The Protecting Access to Medicare Act of 2014 (PAMA) §216 that mandate that local coverage decisions (LCDs) be developed according to the process already spelled out in regulation according to Section 1869 of the Social Security Act. Recently, MACs have issued coverage policies without following the existing requirements and the CAP encourages CMS to enforce adherence to this process, to ensure consistency and beneficiary access to care. However, CAP is disappointed that CMS plans to expand a deeply flawed program (i.e. the Palmetto Molecular Diagnostic Program – MolDx) to all clinical laboratory tests. Finally, the CAP believes that Congress’ intent in passing this section of PAMA was to align MolDx with the LCD process, not to change the LCD process to look more like MolDx, so such a change would fly in the face of Congressional intent.

The CAP is concerned that CMS seeks a goal not envisioned in statute for the LCD coverage process. The Benefits Improvement Protection Act (BIPA) §522 created LCDs that consist only of reasonable and necessary information. However, CMS stated in discussing the MolDx pilot that:

The pilot project’s long-term goal was to assist clinicians by determining whether the molecular diagnostic tests they order actually perform as expected and, thus, ultimately improve clinical care. This goal stemmed from concerns that some tests were
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being marketed directly to physicians without information regarding the test’s performance.

Conformance to accreditation requirements and Clinical Laboratory Improvement Amendments (CLIA) ensure test performance, and this is not the responsibility of the Medicare coverage program. Physicians are used to making medical judgments and need a full panoply of diagnostic and treatment tools in order to determine the right diagnosis and treatment for each patient, given that patient’s clinical presentation and circumstances. **Doctors by virtue of their training are best positioned to judge the medical evidence, relying on specialty practice guidelines, or consulting clinical colleagues, and do not look to CMS or its contractors to provide such assistance. Instead, CMS and its contractors should implement appropriate LCD processes, to achieve the statutory intent.**

**LCD Process Changes**
In this NPRM, CMS proposes several significant changes to LCD process for all clinical laboratory tests:

1. Shortening the comment period
2. Changing the requirement for a carrier advisory committee (CAC) meeting
3. Specifying a timeline for publication of a final LCD and requiring Medicare Administrative Contractors (MACs) to respond to comments
4. Changing timing of the new LCD taking effect

**Comment Period Length:** The CAP opposes shortening the public comment review period from 45 calendar days to 30 days in cases where a MAC does not hold CAC meeting(s). Given sub-specialization, it takes time to locate and communicate with experts within a stakeholder organization like the CAP, to research and comment on the proffered evidence base for the decision and to comment on a policy. The CAP often finds it challenging to accomplish these necessary steps in responding to LCDs in 45 days. Since even the current timeline is challenging, CMS should not shorten it.

The Agency proposes that: “in the event that stakeholders and/or members of the public are not able to submit comments within the 30 day calendar window, the MAC would have the discretion to extend the comment period.” The possibility of this extension is left entirely to the MACs’ discretion and does not allow stakeholders to know at the start of the process how much time they will have to comment. Therefore, as stated above, we believe the comment period should remain 45 days across the board to ensure predictability and adequate time for stakeholder input.

**Carrier Advisory Committee Meetings:** Currently, MACs are required to hold both open public meetings to discuss draft LCDs with interested parties and also to present the draft policy to Carrier Advisory Committees (CACs). **We do not believe that sole authority to determine the necessity of a CAC meeting should rest with a MAC, as the new rule proposes.** While the web does provide opportunities to comment unimaginable even twenty years ago, the web does not take the place of the free exchange of information among interested stakeholders-ordering physicians, pathologists and others—provide in a CAC meeting. This debate often serves to improve the quality and the fullness of information MACs can use to inform their LCDs.
Transparency: CAP supports the NPRM’s statement that the Agency “expect[s] the draft LCDs to outline the criteria the MAC would use when determining whether a specific clinical diagnostic laboratory test or groups of tests are covered or non-covered.” This transparency has been sorely lacking in the LCD process of-late, and highly variable among MACs, making it difficult for stakeholders to know what input will be relevant to the ultimate coverage determination.

Likewise, we support the new proposed requirement for MACs to post all public comments in writing and post the MAC’s response on a public website. We would suggest further that the MAC be required to explain its response at a granular level so that stakeholders can fully exercise their appeal rights and improve their engagement with MACs in the future. For example, the Agency for Healthcare Research and Quality’s (AHRQ) Evidence-based Practice Centers evidence syntheses usually provide point-by-point responses to commenters’ input on draft reports through a table entitled “Disposition of Comments,” that summarizes the feedback received commenter by commentator, indicating the organizational affiliation of the commenter. We suggest that MACs follow the AHRQ model.

