June 2, 2014

Marilyn Tavenner
Administrator and Chief Operating Officer
Center for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244-18559

Dear Administrator Tavenner:

The College of American Pathologists (CAP) is writing to you to communicate our preliminary recommendations on Sec. 216, "Improving Medicare Policies for Clinical Diagnostic Laboratory Tests" of P.L. 113-93, "Protecting Access to Medicare Act (PAMA) of 2014." The CAP is a medical society serving 18,000 physician members and the global laboratory community. It is the world's largest association composed exclusively of board-certified pathologists and is the worldwide leader in laboratory quality assurance. The CAP advocates 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.

Section 216 of PAMA will significantly revise the payment system for clinical laboratory tests paid on the Clinical Laboratory Fee Schedule (CLFS) by requiring new reporting of private payer payments and setting rates based on the weighted median payment for each test. Further, PAMA establishes a new process for assigning temporary codes for new "advanced diagnostic laboratory tests" that are provided by a single laboratory. Given the important roles pathologists play in developing laboratory tests, directing clinical laboratories, and assuring the quality and appropriateness of laboratory testing for their medical communities, the CAP has a significant stake in the outcomes of these new policies. As you begin to work to implement this section of PAMA, we hope that you will keep our recommendations in mind. We also request an opportunity to meet with you or your designated staff to discuss these points further.

The CAP's goal as this new law is implemented is to minimize disruption to the provision of laboratory tests, thus helping to ensure widespread patient access to testing as well as to minimize reporting burdens to the greatest extent allowable under the statute to (1) laboratories, (2) our member pathologists who direct them and (3) the Agency which will receive potentially over a trillion data points to analyze. Last but not least, we recognize the need to balance these goals with the interests of taxpayers who fund Medicare Part B.

SUMMARY OF KEY POINTS

Reporting Requirements: The new statute creates questions of who has to report. CAP believes that CMS should include hospital laboratories that provide the majority of their CLFS services for non-patients. Further, CMS should not rush to promulgate a low expenditure or low volume threshold but should carefully collect data and use a public transparent process to collect the data. The exception from reporting requirements for capitated payments should only apply to per-member, per-month

arrangements. CMS should also work with stakeholders like the CAP to identify ways to ease the burden of reporting as much as possible within the scope of the law. Lastly, the law suggests that the average sales prices for drugs may serve as a model. However, the CAP asserts that the great differences between the markets and contractual provisions between drugs and laboratories tests makes using rules developed for drugs largely inapplicable for laboratory tests.

Finally, the law does not stipulate a requirement for a consideration of the cost of providing a test but whenever possible, CMS should ensure that costs are accounted for so as to ensure continued patient access to laboratory testing.

Advanced Diagnostic Laboratory Tests: The CAP urges CMS to narrowly apply this new category to new tests to tests not specified in statute so as to ensure the current CPT processes.

HCPCS Coding: In implementing the new temporary coding provisions, CMS should use HCPCS Level I (CPT) codes whenever possible. Additionally, at the conclusion of the two-year period specified in statute for a temporary code, CMS should issue a formal temporary HCPCS Level II code sunset list and the test should have already begun the CPT application process. CMS should also end the practice seen in the MolDx program of using coding to distinguish between FDA-cleared or approved tests and laboratory developed tests (LDTs.)

Expert Advisory Panel: CMS should appoint pathologists –those with molecular as well as those with expertise in other disciplines of pathology to the new statutorily-- created panel. Also, the Agency should consider the appointment of individuals with expertise in laboratory accreditation.

Local Coverage Decision: CAP supports the provisions in the new statute that require conformance to Section 1869(f)(2)(B) of the Social Security Act and regulations at 42 CFR 426 as of January. We urge that not only new decisions but also those up for periodic review adhere to these requirements and believe that doing so will ameliorate some of the significant shortcomings in the current MolDx program such as lack of transparency and stakeholder input into decisions. CMS has discretion under the law to use one to four Medicare Administrative Contractors (MACs). CMS should use four in order to encourage the development and sharing of best practices.

