



September 4, 2012

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Department of Health and Human Services
Room 445-G
Hubert Herbert Humphrey Building
200 Independence Avenue, SW
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Attention: CMS-1590-P

Subject: CMS-1590-P: Medicare Program; Payment Policies Under the Physician Fee Schedule, Other Revisions to Part B for CY 2013; Proposed Rule; (July 30, 2012)

The College of American Pathologists (CAP) appreciates the opportunity to comment on the proposed rule CMS-1590-P entitled "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2013." 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 comments in this letter focus on the following subjects included in the proposed rule: 1) payment for molecular pathology services; 2) identification and review of potentially misvalued services; 3) expansion of the multiple procedure payment reduction policies under consideration for future years; 3) specific edits to the practice expense inputs of 88120 and 88121 and 4) physician quality reporting initiatives.

Payment for Molecular Pathology Services

The College of American Pathologists (CAP) supports placement of the new molecular pathology CPT codes on the Medicare physician fee schedule and welcomes this opportunity to provide additional information in support of this position. The new molecular pathology CPT codes relate to professional interpretations of the test results of individual patients. Complex tests that require professional interpretation of the data generated by instruments to be clinically meaningful belong on the physician fee schedule. The data generated by molecular pathology procedures cannot be released to the ordering clinician prior to professional interpretation into a clinically meaningful result. The Physician Fee Schedule (PFS) provides for the true resources to be continuously reviewed and scrutinized through the relative value update processes, taking into account changing technology and increased efficiencies as technology is adopted and becomes more widespread. It is for these reasons and others that the CAP supports placement of the new molecular pathology CPT codes on the Medicare physician fee schedule. In addition, we are including a copy of a White Paper submitted to CMS earlier this year

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entitled "Reimbursement of Molecular Pathology Services: Legal and Policy Basis for Placement of Molecular Pathology CPT Codes on the Medicare Physician Fee Schedule." This document provides additional reasons for placing the new molecular pathology CPT codes on the Medicare Physician Fee Schedule.

Utilization

The molecular pathology codes are used to describe molecular procedures involving the analyses of nucleic acids to detect variants in genes that may be indicative of germline (eg, constitutional) or somatic (eg, neoplastic) conditions, convey prognostic information, predict drug responsiveness, monitor disease progression, or test for alleles used to determine histocompatibility in transplantation. The increased specificity of the new molecular pathology CPT codes will provide the agency with greater ability to assure medically appropriate utilization. The new CPT code selection is typically based on the specific gene(s), variants, or translocations that are being analyzed. Besides the professional work necessary to transform the data generated into a clinically meaningful result, the new molecular pathology codes, when reported globally, include all technical or analytical steps performed in the test (eg, deparaffinization, cell lysis, nucleic acid stabilization, extraction, digestion, amplification, and detection).

The technical steps included in the new molecular pathology CPT codes were previously reported by the "stacking" of existing method-based molecular diagnostic CPT codes on the clinical laboratory fee schedule (CLFS). The "stacked" codes reflected each laboratory's particular methodological steps involved in performing the test, rather than codes specific to the analyte (gene) being examined. This billing structure resulted in significant variability among laboratories billing for molecular pathology procedures, and consequent confusion by CMS and its administrative contractors as to exactly which tests were being billed at what price. For example, some molecular pathology procedures may be performed in 5 molecular steps or in 10 steps, meaning that a laboratory could be reimbursed significantly more, or significantly less, depending on the number of technical steps used in the molecular methodology and coding approach for molecular analysis of the same analyte.

Because the "stacked" methodology codes provided no information about which test was actually performed, a direct utilization comparison between the new codes and previous stacking methodology codes cannot be made. Moreover, we do not believe that existing volume data for the technical stacking codes can be used to accurately predict future Medicare volume with any degree of confidence. Under the new coding structure, all technical steps for analysis of a single analyte will be consolidated under a single CPT code. The typical technical steps, as well as the interpretive service associated with each new code, were described in the CPT proposal developed by the AMA multi-stakeholder workgroup. Finally, it is expected that use of the new codes will also be reduced by NCCI edits or MUE's associated with the reporting of services provided to Medicare beneficiaries.