Final LCD Effective Date: The CAP supports making the final LCD effective immediately upon publication assuming that the Agency does not shorten the current 45-day LCD comment period and provides adequate process transparency. We note that Palmetto often posted the MolDx tech assessments after the effective dates of the LCDs, and appreciate CMS efforts to correct this issue.

Further Comments on Palmetto MolDx Pilot

While the CAP supported the PAMA changes to the LCD process to ensure greater transparency and fairness, the CAP, both alone and in cooperation with other organizations, has catalogued numerous concerns about the Palmetto MolDx program. Its lack of transparency, granularity of coverage decisions, 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. CAP notes that the process of assigning CPT codes to new molecular tests has results 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 to use four MACs for clinical diagnostic laboratory tests. Relying on four 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...
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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. **The CAP 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...”

**The CAP 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 LCDs nor NCDs need be specified beyond the level of the CPT code.** The CPT molecular pathology Tier 1, Tier 2 codes with the CPTgene identifiers, and CPTMultianalyte Assays with Algorithmic Analyses (MAAA) codes already cover many of the new tests in current clinical use. These CPTcode and CPTgene 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 CPTmolecular 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 MolDx coverage process entitled, “The MolDx Clinical Test Evaluation Process (CTEP),” 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 proband 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 diagnosis can range over many approaches to a patient's illness. 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.

The CAP opposes 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.

7) QUALITY REPORTING INITIATIVES

The College appreciates the inclusion of three pathology measures in the proposed 2015 Physician Quality Reporting System (PQRS). This should improve participation by pathologists; however, there are still some pathologists who will not have any available measures to report. In a 2014 survey of CAP Members, 11% of the respondents indicated that they did not have PQRS measures to report. While the new pathology measures proposed for 2015 will allow some of them to participate in the 2015 PQRS, the new measures will not cover all of those without measures. In addition, many of those pathologists will have only one measure to report. As CMS proposes to continue to impose penalties on non-participants in the program, we insist that CMS not penalize in 2017 those eligible providers who cannot report in 2015 due to lack of applicable measures.

J. Physician Compare Website

The College applauds CMS for proposing to provide physicians an opportunity to review their personal information that will be included on the CMS Physician Compare website prior to posting. Prior review by physicians will give physicians the opportunity to improve their processes when deficiencies are identified; and is aligned with the stated program goals of improving health care quality. The College asks that the 30 day preview period be extended to 60 days to give physicians adequate time to review any inaccuracies they may find during the review process and that CMS provide a specific methodology through which physicians can correct potential inaccuracies prior to CMS publically posting the information. Anecdotally, we found close to 50% of the entries related to CAP Members found were

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inaccurate. For example, some entries failed to note participation in the PQRS when the Member had participated and received an incentive, and the opposite was also true, physicians who had not participated had notations that they had. Accurate information should be the first and highest priority before any additional information is considered for the site.

The College reiterates its comments from previous years that encourage CMS to develop educational tools for patients viewing the Physician Compare website. The quality programs that CMS proposes including on the website are complex and do not apply to all physician practices. The College believes it is important to note when a physician could not participate in the programs listed due to circumstances beyond their control, (e.g. PQRS due to lack of applicable measure or ERx because they do not meet minimum criteria set by CMS or write prescriptions as part of their medical practice.) The absence of this explanatory information is potentially misleading and could imply a lack of interest in quality when the issue centers on applicability of the program to that physician. For example, the CMS proposal to publically report patient experience data drawn from the Consumer Assessment of Healthcare Providers & Systems (CAHPS) measures and the CMS finalization of reporting on PQRS Cardiovascular Prevention measures group will not apply to all physician specialties, including pathologists. The College reiterates the need to indicate clearly on the website when a program does not apply to a particular physician.

K. Physician Payment, Efficiency and Quality Improvements - Physician Quality Reporting System

Proposed Requirements for the PQRS Reporting Mechanisms

The CAP urges CMS not to change requirements for PQRS reporting from year to year. The rapidly changing PQRS requirements interfere with physicians’ ability to successfully participate and unfairly give administrative and cost advantage to larger institutional practices as compared to smaller practices which may serve rural and other underserved communities. There are several changes in the 2015 proposed rule that will make it more difficult for our members to participate in 2015 PQRS. We provide further explanations of how these changes will negatively impact pathologists below:

- The time required to adapt registries and measures programs to the changes is often longer than a year making it difficult for specialty societies to respond with appropriate measures in a timely manner.