Complexity of Reporting: Given different insurance arrangements and cost-sharing practices, these new requirements will be complicated to implement for both the Agency and laboratories. Therefore, CMS will need to work in an open and transparent manner to implement the reporting requirements in ways that are "least burdensome."

DETAILED COMMENTS

WHAT SHOULD BE COVERED

Applicability of New Reporting Requirements

Section 216 of PAMA requires "applicable laboratories" to report "applicable information" for a "data collection period" for each clinical diagnostic laboratory test that the laboratory furnishes "for such period for which payment is made under this part." An "applicable laboratory" derives a majority of its Medicare revenues from Section 1833 (h) or Section 1848.

An "applicable laboratory" includes entities that receive payment on the CLFS as well as on the physician fee schedule (PFS). Hospital laboratories are required to report "applicable information" if they receive the majority of their Medicare revenue from testing that is separately billable on the CLFS, that is, not provided as part of a bundled payment such as a Diagnosis Related Group (DRG) payment

to an inpatient hospital or an Ambulatory Payment Classification (APC) payment to a hospital outpatient department. The new law applies the payment amounts computed according to the newly legislated formula to hospital laboratories "if such test [provided by a hospital laboratory] is paid for separately and not as part of a bundled payment..." *Therefore, the CAP recommends that in the case of hospitals, any laboratory taxpayer identification numbers (TINs) that provides the majority of its CLFS services for non-patients should be required to report.*

Further, an "applicable laboratory" includes independent laboratories (place of service 81), as well as entities that receive either facility or non-facility payments on the PFS. We believe that the Congressional intent was to require reporting of "applicable information" by the broadest possible set of laboratories, to ensure that the weighted median payment reflects the rates paid to all of the over 200,000 laboratories in the United States that hold a Clinical Laboratory Improvement Amendments (CLIA) certificate. *Thus, CAP urges CMS not to create arbitrary criteria for excluding any laboratories – including physician office laboratories -- from the first round of data reporting.* Once CMS has received data from all "applicable laboratories" the agency should have sufficient data to inform the setting of a threshold for low volume laboratories that will not distort the collected data.

The CAP also notes that laboratories do not always receive insurer Statements/Explanations of Payment that itemize reimbursement on a test-by-test / code-by-code basis, particularly in instances where a large number of individual tests were provided. Implementing regulations will need to address how to allocate a payment on a per-patient or per-visit basis to each of the individual tests performed for the patient or during the visit. CAP would welcome the opportunity to collaborate with CMS and other interested stakeholders on a transparent and "least burdensome" methodology to account for tests where the reimbursed price is not individually itemized. *The CAP also suggests that the Agency undertake education of private payers as to the requirements of the new law so that the Agency can get the most accurate information possible.*

Low Volume or Low Expenditure Threshold

Sec. 216 (a)(2) allows the Secretary to "establish a low volume or low expenditure threshold for excluding a laboratory from the definition of applicable laboratory" for the purposes of the reporting requirements. The CAP urges CMS to ensure that this exception is *not* applied in the first round of data reporting. Further, CMS should array the data submitted by laboratories to identify a low-volume or low-expenditure threshold that will minimize the reporting burden for very small laboratories, but only to the extent this can be done without significantly changing the weighted median payment rate. This will ensure that the new payment rates on the CLFS to be used on or after January 1, 2017 are reflective to the greatest extent possible of the full range of laboratories providing the test. Given the wide variation in the volume of tests performed at laboratories across the US, a volume-weighted median that excludes large categories of laboratories (such as physician offices or hospitals) will be artificially weighted in favor of the highest volume laboratories. Defining such a threshold rationally – based on data, not conjecture – will help protect patient access to tests by ensuring that the weighted median is not artificially pushed lower than the legislative intent of ensuring that CLFS pricing is based on actual weighted median pricing nationally. *We urge CMS to use Notice and Comment rulemaking to establish the threshold to ensure transparency and adequate stakeholder input.*

Exception for Capitated Payments

Sec. 216 (a)(3)(B) provides for an "exception for certain contractual arrangements" and excludes from the reporting requirement laboratory tests "for which payment is made on a capitated payment or other similar payment basis..." For the same reasons as above, *CAP urges CMS to define this exception to apply only to global bundled or per-member-per month arrangements in which there is no separately*

identifiable per service payment.