We strongly question the validity of the non-provider specific data CMS may have received from independent laboratories. We believe these laboratories focus on higher volume procedures and many of the higher volume new molecular pathology CPT codes, such as those for cystic fibrosis, will rarely be used in the Medicare population.

Examples of codes with infrequent utilization in the Medicare population are as follows:

81200, 81205, 81209, 81242, 81250, 81251, 81255, 81260, 81290:

These tests are almost exclusively used for pre-pregnancy, prenatal planning, and perhaps a small number of affected children or young adults. Thus, they would rarely be performed in the Medicare population.

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81228 and 81229:

Cytogenomic array testing for congenital disorders have been estimated at 50,000 - 100,000 tests per year within the general population. However, most will be performed in children or young adults, and almost never in an elderly person. Therefore, the Medicare test volumes should be very low (including testing in persons with disabilities).

81243 and 81244:

The vast majority of these tests are performed in young patients suspected of having X-linked mental retardation, with only a small number performed in elderly patients for tremor/ataxia.

81302-81304:

MECP2-related disease usually presents in infancy or childhood. Testing is performed for diagnosis in young patients or rarely for pre-pregnancy/family planning reasons in a mother who is suspected of having skewed lyonization. It would almost never be performed in Medicare patients.

81331:

Testing is for Prader-Willi syndrome or Angelman syndrome both of which present in early childhood and are diagnosed in children or young adults. Testing would almost never be performed in the Medicare population.

Despite the difficulty in accurately estimating projected volumes of the new molecular pathology CPT codes noted above, the RUC provided volume estimates to the CMS for the majority of the new CPT codes based on the recommendation from CAP from utilization of CPT code 83912, Molecular diagnostics; interpretation and report. Typically, one report coded with 83912 would be included with a code "stack" describing the methodology utilized by a specific laboratory in performing a molecular pathology procedure. CAP then reviewed medical literature and other available data to provide an estimate of utilization in the Medicare population for each new analyte specific molecular pathology CPT code. The CAP believes that the submitted utilization data represent more accurate and valid estimates for use in establishing relative value units under Medicare's physician fee schedule.

Establishing National Payment Rates on the Physician Fee Schedule

We urge CMS to establish national relative value units and national payment rates for the new molecular pathology CPT codes. The RUC provided realistic utilization estimates necessary to establish national values. The data developed by CAP and refined by the RUC represent accurate inputs for practice expense and comparisons on the relative value scale to other professional services.

We are also concerned with the establishment of local payment rates by the individual Medicare contractors for the new molecular pathology codes. It is unlikely that individual carriers can duplicate the extensive, detailed and highly accurate process that the RUC used to value each molecular pathology code. Moreover, carrier pricing would add unnecessary administrative complexities and unnecessary costs to providers and beneficiaries. Variations in carrier pricing would be disruptive to providers, patients, and healthcare institutions and could result in movement of sites of testing to the highest paying regions in order to maximize Medicare reimbursement for individual services. *In addition, carrier pricing is not necessary as the values for the molecular pathology codes would be interim for 2013, the agency has the opportunity to revise the values prior to finalization.*

CMS has additional data generated from its transmittal requesting providers to report both the old stacking codes and the new molecular pathology codes on claim forms in 2012. We are concerned that because of the complexity of determining payment for the new molecular pathology codes, a gap-fill process utilizing individual carrier pricing to establish a subsequent national payment rate would lack the breadth of input, external scrutiny and relativity utilized in the RUC process.

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Further, CAP has significant concerns about the validity of a molecular pathology payment program established by Palmetto, which we believe establishes pricing arbitrarily and lacks the extent of scrutiny and breadth of input of the CPT and RUC process. The CAP and the AMA have each previously communicated to CMS their reasons for opposing the Palmetto program. A copy of CAP's previous correspondence is attached.

Unique Providers of 83912

Frequency data shows that the majority of unique providers of 83912 are physicians. CMS should find from Medicare's 5% claims file for the year 2009, that 52% of the unique providers of 83912 report the service on the physician fee schedule. This information was obtained from a study to find the number of unique providers of 83912 that are billing on the CLFS and the PFS, respectively. The results are as follows:

Physicians	370	52%
Independent Labs	338	48%
Total unique providers	708	100%

The typical provider of these services is the physician, rather than the independent laboratory.