- CMS has proposed removal of a significant number of measures available via claims-based reporting in 2015 and has indicated a desire to eventually eliminate claims-based reporting altogether. We urge the Agency to maintain claims-based reporting as long as the other options are not viable for all eligible providers.

- CAHPS survey questions do not apply to all EPs (such as pathologists). CMS is requiring groups of 100 or more EPs who choose to participate in GPRO to report and pay for the collection of CAHPS measures. Not all EPs will be able to report on the CAHPS measures since CAHPS does not apply to them, and these EPs should not be required to report on these measures. For example, the CAHPS Survey asks patients questions about getting appointments, wait times, and whether the physician listened to and respected the
patient, etc. While these questions may be important they do not make sense for a physician who does not have an appointment-based practice, a reception area or face to face contact with the patient. **For these reasons, we ask that CMS specifically exempt pathologists from reporting on CAHPS measures.**

- **CAP seeks clarity on the definition of face to face encounters; CAP specifically requests that CMS list which codes will be considered face to face.** CMS has not provided enough clarity for us to determine whether encounters such as the performance of a fine needle aspiration or bone marrow biopsy retrieval would be covered by the CMS definition provided. Pathologists may have a small number of procedural encounters that CMS might count depending on the definition. Yet, none of the supposedly cross-cutting measures are applicable, including CAHPS for PQRS as described above. Additionally, the cross-cutting measures are very primary care focused, which leaves our members with no reporting options. **For this reason, we ask that CMS not include procedural encounters as face to face.** If pathologists have to report cross-cutting measures, they will not be able to use the CAHPS measure. While pathologists will have 8 quality measures to report in 2015 if our 3 new measures are finalized, none of the measures have any overlap and could not be reported as cross-cutting measures.

- **CAP believes that the threshold that requires the reporting of cross-cutting measures is too low. We urge CMS to increase this threshold from the current proposal of seeing one Medicare patient in a face to face encounter, particularly because the cross-cutting measures are not applicable to all physicians, such as pathologists.**

**The CAP requests that CMS specifically address whether eligible providers who cannot participate in the PQRS because they have no applicable measures will be subject to the PQRS payment adjustment in 2017. In addition, CAP believes it is premature to ramp up the criteria for satisfactory reporting before all physicians have applicable quality metrics.**

**Proposed Criteria for Satisfactory Reporting for Group Practices Selected to Participate in the Group Practice Reporting Option (GPRO):**

CAP seeks clarification from CMS regarding publication of its list of PQRS registries. CMS is proposing to require group practices to register for GPRO participation by June 30 of the year in which the reporting period occurs. Since there are 3 new pathology measures proposed for 2015 PQRS reporting, groups will need to know if there are registries available to them to report these measures. **We urge CMS to publish the list of registries earlier than June 30, 2015 for 2015 PQRS or move the date for GPRO registration until after the list of registries has been published.**

We applaud the CMS proposal to reduce the patient sample size from 411 to 248 for group practices of 100 or more EPs that report PQRS measures via the GPRO Web Interface. This will reduce the reporting burden on our members. It will also help them better participate in the program.

**Proposed PQRS Quality Measures:**

**CAP appreciates inclusion of 3 new pathology measures in the proposed 2015 PQRS and encourages CMS to finalize those measures.** We had broad support for these measures as demonstrated by the 2013 letter CMS received from 58 pathology organizations urging CMS to include these measures in PQRS. The additional measures will go a long way towards allowing
pathologists to participate; however, the minimum reporting requirement is 9 measures and the 3 new pathology measures, if finalized, will bring the total number of pathology measures to 8. Unfortunately, we do not believe all pathologists have applicable measures to report. Therefore, before raising the reporting requirements, CMS should ensure that every physician is able to participate in some way or avoid penalty if participation is not feasible.