Treatment of Discounts, Rebates, Co-Payments and Deductibles

Sec. 216(a)(5) discusses treatments of discounts and states that they be similar to the treatment of discounts for the Average Sales Price (ASP) of a drug. While CAP understands the intent of the provision, we hope that *CMS will consider the following significant differences between a pharmaceutical and a laboratory test, and be extremely judicious in applying the formula to the laboratory.*

ASP is defined as the manufacturer's sales to all purchasers in the United States (excluding units associated with identified exempted sales) for the National Drug Code (NDC) for a quarter, divided by the total number of units of that NDC sold by the manufacturer in the quarter. Laboratory tests do not have an equivalent to the NDC code, since laboratories differ in their test menus, as well as the composition of their test panels. We urge CMS to ensure that the calculation of the weighted median payment rate reflects an "apples-to-apples" comparison of like tests.

Additionally, drug manufacturers' reported ASP data must include all volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, and related charge-backs and rebates. While each of these types of discount and rebate arrangements are common features of contracts between pharmaceutical benefit managers (PBMs) and pharmaceutical manufacturers, most of them are non-existent in contracts between clinical laboratories and health plans. Most clinical laboratory tests are paid by private payers either at a contracted rate that is based on a percentage of Medicare's CLFS payment rate or on a capitated basis. Over time, the laws of economics predict that private payer rates will be updated to reflect changes in Medicare's rates. However, those rates are unlikely to include rebates and discount such as are common in the drug industry.

Further, the regulations implementing the ASP methodology were revised over time (from the April 2004 interim final rule to the September 2004 final rule) to reflect real-world concerns of pharmaceutical manufacturers about the timing of payments of those discounts. The ASP final rule directs manufacturers to use a methodology based on a rolling average percentage of price concessions divided by total sales in dollars when data on prompt pay discounts, rebates, and other price concessions are available on a lagged basis. The use of the rolling average methodology was necessary to smooth out what would otherwise have been large changes in payment rates from one quarter to the next. CAP urges CMS to consider this experience with the implementation of ASP and to work with stakeholders to understand the many differences between private payer contracts for laboratory services versus drugs, to avoid unintended consequences in the implementation of the new law.

Another area of concern is the treatment of charity care, including discounts given for patients that pay by cash or payments that are pro-rated in charity cases. Requiring inclusion of these cases without adjusting for these discounts would bias the resulted weighted median. Further, CAP seeks discussion on how CMS's methodology will account for the differences in payment rates between in-network and out of network laboratories.

Given co-pays, deductibles, out of network versus in-network payments, charity care, payer statements that do not necessarily indicate payment on a per test basis, these new requirements will be complicated to implement for both the Agency and laboratories. *CMS will need to work in an open and transparent manner to implement the reporting requirements in ways that are "least burdensome."*

CLFS UPDATE FOR TECHNOLOGICAL CHANGE

As the CAP indicated in its comments on the proposed 2014 physician fee schedule, CMS's plan to update the CLFS to account for technological change would have been an enormous undertaking, fraught with the risk of highly disruptive change. We are therefore pleased that PAMA explicitly forbids the application of a technological adjustment or any other adjustment.

LIMITS ON PAYMENT REDUCTIONS FOR EXISTING TESTS

The new law establishes reference pricing for tests provided for under the CLFS. We are concerned, however, that this resulting reference price may not bear a direct relationship to the cost of providing the test. To the extent that the statute provides CMS with regulatory flexibility, *we would urge CMS to factor costs, not just prices into its calculations and policymaking in order to ensure adequate patient access to laboratory services nationwide.*

"ADVANCED DIAGNOSTIC LABORATORY TESTS" (ADLTS)"

The statute provides special rules for ADLTs, which are defined as a: *"clinical diagnostic laboratory test... that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner) and meets one of the following criteria:*

- *'(A) 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.*
- *'(B) The test is cleared or approved by the Food and Drug Administration.*
- *'(C) The test meets other similar criteria established by the Secretary.""*

The CAP recommends the CMS to narrowly define any criteria in C above so as to include only tests that cannot be accommodated through existing HCPCS Level I CPT process. Doing so also preserves the ability of all stakeholders to participate in an established and transparent process, the current CPT process, helping to ensure the validity of these tests in actual clinical practice.