Clarifications Regarding NPRM

CMS' NPRM states that the "AMA RUC reviewed the 101 new molecular pathology CPT codes and concluded that 79 of 101 new molecular pathology codes include work furnished by a physician." This statement is in error as the CAP and AMA RUC agree that all of the molecular pathology codes include work furnished by a physician. Specifically, CAP and the AMA have clarified that, for a select few of these services, it is not currently typical that physicians perform them, but physicians do perform these services.

CMS' NPRM also states that "at our request, CAP provided CMS with direct PE input recommendations for 15 of the remaining 22 CPT codes to the best of their ability". To clarify, CAP provided both physician work crosswalks and detailed practice expense inputs to CMS for these 15 codes.

In addition, CAP and the AMA RUC made assumptions about the typical laboratory setting and batch size to determine the typical direct PE inputs for each service. We believe these batch sizes represent those encountered by the typical mid-sized laboratory, any larger batch size would likely price smaller community laboratories out of the market.

Concerns with Automated Services and Negative Results

We understand that CMS is concerned that some of the newly established molecular pathology CPT codes should not be on the physician fee schedule, as their results may be "clearly negative," or they may be "automated" and produce obvious results. We disagree with this assessment. The services captured by the new molecular pathology CPT codes produce data that must be reviewed and interpreted for their results to have clinical significance. Results of these technical procedures require interpretation of the raw data generated, and ultimately conversion into clinically usable results for the treating physician. Physicians assume the responsibility for the generation of these results, and perform the work associated with interpreting them, irrespective of whether the patient has a positive or negative result. The proportion of positive results varies by procedure and patient population. For some oncology assays the positive rate may be 50% or greater. However, irrespective of the fraction of positive test results, a negative result does not imply a lack of physician work. Rather, even in negative cases a physician must review the data and interpret it, converting it to a clinically meaningful result,

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prior to releasing it to the patient's chart. This is in contrast to codes on the CLFS, for which results generated by an instrument (e.g. glucose) may be directly entered into the laboratory information system and utilized by a treating physician without interpretation by a pathologist or other laboratory physician. We believe a professional approach to molecular pathology testing is consistent with the highest standards of care for patients, many of whom are Medicare beneficiaries.

The new molecular pathology codes were developed as global services, including professional and technical components. Representative vignettes were provided for each code, which expand on the professional service rendered. The following are example vignettes developed as part of the CPT and RUC processes, which demonstrate the incorporation of the technical steps and the professional service associated with each code:

81316:

Clinical Vignette (81316)

Quantitative PCR testing is requested on a 45-year-old male with an established diagnosis of acute promyelocytic leukemia to assess for treatment effectiveness and disease relapse. Anticoagulated marrow is sent to the laboratory for PML/ RARalpha translocation testing for the previously identified breakpoint by quantitative real-time PCR.

Description of Procedure (81316)

Upon receipt of the specimen, total RNA is isolated and assessed for quality. Quantitative real-time reverse transcriptase PCR is performed to detect and quantify the patient's specific breakpoint and the Abelson gene (ABL1). The pathologist analyzes the blue fluorescent curves that are produced as the PCR products are generated to determine the status of the translocation. He or she relates the crossing threshold to previously generated standard curves for the PML-RARA and ABL transcripts to determine the normalized and absolute copy numbers of the PML-RARA transcript present in the specimen at the time of testing. The pathologist composes a report that describes the transcript status and the normalized copy number, and compares these breakpoint specific results with the patient's previous results. The report is edited and signed, and the results are communicated to appropriate caregivers.

81342:

Clinical Vignette (81342)

A 55-year-old male patient presents with fever, episodic night sweats, weight loss, and lymphadenopathy. A biopsy of an enlarged supraclavicular node is taken; initial morphologic and immunologic studies demonstrate a T-cell population that is suspicious for malignancy. A frozen sample of the lymph node is submitted for T-cell antigen receptor gene and gamma rearrangement studies as part of a pathologic evaluation for lymphoma.