Informal Review:
We believe that the deadline for request for informal review to 30 days after release of feedback reports is too short. Feedback reports are difficult to obtain and many EPs will not realize that they are subject to an adjustment until it is already applied. **CAP recommends a 60 day review period that should begin when the adjustment is applied.**

L. Electronic Health Record (EHR) Incentive Program

As CMS works to harmonize the Meaningful Use (MU) and PQRS measures, **the College requests that CMS be mindful that the MU criteria are generally not applicable to pathology practice, making it impossible for most pathologists to meet the requirements.** While under the EHR Incentive Program Eligible Providers without applicable measures are allowed to report zero, the program rules require that Eligible Providers do so using certified electronic health record technology. The vast majority of pathologists practice in Laboratory Information Systems (LISs), not EHRs so not only are there no applicable Clinical Quality Measures (CQMs) for pathologists, there is no way for them to report CQMs generally at all given the different clinical systems used. In addition, the MU program accepts a zero performance rate for non-applicable measures, while the PQRS program does not. As we have noted before, CMS has not provided a feasible way for physicians who cannot meet the requirements of MU program to participate in a program that combines these two initiatives.

In its final 2012 EHR Incentive Program Stage 2 Rule CMS granted an automatic significant hardship exception to pathologists, later defined to be PECOS code 22, from MU penalties. Pathologists do not practice in Electronic Health Records (EHRs); they practice in Laboratory Information Systems (LISs), which are often the source system for laboratory data in EHRs. Separately, approximately 90 members of Congress have asked the Agency to extend the relief from MU penalties to pathologists beyond 2015, a recognition that pathologists should not be penalized for failing to meet the requirements of a program designed for office-based physicians that pathologists cannot generally meet. Therefore, all efforts to align measures across programs must account for specialty practice differences in clinical information systems used and the nature of the typical patient relationship (e.g. typically face-to-face or behind the scenes.)

M. Medicare Shared Savings Program (MSSP)

M. 3b. Proposed Revisions for Benchmarking Measures That Are “Topped Out” (p.425)
The CAP supports the changes CMS is proposing for the quality metrics in the Medicare Shared Savings Program that improved the measures and reduce reporting burden. In particular, CAP supports CMS proposal to reward improvement as well as quality attainment, but setting flat percentage benchmarks for measures that are topped out.
N. Physician Value-Based Payment Modifier (VBM) and the Physician Feedback Reporting Program

The 2015 proposed rule includes plans for expanding the value-based payment modifier program in 2017 for all group practices and individual eligible professionals, increases in the payment adjustment amounts, and increased reliance on the CAHPS survey. Many of the proposals are aimed at primary care and do not take into account their effect on non-primary care specialties. For example, the Act requires that “… costs shall be evaluated, to the extent practicable, based on a compositive of appropriate measures of costs established by the Secretary.” At this time, there are no appropriate cost measures for pathologists. We address specific proposals below.

N. 4c. Approach to Setting the VM Adjustment Based on PQRS Participation

We believe that CMS yearly changes to the VBM increase make it unnecessarily difficult for EPs to continue to be successful in the PQRS and VBM programs. In addition to the burden on individuals to update their systems each year to meet the new criteria in a short time frame (usually less than 2 months for claims based reporting); specialty societies must use considerable resources communicating these changes to their Members. We ask CMS to put a moratorium on changes to the program and focus on helping EPs participate.

N. 4f. Payment Adjustment Amount

CMS proposes to set the VBP modifier at -4.0% for all physicians who do not satisfactorily report on PQRS measures. CAP opposes this increase in the penalty. We note that for many pathologists, 2015 may be the first year that they are able to participate in the PQRS due to lack of applicable measures in previous years. The total -6% penalty (PQRS +VBM) is too high, especially for those who have not had an opportunity to participate in the PQRS and learn the system. As stated in previous years, the CAP believes that it is premature to raise the adjustment amount before all physicians have applicable cost and quality metrics and have had an opportunity to participate in the programs. CMS noted that it believes that smaller groups and solo practitioners have had sufficient lead time to understand how the VM works and how to participate in the PQRS. CAP disagrees with this statement. As noted above, 2015 will be the first year in which many of our Members will be eligible to participate in the PQRS.

As with the PQRS penalty, we continue to urge that eligible professionals who cannot report on PQRS measures in 2015 due to lack of applicable measures in the program have the VBM set at 0.0 percent in 2017. CAP requests that CMS specifically address in the Rule how it will apply the VBM to physicians who cannot participate in the PQRS because there are no applicable measures for them to report.

