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Ms. Charlene Frizzera
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2010; Proposed Rule; 74 Fed. Reg. 33,520 (July 13, 2009).

Dear Acting Administrator Frizzera:

The American Medical Association (AMA) appreciates the opportunity to provide our comments regarding the Centers for Medicare and Medicaid Services' (CMS) proposed physician fee schedule rule for calendar year 2010. Our detailed comments are set forth below and our principal recommendations are as follows:

- The AMA applauds and urges CMS to finalize its proposal to retroactively remove the cost of physician-administered drugs from its calculations of allowed and actual spending under the sustainable growth rate formula.

- We appreciate that CMS is using the results of our new multi-specialty practice expense survey to update the practice expense data in the relative value scale.

- CMS should provide an opportunity for specialty societies to provide data supporting lower equipment utilization rates for their services than the rate it proposes for all equipment over one million dollars.

- While there may be both advantages and disadvantages to CMS' consultation coding proposal, the AMA has strong concerns about finalizing it in November 2009 and implementing it in January 2010. CMS should first explore potential revisions to its proposal and alternative options for addressing concerns about consultation coding before moving forward prematurely with a plan that will put Medicare and CPT at odds with one another and with other payers.

- A new expert panel is unnecessary because CMS has adopted RVS Update Committee (RUC) recommendations for increased primary care relative values that have required significant redistributions from other services and left few services overvalued, and the RUC has the unique skills needed to assist in identifying misvalued services and maintaining the resource-based relative value scale (RBRVS).

- The AMA supports CMS efforts to expand physician quality reporting options and streamline reporting periods and criteria to reduce reporting burden and confusion. We have concerns, however, about moving too rapidly to eliminate claims-based reporting, and about public reporting of performance results.

- The AMA strongly supports the CMS proposal for the 2010 e-prescribing incentive payment program to reduce the reporting burden from 50 percent of all applicable services to 25 services involving electronic prescriptions.

MEDICARE PHYSICIAN PAYMENT FORMULA

The AMA is extremely grateful to CMS and the Obama Administration for acknowledging that physician-administered drugs do not belong in calculations of the sustainable growth rate (SGR) formula, and therefore is proposing to remove these drugs from calculations of allowed and actual Medicare physician spending retroactive to the 1996/1997 base year. We strongly urge CMS to finalize this proposed policy change.

The AMA has advocated for years that physician-administered drugs be removed from SGR calculations. We are very pleased that CMS agrees, and we applaud the discussion set forth in the proposed rule that sets forth CMS' rationale for removing drugs from the SGR. CMS acknowledges that spending on physician-administered drugs has been growing at much higher rates than spending for all other physician services and has contributed significantly to the deviation between target and actual spending, as well as to the large projected reductions in future physician payment rate updates. In fact, from the first quarter of 1997 through the first quarter of 2005, the average annual growth in Medicare spending on drugs included in the SGR was 22 percent compared with 6 percent for all services (including drugs) included in the SGR. As a result, since the inception of the SGR, prescription drugs have accounted for a disproportionate amount of the growth in spending on physicians' services.

Because of the significant and disproportionate impact that the inclusion of drugs has had on the SGR system, CMS believes it is appropriate to revise the definition of "physicians' services" for purposes of the SGR. CMS further expresses its view that the Secretary has clear discretion to remove physician-administered drugs from the definition of "physicians' services" for purposes of calculating the SGR and levels of allowed and actual spending for all prior and future years. Finally, CMS notes precedents for these retroactive changes insofar as it has revised actual spending amounts to reflect spending on "missing codes" that CMS later discovered had not been included in SGR actual spending calculations.

We agree with CMS' rationale for removing drugs from the SGR. Many physician-administered drugs are life-saving and their development has been encouraged by various federal policies. The AMA shares the goals represented by these policies, such as expanded funding for the National Institutes of Health (NIH) and streamlining of the drug approval process. It is not equitable or realistic, however, to finance the cost of these drugs through cuts in payments to physicians. In fact, steep physician payment cuts would restrict access to the very drugs that these policies are intended to make more accessible. Removal of drugs from the SGR is a step toward preserving access to these important drugs and other critical physicians' services.

Further, our nation has a historic opportunity for health reform this year, and fixing the Medicare payment formula once and for all, along with averting a 21.5 percent physician payment cut due January 1, 2010, is a cornerstone of this effort. Removal of drugs from the SGR significantly reduces the cost of legislation to repeal the SGR and, therefore, paves the way for Congress to ensure stable payment rates that reflect increasing medical practice costs, which is fundamental to comprehensive health reform.