Category "A" is precisely the type of LDT that CAP considers to be "high-risk", and is the only type of laboratory developed test requiring an FDA clearance or approval under the CAP's three-tiered, risk-based approach to LDT regulation. (See http://www.cap.org/apps/cap.portal?_nfpb=true&cntvwrPtlt_actionOverride=%2Fportlets%2FcontentViewer%2Fshow&cntvwrPtlt%7BactionForm.contentReference%7D=advocacy%2Fldt%2Fldt_oversight_faq.html&_pageLabel=cntvwr.)

HCPCS Coding

As CMS implements the new statutory requirement to adopt temporary HCPCS codes to identify new ADLTs as well as new FDA-cleared or approved tests, and the provision to assign "unique identifiers" upon request, CAP has several recommendations. First, *CMS should 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 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, 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 identifiers will help providers, payers, and coders during the claims submission process. These official gene 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 approximately 550 tests that are associated with these nine codes. The list was

published online on March 12, 2014 and is available for download at https://login.ama-assn.org/account/login.)

Additionally, at the conclusion of the two-year period specified in statute for a temporary code, CMS should issue a formal temporary code sunset list. Such a sunset is in synch with CMS' desire to add greater transparency to the coding process, as in its pending demonstration of a web-based notice and comment mechanism for allowing public input on requests to discontinue Level II HCPCS codes that are Agency-generated. (See http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/index.html.)

Similarly, CAP believes that before the end of the two-year temporary coding period, laboratories that have received temporary HCPCS codes should have applied for permanent successor CPT codes, to ensure broad stakeholder input into the code development process.

CMS should not use the coding process to differentiate between FDA-approved or cleared and laboratory developed (LDT) tests. The MolDX program distinguishes services not on the basis of any recognized system of nomenclature or coding, but rather on privately supplied supplementary designators, which are used to differentiate among clinically equivalent services which are otherwise identically coded under HIPAA-approved systems of nomenclature. By requiring the use of the Not Otherwise Classified (NOC) code, for FDA-approved or cleared versions of a test, and use of the CPT code for other tests, the median prices that are being used to establish the National Limitation Amounts for the CPT codes are distorted due to the exclusion of the FDA approved or cleared version.

Finally, the MolDX program includes rules that create differential pricing between in vitro diagnostic kits that have been FDA-approved or cleared LDTs as performed in clinical laboratories in compliance with CLIA. We believe that Medicare coverage and payment policy is not the appropriate avenue for addressing any perceived concerns about LDTs. CAP members would be pleased to help CMS understand emerging technologies in the field, such as so-called Next Generation Sequencing (NGS), that are performed in CLIA certified clinical laboratories.

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

EXPERT ADVISORY PANEL

Given the unique expertise from their medical training and experience as laboratory medical directors, CAP requests that CMS appoint pathologists to the advisory panel created by the new law. While the new law states that the appointed experts may include "molecular pathologists," *CAP suggests the appointment of pathologists practicing in molecular and in other applicable areas of diagnostics to the panel.*

We note further that the statute, in citing the desired expertise for the panel, encourages the nomination of "individuals with expertise in laboratory science or health economics, in issues related to clinical diagnostic laboratory tests, which may include the development, performance and application of such tests..." The CAP notes that it is CMS-deemed accreditors that have the greatest expertise in test validation and performance and application. Therefore, *the CAP believes strongly that among the individuals appointed to the new panel should be those with a background in laboratory accreditation.*

COVERAGE REQUIREMENTS

Local Coverage Decision Process

The statute states that "as of January 1, 2015, any local coverage determination (LCD) would be required to be made following the development and appeals processes for local coverage determinations as set forth in Section 1869(f)(2)(B) of the Social Security Act and regulations at 42 CFR 426." *CAP recommend that CMS also to require that as of that specified date, all LCDs going through their statutorily mandated periodic review be required to be brought fully into conformance with all specified legal and regulatory forms and processes.*

Number of Medicare Administrative Contractors (MACs) for Clinical Diagnostic Laboratory Tests

The new law mandates CMS to consolidate local coverage decision 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 only have a single MAC, then the national coverage decision 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.