N.4h. Quality Measures

CMS describes its current methodology for determining benchmarks for the PQRS measures in the proposed Rule as follows: Under §414.1250, benchmarks for the quality of care measures for the VM are the national mean of a measure’s performance rate during the year prior to the performance period. CAP suggests that CMS take a similar approach as that taken in the MSSP and reward quality improvement as well as quality attainment by setting a threshold for topped out measures above which a group practice would not be defined as low quality. Using the current methodology, a group with a 95% performance rate might be rated as low quality.
quality. **CAP suggests that CMS adopt an approach that doesn't penalize high performing group practices; to do otherwise would be counter to the goal of the VBM.**

N. 4i. Proposed Expansion of the Informal Inquiry Process to Allow Corrections for the Value-Based Payment Modifier

The CAP supports the proposal to expand the informal inquiry process to allow a group to request a correction of a perceived error made by CMS in the determination of its CY 2015 VM payment adjustment. **CAP recommends that CMS align the VBM informal inquiry with the PQRS review process and set the deadline for the end of February 2015.** We oppose the proposal to set the timeframe for the review process with release of the QRUR report beginning in 2016. We believe the proposal for a 30 day period for review requests following release of the QRUR reports is insufficient. The QRUR reports are difficult to obtain; it often takes longer than 30 days just to get the reports and many EPs will not know they will be receiving a negative adjustment until it is applied. **The CAP recommends that the review timeframe should continue to follow the application of the VBM each year as has been proposed for the 2015 VBM.**

N. 4k. Discussion Regarding Treatment of Hospital-Based Physicians

The CAP supports allowing an option for hospital-based physicians to use the hospital value-based purchasing (VBP) program score for the physician VBM. CMS specifically asked for feedback in areas addressed by CAP in its July 2013 proposal to CMS on the VBM and we address this again below.

The CAP opposes the use of the Meaningful Use (MU) definition of hospital-based as this definition would exclude most pathologists that the CAP proposal was designed to cover. EPs could identify the hospital they are associated with at the time they elect the option to tie their VBM to their hospitals’ scores via attestation or some other mechanism. The CAP proposal suggested that the total performance score of the hospitals that a pathologist is associated with could be weighted relative to the number of patients for which they provide services for in each hospital to derive a score.

CMS considered three options to determine what part of the Hospital VBP Program’s total performance score (TPS) to include in the VBPM:

a. Include the entire TPS in the cost composite.

b. Include the Efficiency and Cost Reduction domain score in the cost composite and include all or a subset of the other domain scores in the quality composite.

c. Include a subset of the measures in the cost and quality composites.

As noted in our proposal, the CAP suggests that the hospital VBP calculation based on the Hospital Inpatient Quality Reporting (IQR) measure reporting would replace the cost component of the physician VBM. Pathologists who can report on specific measures would prefer that their efforts on PQRS performance measures be included in the quality calculations of the VBM.

Physician Feedback Reports and Quality Resource Use Reports (QRURs)

As noted in previously, the feedback reports distributed to CAP members showed performance on measures in practice areas that pathologists cannot affect and that were completely unrelated to the services pathologists provide. The QRURs received by
Quality Reporting Initiatives - Conclusions

Despite considerable efforts by this organization, pathologists are still struggling to comply with requirements from prior years while also trying to adapt to the constantly changing and more complex quality reporting environment. We believe that Congress is willing to fix problems legislatively as demonstrated in the SGR bill that includes creation of clinical practice improvement activities. CMS has the ability under current law to use its regulatory powers to address some these issues, and we request that you use all the tools available to you.

The College believes that meaningful improvements in health care quality depend on the collaboration of clinicians. Laboratory testing provides essential information that influences the delivery of health care and measurement of outcomes; it is crucial that pathologists, as directors of medical laboratories, have a voice in quality initiatives. Unfortunately, contributions of pathologists are not easily captured through current performance measurement reporting mechanisms.

As noted, given sub-specialization, some pathologists still do not have applicable measures in the PQRS. The College requests that CMS not apply penalties associated with PQRS, value-based payment modifier, and Meaningful Use programs, to eligible professionals who cannot participate due to the lack of applicable measures or an applicable mechanism to participate. We look forward to working with the Agency to advance high-quality efficient care that is sensitive to the needs of individual patients and populations, as well as to different types of physicians and other providers, and the health care system as a whole.

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The College of American Pathologists is pleased to have the opportunity to comment on issues and appreciates your consideration of these comments. Please direct questions regarding these comments to Jennifer Madsen, Sr. Director of Economic and Regulatory Affairs at CAP, (202) 354-7105 / jmadsen@cap.org.