Description of Procedure (81342)

High quality genomic DNA is extracted from a lymph node sample. In order to detect a clonally rearranged population of T-cells against a background of poly-clonal T-cells, two multiplex PCR reactions are performed using fluorescent linked primers directed toward the variable and joining regions of the T-cell receptor gamma genes. The resulting PCR products are separated using capillary electrophoresis. The pathologist evaluates the capillary tracing for a predominant fragment of discrete size and appropriate shape against background polyclonal or oligoclonal peaks for evidence of clonality. The pathologist composes a report that specifies the clonality status of the T-cell population. The report is edited and signed, and the results are communicated to appropriate caregivers.

81281:

Clinical Vignette (81281)

A 34-year-old Caucasian male is referred to a cardiologist by his family physician for evaluation and possible genetic testing. His 38-year-old sister recently underwent testing for a panel of 12 genes

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associated with long QT syndrome and was diagnosed with a known pathogenic variant in the CACNA1C gene. A blood sample is submitted for targeted gene sequence analysis of the relevant region of the CACNA1C gene.

Description of Procedure (81281)

High quality genomic DNA is isolated from whole blood and subjected to PCR amplification for the CACNA1C gene exon which contains the known familial mutation. The PCR products undergo bidirectional dideoxynucleotide chain termination sequencing using capillary electrophoresis. The pathologist evaluates the sequencing electropherograms for the known familial mutation and any other variants that may be present. The pathologist composes a report that specifies the patient's mutation status. The report is edited and signed, and the results are communicated to appropriate caregivers.

Creation of HCPCS II G Code

Currently the interpretation of molecular pathology services is reported by CPT code 83912. This code is reported by laboratories on the CLFS when a qualified healthcare professional other than a physician provides the interpretation, and on the physician fee schedule as 83912-26 when the service is reported by a physician. While CAP's review of utilization of CPT code 83912 concludes that the majority of the entities reporting CPT code 83912 are physicians, we encourage CMS to establish corresponding G codes for use on the CLFS by independent or reference laboratories which perform molecular pathology services for which the interpretation and report is provided by doctoral level scientists.

Conclusions

Placing the molecular codes on the PFS will benefit Medicare beneficiaries. Codes placed on the PFS have their valuation periodically examined and updated by the RUC. There is no similar process for updating code valuations on the CLFS. As each molecular test evolves, its associated technical costs decrease (as with any maturing technology). This is particularly true of gene sequencing, which is undergoing rapid technological advances that are likely to bring exponential decreases in sequencing costs in the near future. Placing the CPT codes for these molecular pathology services on the PFS will enable the healthcare system to capture those savings. Again, we urge CMS to place the new molecular CPT codes on the PFS with nationally established values as recommended by the RUC and by CAP.

Identification and Review of Potentially Misvalued Services – Table 9, 88348

The CAP disagrees with the methodology and construction of CMS' Review of Services with Stand Alone PE Procedure Time potentially misvalued screen. This screen purportedly includes CPT codes with stand alone procedure times that are not based on physician time assumptions as is typical in the development of non-facility PE RVUs. In addition, CMS asserts that when the clinical staff intra-service time is not linked to physician intra-service time, RUC review of service time is less rigorous. CAP disagrees with these assertions for several reasons.

The RUC process of reviewing direct practice expense inputs involves three main levels of expert panel review: specialty society expert panel review and attestation of the data provided; RUC Practice Expense Subcommittee review; and full RUC member review. This process is extremely rigorous for every CPT code to which it is applied, irrespective of the amount of physician work involved.

It is also important to note that clinical labor time and equipment time associated with most CPT codes is typically not solely associated with physician time, but rather represents the time associated the accomplishment of the entire procedure or service, inclusive of the pre, post, and intra service periods. Practice expense clinical labor and equipment component times are often unrelated and vastly

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different than the physician time for a given medical service. This is especially true for pathology services. In addition, there are numerous examples from other specialties such as radiology, radiation oncology, cardiology, neurology, psychology, and sleep medicine for which the clinical labor and/or equipment time may be only remotely related to physician time. For the majority of XXX global services on the physician fee schedule, the direct practice expense inputs of clinical labor and equipment time cannot be simply related to the typical physician time. This is certainly the case for pathology services. Thus, we believe code 88348 should be removed from the screen.