Problems with the Current MolDX Program Coverage Process

The CAP has serious concerns with the MolDX program and the inconsistencies of the program with the established LCD process. The LCD is recognized as 'clear policy' on medical coverage for Medicare beneficiaries. The above delineated statutory changes in the LCD process will help to address some of the problems we have seen with a lack of transparency in both coverage and pricing.

As you know, the purpose of the LCD is to be used for medical review, including initial determinations, development of automatic coverage or denials, and all levels of appeal including Administrative Law Judge (ALJ) reviews, as well as program integrity review and audits. The Medicare Program Integrity Manual states in PIM 83 Chapter 13 that an LCD should "specify under what clinical circumstances a service is considered to be reasonable and necessary" and that a contractor "shall" develop a new or revised LCD when it identifies an item or service that is never covered under certain circumstances.

The Molecular Diagnostics LCD, issued by Palmetto and adopted by Noridian, applies a non-coverage decision to an extremely broad category of tests virtually encompassing all molecular procedures but does not refer to any particular items or services or clinical circumstances under which items and services would be considered "reasonable and necessary." Rather than developing LCDs to set forth its decisions about whether particular items or services are covered, Palmetto has done so in webpage statements published on the MolDX website.

This is a "shell" LCD, and counter to the LCD process, in that it denies all stakeholders, including the public, the medical community, and the Coverage Advisory Committee (CAC) the opportunity to comment on the decisions. Critically important, the webpages, unlike Articles, are not posted in the Medicare Coverage Database, further complicating claims processing, including automated reviews and potential requests for refund of overpayment.

The webpage statements also declare that Palmetto has concluded that the tests in question are "statutorily excluded". We disagree with this conclusion. CMS has specifically stated that the statutory exclusion which prohibits coverage of screening services [based on §1862(a)(7)] applies to services or procedures "furnished in the absence of signs, symptoms, complaints, or personal history of disease or injury." CMS has clarified that the statutory exclusion only applies when a procedure is performed in the asymptomatic person. Use of the test in a symptomatic person is to be considered a diagnostic test.

In our analysis, the reason cited for denying coverage meets the CMS definition of a screening exclusion in only 7 of the 49 statements. Medicare contractors have broadly interpreted some tests as "screening tests" without fully examining the indications in which those tests are used, and require physicians to follow clinical guidelines for tests, some of which are out-of-date. The dual use of the word 'screening' by Medicare as a payer and by physicians and clinical laboratories has resulted in the inappropriate classification of some clinical laboratory procedures as statutory exclusions. Providers do not have the ability to dispute Palmetto's conclusion, as providers are not able to request reconsideration of the decision, as they can for published LCDs.

We are not opposed either to proper LCDs for each of these services, or to an actual National Coverage Determination. What we do oppose, and seek to have rescinded, are 1) the above-described present actions purporting to be LCDs by those administrative contractors that improperly make coverage determinations as above, and 2) those "LCDs" promulgated by other administrative contractors with no substantive content except reference to another contractor's determinations, which extends the initial lack of proper process or meaningful consideration to other jurisdictions.

Again, these Noridian and Palmetto actions support the need for the LCD reforms contained in the statute. *We look forward to working with CMS to ensure that these reforms are expeditiously and fully implemented so as to resolve the problems enumerated herein.*

The recommendations below outline a streamlined, transparent, and evidence-based process that is administratively efficient and will result in appropriate coverage of molecular pathology and next generation sequencing diagnostic services that is beneficial to the Medicare population.