Further Expansion of the Multiple Procedure Payment Reduction Policies

The College disagrees with CMS's assumption that a MPPR is a valid and accurate mechanism to value services when performed on the same date of service. We recognize, and the RUC practice expense and physician work recommendations have incorporated, efficiencies that can be gained when multiple services are performed by the same physician on the same date of service, but only when certain clear criteria are met. CMS's current proposal does not meet these criteria.

The RUC and the CPT Editorial Panel have undergone an extensive, reasoned process to fairly address those specific instances for which services can appropriately be bundled together to reflect enhanced practice efficiencies. The Joint CPT/RUC Workgroup on Codes Reported Together has spent considerable specialty society time and resources bundling services that are performed together 95 percent and 75 percent of the time, and provides coding solutions that accurately value services commonly reported together.

Based on these considerations, the College believes that evaluating potentially duplicative work in services performed on the same date of service needs to be conducted at the individual code level, rather than through across-the-board payment policy modifications proposed by CMS. Otherwise, the resulting service valuations may not accurately reflect the resources required. In a good faith effort, organized medicine has worked to resolve duplications in the Resource-Based Relative Value Scale (RBRVS) over the past several years, and will continue to comply with these efforts in coming years.

Therefore, we urge CMS not to adopt its proposal to expand the MPPR on either the professional or technical component of any additional services.

Specific Edits to the Direct Practice Expense Inputs of 88120 and 88121 - Cytopathology, in situ hybridization (eg, FISH),

In February 2012, CAP conveyed to CMS staff specific practice expense input edits for CPT codes 88120 and 88121 that correct inaccuracies in the original RUC recommendations from October 2009. These edits involve a revised price of the UroVysion test kit supply item, and time corrections for several equipment items. We urge CMS to make these edits for CY 2013. These practice expense edits are listed below, and the revised RUC practice expense spreadsheet and additional reference documentation is attached:

Supplies

1. SA105 - UroVysion Test kit (line 57) has an inaccurate price within CMS' practice expense database. The attached invoice indicates the price to be \$229.83. This price is calculated through the sum of the cost of a 100 assay kit, plus the total shipping costs of \$66.55, which totals \$18,616.55. This total of \$18,616.55 is then divided by 100 to get to \$186.17. The \$186.17 is then divided by an efficiency factor of 0.81 (listed in the FDA information, attached) which results in the total cost of \$229.83. This amount is then multiplied by the specific quantities listed for CPT codes 88120 and 88121 recommended by the RUC. See attached invoice and page 5 of the test kit data sheet as references.

Equipment

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1. EP088 - ThermoBrite (line 78). This equipment item was originally submitted to the RUC's practice expense subcommittee as 107 minutes for 88120 and 26.75 minutes for 88121. This was in error as the time should have been 321 minutes and 160.5 minutes respectively. The error on our part was that these numbers were initially divided twice instead of once to account for the batch size of 3 for 88120 and 6 for 88121.
2. EP091, EP090 - Ikonilan Scope and Software (lines 80 and 81). This inaccuracy was due to a typographical error for CPT code 88121. The number of minutes should not have been 2.97. The time should be 29.7 minutes.
3. EP092 - Olympus BX41 Fluorescent Microscope (line 83). This item was listed as 1.33 minutes when it should have been 1.33 hours. This converts to 79.8 minutes. This time can be broken down to 43 minutes of clinical labor staff use and 30 minutes of physician use. We cannot justify any additional time so that would equal 1.22 hours (73 minutes).
4. EP093 - Filters (line 84). This item is used with the Olympus BX41 Fluorescent Microscope (line 83) and therefore should also have 73 minutes of equipment time.

Quality Reporting Initiatives

The College appreciates the inclusion of five pathology measures in the proposed 2013 Physician Quality Reporting System (PQRS). However, there are still many pathologists who will not be able to participate due to lack of applicable measures. As CMS begins to impose penalties on non-participants in the program in 2015, we request that eligible providers who cannot report in 2013 due to lack of applicable measures not be penalized beginning in 2015.

Physician Compare Website

The College encourages 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 may not apply to all physicians. The College believes it is important to note when a physician could not participate in the programs listed, (e.g. PQRS due to lack of applicable measures, MOC incentive program due to incompatibility with specialty MOC requirements¹.) The absence of this information is misleading and could imply a lack of interest in quality rather than an issue with the applicability of the program. For example, CMS request for comments on the reporting on PQRS Cardiovascular Prevention Measures group, composite measures at the disease module level, patient experience, and the Shared Savings Program may not apply to many physicians. The College reiterates the need to note when a program does not apply to a particular physician.

The College suggests that CMS provide physicians an opportunity to review the information about them that will be included on the CMS Physician Compare website prior to posting. Prior review by physicians would increase confidence in the program and improve accuracy. In addition, giving physicians the opportunity to improve their processes when deficiencies are found is in alignment with the stated program goals of improving health care quality.

¹ The American Board of Pathology MOCP cannot meet the requirements of a qualified MOCP practice assessment. Even if it were feasible, participation would be limited to pathologists who can already participate using the two existing measures on breast and colon cancer reporting. We noted that for pathologists not required to participate in MOC, "more frequently" may be considered to be a single practice assessment. However, successful participation requires a survey of patient experience with care which is not part of the pathology MOCP. There are 4 components to the ABP's Part IV program – peer attestations, documentation that they work in an accredited lab, lab participation in an inter-laboratory performance improvement (PI) and QA program, and the individual pathologist must participate in at least **one lab PI/QA activity** per year. The ABP accepts a variety of activities for the last component, and does not require a "practice assessment" including demonstration of evidence-based medicine, survey of patient experience, and implementation of a QI intervention.

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CAP welcomes the opportunity to collaborate with CMS to develop measures relevant to our specialty and to the patients we serve. These could be broader than just the individual physician and encompass the laboratories where pathologists practice.

Physician Payment, Efficiency and Quality Improvements – Physician Quality Reporting System

The College supports expanding the definition of group practices for the purposes of the Group Practice Reporting Option (GPRO) to groups with 2 or more eligible professionals under single TIN. Expanding this option will increase the number of eligible professionals who can participate in the program, in particular for single specialty groups to whom the GPRO web tool does not apply. However, the College suggests that the claims and registry reporting options be expanded to include group practices with 99 or greater members as well, so that EPs in those larger single specialty groups with no applicable measures will have a mechanism to participate in the PQRS. Neither the GPRO web tool nor the EHR reporting mechanisms will be feasible mechanisms for the pathology groups with >99 EPs as none of the measures used by these reporting mechanisms are applicable to pathology practice. For example, there may be large reference laboratories or departments in large academic medical centers that would fall into this category. In addition, the NPRM proposes to base the Value-based Modifier (VBM) on participation in the PQRS by group practices with 25 or greater Members. Single specialty group practices with greater than 99 Members will have no means of meeting this requirement, if they are restricted to participation through the GRPO web tool, which does not include any applicable measures for many specialties.

While CAP supports alignment across CMS programs, at this time the measures included in programs other than the PQRS are much more limited. While participation in the PQRS by pathologists **with applicable measures** is relatively high (61.5% of 7722 eligible providers in 2010), there are still no applicable measures for over half of the 17,500 Board-certified pathologists practicing in the United States. CMS should keep in mind that alignment will limit the number of eligible professionals that can participate in the programs if the measure pool is not increased for all the programs when programs are aligned.

CMS has proposed that group practices planning to participate in the group practice reporting option indicate their intent to do so and which method they plan to use by January 31st of the reporting year. The eligible registries for a given year are not usually posted until the summer of the reporting year, therefore a group practice will have no way of knowing if there is an appropriate registry know at the time of registration for the GPRO (January 31 of the reporting year) if a suitable registry is available for reporting, making the requirement to provide this information at the time of registration difficult or impossible. The College suggests that CMS provide an opportunity for group practices to change their reporting mechanism after the list of registries is published.

The College requests that CMS provides more clarity on the administrative claims mechanisms. The College is unclear from the Proposed Rule how the Agency plans to assess credit for reporting. The proposed rule suggests that CMS will determine performance rates for the included measures. Is this mechanism actually a performance assessment rather than a reporting assessment? How will this mechanism be used when the measures are not applicable to a particular provider?