Recommended Sources of Input and Evidence:
CMS adopt a process for coverage of molecular pathology diagnostic services that:

- Preserves the LCD process and maintains a number of MACs responsible for coverage, pricing, and payment determinations.
- Leverages existing transparent, evidence-based, stakeholder-driven processes, to expand the quality and scope of input the agency receives and relies upon from recognized clinical subject matter experts, to support coverage and payment determinations by MACs. The foregoing includes, but would not be limited to, application dossiers for CPT codes presently provided to the CMS Representative on the CPT Editorial Panel.
- Provides a central majority role for molecular pathologists, medical geneticists and other medical genetics professionals with the requisite expertise in how the tests are performed and used in the diagnosis and/or management of patients. The foregoing could include, but should not be limited to, establishing a Federal Advisory Committee that provides recommendations to the agency on pricing, payment and coverage of molecular pathology and next generation diagnostic services. This goal could be accomplished through full and timely implementation of the new advisory committee created in PAMA.

Recommended Short-Term Actions:

- CMS authorize payment for all claims previously filed using Tier 1 and Tier 2 CPT codes, retroactive to January 1, 2013, without requiring submission of an appeal for every claim, unless a MAC has issued a LCD for noncoverage that complies with existing regulatory requirements including code-specific notice and comment.
- The CPT Editorial Panel provides the agency with CPT code application dossiers including clinical evidence. The CPT process includes an in-depth examination of each test's utilization in clinical practice, published evidence in peer-reviewed literature, solicitation of expert opinion, and a consensus-driven review by a panel of experts in the relevant field.

- While the CPT process is designed to establish codes—not coverage—it is the only existing process involving molecular pathology diagnostic services and next generation sequencing services that is transparent, and involves participation by a broad cross-section of interested stakeholders, with decisions based on clinical evidence and the recommendations of those with the greatest expertise in the use of these tests in the diagnosis and/or management of patients.
- Several MACs are developing LCDs that comply with existing regulation and, to the extent that blanket coverage determinations on Tier I and Tier II services would be in conflict with these LCDs, we recommend deferring to the LCD process where MACs have complied with the regulatory requirements.

Recommended Permanent Process:

- Once the NGS CPT codes are implemented and new molecular pathology code requests processed, these new CPT codes would share the same disposition as any other new Medicare service, and would presumptively be covered. However, MACs would continue to have the authority and discretion to create exceptions (based on appropriate determinations of non-coverage or limitation of coverage) through the existing LCD process.
- CMS and its contractors should process and pay claims for these services in the same manner as all other existing and new services with CPT codes for which there is no specific NCD or LCD defining coverage status.
- CPT codes provide the clinically appropriate level of specificity and represent a single test, though methodology within codes may differ; this is the basis on which CPT codes are assigned:

  Step 1: CMS and MACs receive CPT application dossiers of clinical evidence
  Step 2: MACs process and pay CPT code claims
  Step 3: Either MACS, at their discretion, issue an LCD on coverage of the CPT code; or, a National Coverage Determination is issued, if sought.

Finally, please note that CAP does not support:

- Modifications to the LCD process requirements that deviate from existing regulatory requirements or that undermine notice and comment.
- Establishment of a single MAC to make recommendations or to administer pricing, coverage, and payment, as this will undermine the LCD process and effectively render all such determinations National Coverage Determinations, without the protections and processes provided for such national determinations.
- The use of identifiers as the basis for making coverage and / or payment determinations that discriminate among tests within a CPT code based on any criterion beyond the identification of the gene; e.g., based on the methodology or laboratory performing the test.
- Conditioning coverage on participation in clinical trials.

CONCLUSION

Thank you for considering CAP's recommendations. We would welcome the opportunity to meet with you to discuss these further, and look forward to participating in the forthcoming regulatory processes through comments and other appropriate means as you implement the law. In the meantime should you have questions, please do not hesitate to contact us through Julie Cantor-Weinberg, Director, Economic and Regulatory Affairs at jweinbe@cap.org or (202) 354-7136.

Regards,

Jonathan L. Myles, MD, FCAP
Chair, CAP Economic Affairs Committee

cc: Amy Bassano, Director, Hospital and Ambulatory Policy Group Center
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