Aligning PQRI and Meaningful Use (MU) measures: As CMS works to harmonize the Meaningful Use and PQRS measures, the College requests that CMS be mindful that the Meaningful Use criteria are generally not applicable to pathology practice, making it impossible for pathologists to meet the requirements. Our prior experience with measures that supposedly apply to all physicians (e.g. BMI or blood pressure measures) is that they do not account for the unique characteristics of pathology practice (such as the nature of pathologists' typical interactions with patients).

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As we have noted before, CMS has not provided a feasible way for physicians who cannot meet the requirements of the Meaningful Use (MU) program to participate in a program that combines these two initiatives. In addition, CAP would like to note that pathologists employed at independent laboratories may be eligible for the MU incentive but cannot participate in the PQRs because of the billing mechanism they use. CAP has sought clarification on whether changes in the use of POS on claims that go into effect in October 2012 will affect independent laboratories' ability to participate in the PQRs, but to date we have not received a response from CMS.

Proposed PQRs Individual Core Measures Available for Claims, Qualified Registry, and EHR-based Reporting for 2013 and Beyond

The CAP does not believe a core measure set can be designed for applicability to all specialties. CAP requests clarification of the purpose of including core measures in the PQRs; CAP questions the value of developing "core" measures that clearly are not applicable to many specialties. The use of a core measure set for MU makes it impossible for pathologists to meet the MU criteria, unless reporting "does not apply" to each measure is acceptable to the Agency. If CMS attempts to apply a core set of measures for the PQRs, pathology as well as several other specialties will likely need to be excluded from the program, as the requirements will become impossible to meet. The CAP, however, would welcome the opportunity to explore system measures with the Agency, that capture the contributions of various physicians to the provision of appropriate care, which may be more universally applicable, but would require more development work.

Medicare Shared Savings Program (MSSP)

The NRPM reiterates that ACO participant TINS and Individual ACO providers/suppliers who are eligible professionals cannot earn a PQRs incentive outside the MSSP, and in fact, EPs participating in an ACO are prohibited from participating in the PQRs through another mechanism. The College requests that CMS specifically note that the PQRs penalty and VBM will not apply to EPs non-ACO claims, even if the majority of their patients are not participating in the ACO, and that an informal review process be in place should participants in these programs find the PQRs penalty or VBP modifier being applied inappropriately.

Physician Value-Based Payment (VBP) Modifier and the Physician Feedback Reporting Program

The 2013 proposed rule includes plans for the initiation of a value-based payment modifier in 2015 for group practices with 25 or greater eligible professionals. CMS proposes to set the VBP modifier at -1.0% for all physicians who do not satisfactorily report on PQRs measures. As with the PQRs penalty, we request that eligible professionals who cannot report on PQRs measures in 2013 due to lack of measures have the VBP modifier set at 0.0 percent in 2015. While we do not disagree with CMS beginning the program with large group practices, we think CMS should still accept satisfactory PQRs reporting by individual EPs. If CMS finalizes the proposal to only count satisfactory reporting through the group practice reporting option, it is essentially forcing EPs who reported as individuals to switch reporting processes with very little lead time, in a year that will affect both PQRs penalties and the VBP modifier for the first time. CMS should allow group practices additional time to put processes in place before penalizing them, or accept good faith attempts to report using the group practice option in the first year of the program. In the proposed rule, CMS suggests that the administrative claims-based reporting option be used as a default mechanism for those group practices that attempt to report but do not meet the PQRs criteria for satisfactory reporting. CAP would support this suggestion provided additional details were provided on how this option would be applied when the Administrative claims measures do not apply to a specialty group practice.

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CAP recommends that CMS finalize the proposal to allow group practices that successfully report through PQRS the option to set the VBP modifier at 0.0 percent or to choose the quality-tiering approach described in the proposed rule. However, CAP notes that most practices will not know if they successfully reported in 2013 until the fall of 2014. CMS proposal that group practices choose a VBP option in December of the reporting year therefore means this choice would have to be made without the benefit of knowing their PQRS status.

CAP also recommends that CMS set the VBP modifier at 0.0 percent for EPs participating in the Medicare Shared Savings Program or the Pioneer ACO program, as these programs have overlapping goals of providing low cost high quality care. Applying the VBP modifier to participants in those programs will add confusion without added benefit as participants already have payment linked to the quality of the services they provide.

Physician Feedback Reports and Quality Resource Use Reports:

A review of the Feedback reports distributed to CAP Members in four pilot states showed performance on measures in practice areas that pathologists cannot affect and that were completely unrelated to the services pathologists provide. CAP recommends that any future reports conform to the recommendations of the AMA ad hoc workgroup on QRURs. The current reports are not generally actionable by pathologists. We are also concerned that several of these reports are missing cases and have incomplete data.

CAP recommends that CMS develop a VBP modifier for hospital-based physicians that could take advantage of the existing hospital performance programs. Pathologists have long been responsible not only for diagnosing individual patients but for key global elements of care of the whole population of patients in hospitals (e.g. ensuring appropriate utilization of scarce blood and blood products, MRSA screening). For this reason, we are interested in exploring with CMS how to define a mechanism that measures value in the care setting where the majority of an eligible professional's services are provided.

While we understand that CMS is working to align its multiple programs, we suggest that CMS not use the Meaningful Use Definition of hospital-based, as this definition is far too limiting. Under the HITECH Act as modified by the Continuing Extension Act of 2010, most pathologists do not meet the EHR Incentive Program (Meaningful Use) definition of hospital-based. For purposes of the VBM, CMS could modify the definition either by (1) including hospital outpatient services to the listing of settings included in hospital-based; or (2) lowering the percentage threshold. We would welcome the opportunity to work with CMS and other stakeholders to arrive at the most appropriate criteria for defining hospital-based for this new program.

Outcome Measures for Groups of Physicians

CAP does not think the outcomes measures proposed for use in calculating the VBP modifier will provide relevant information on the performance of single specialty group practices, in particular in the diagnostic specialties. Using these measures may make sense for a group practice providing primary care; however, the data collected will not provide meaningful information on the performance of a pathology group. CMS should consider developing different reports for different types of physicians.

Proposed Cost Measures

The Act requires that "... costs shall be evaluated, to the extent practicable, based on a composite of *appropriate* measures of costs established by the Secretary" The College does not believe that the five measures chosen to calculate the cost composite for the value-based modifier are an appropriate means to measure the resource use of all physicians. CAP recommends careful consideration be given

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when attributing the resource use to the appropriate provider and when addressing laboratory and radiological services because pathologists and radiologists perform many services under the direction of other health care providers, who order diagnostic testing on behalf of their patients. The proposed modifier does not account for the fact that pathologists cannot always control utilization, but instead frequently perform, direct and interpret tests ordered by other providers. Pathologists do routinely make decisions about the appropriateness of tests to be made available by their laboratories and their subsequent utilization for specific patients; however, this contribution cannot be easily measured and is not generally in the areas measured by the proposed cost composite measures (e.g. COPD, heart failure, CAD).

Attribution of Quality and Cost Measures

CAP does not believe the *degree of involvement* attribution methodology accurately captures all physician specialties' involvement in patient care. While the individual reports produced for physicians in four states may have provided some actionable information for primary care physicians, in many cases the report yielded results that were nonsensical for those specialties that do not frequently bill office visits. If CMS persists in using this methodology, CAP recommends that CMS not combine the directed and influenced categories, as this will only exacerbate problems with the methodology. CMS should not apply the value-based modifier to eligible professionals who do not have applicable quality and cost measures or cannot control utilization. In the rule, CMS proposed that a VBP modifier would not be calculated in the case where either a reliable quality of care composite or cost composite could not be developed. The CAP agrees with this proposal, and further believes this to be the case with respect to pathologists' practice and, therefore, the modifier should not be applied until more reliable methodologies can be developed.

Conclusions

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. The contributions of pathologists are not easily captured through current performance measurement reporting mechanisms.

As noted, given sub-specialization, many 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 please to have the opportunity to comment on issues and appreciates your consideration of these comments. Please direct questions regarding issues related to the Medicare physician fee schedule to Todd Klemp at (847) 832-7403 (tklemp@cap.org), and questions regarding the physician quality reporting initiative to Fay Shamanski at (202) 354-7113 (fshaman@cap.org).

Enclosures (4)