Finally, CMS estimates that even after removing drugs from the SGR, the physician payment rate update scheduled for 2010 will be 21.5 percent. A correction notice to the proposed rule indicates that updates from 2011 through 2014 will be between -3.1 percent and +1.4 percent. We would appreciate if CMS could publish in the final rule its estimates of the annual updates for 2011 through 2014.

RESOURCE-BASED PRACTICE EXPENSE RELATIVE VALUE UNITS

To update the specialty-specific practice expenses (PE) data used in developing the PE relative value units (RVUs), the AMA conducted a new survey, the Physician Practice Information Survey (PPIS), which was administered in calendar year (CY) 2007 and CY 2008. **We appreciate that CMS has adopted the results of our PE survey in updating the PE data.**

CMS currently utilizes practice expense data and physician hours from the 1995-1999 AMA Socioeconomic Monitoring System (SMS) survey to calculate a "practice expense per hour" estimation and direct-to-indirect cost ratio for each specialty. Although the SMS was not designed specifically for use in the Medicare practice expense payment methodology, we understand that it provided the best available data to estimate physician costs. The SMS survey became increasingly expensive as physician responses have become more difficult to obtain. In 2004, the AMA began to receive solicitation from the RUC and organizations within the Federation to reconvene data collection activities to utilize in the CMS practice expense methodology. On March 24, 2006, a sign-on letter from the AMA and more than 75 specialty societies was submitted to CMS with the following recommendation:

We are all in agreement that moving forward it is imperative that a multi-specialty practice expense survey be conducted to collect recent, reliable, consistent practice expense data for all specialties and health care professionals.

The AMA agreed to coordinate the survey collection effort in 2007 and 2008, with significant support from the national medical specialty societies and other health care organizations. Every effort was made to ensure that the survey was conducted in a transparent manner. Frequent updates were provided to all specialty societies and each society communicated the benefit of participating on their own web sites and in cover letters to the survey participants. All specialties had the opportunity to assist in the survey development process. We are pleased that we were able to complete the survey effort and meet the CMS requirement to submit practice expense per hour computations by March 31, 2009.

We applaud CMS for also being an active participant in this process and for offsetting the substantial cost of the survey by purchasing data computations from the AMA. This effort was made possible by the joint financial and staff support of the AMA, CMS, and more than 70 national health care organizations. The AMA neither endorses nor disputes any individual specialty society results and understands that implementation of these data will redistribute practice expense payment amongst specialties. However, the AMA agrees that the survey process was conducted in a fair and consistent manner for all specialties.

The AMA expresses serious concern regarding the acknowledgement by CMS that the Medicare program is only able to recognize and pay for 50.8 percent of direct costs under the current practice expense methodology (Table 1, page 33529). CMS has accepted the RUC's direct expense recommendations for individual physician services, however budget neutrality implications are distorting the final relative value assignment. For example, CMS has accepted and published data that a physician incurs $16.50 in cost for each 99213 service (labor $13.32, supply $2.98, equipment $0.19); however, the methodology allows for payment of only $8.29 (labor $6.85, supply $1.44, and equipment $0.00). For services with high direct cost, the impact is significant and will limit a physician's ability to provide these services in the office setting. The AMA urges CMS to work with the RUC to determine how the practice expense methodology may best recognize actual physician direct costs.

EQUIPMENT UTILIZATION RATE

As part of the PE methodology associated with the allocation of equipment costs for calculating PE RVUs, CMS is proposing an equipment usage assumption of 90 percent instead of the current 50 percent for equipment priced over $1 million. This proposal responds in part to the RUC's and the Medicare Payment Advisory Commission's (MedPAC) recommendations that the existing 50 percent standard utilization rate for all equipment is not an accurate measure. The AMA appreciates that CMS proposes to implement this proposal by distributing the savings across all physician services.

The AMA conducted a survey of equipment utilization, and although there was a relatively small sample size, the survey responses suggest that equipment utilization varies depending on the type of equipment involved. Therefore, we urge CMS to provide an opportunity for specialty societies to provide data supporting lower utilization rates, if appropriate. This would allow for varying equipment utilization rate assumptions, depending on the type of equipment being used, rather than a single utilization assumption.

CONSULTATION SERVICES

For 2010, CMS is proposing to eliminate the use of all inpatient and office/outpatient consultation codes on a budget neutral basis, and in its place will increase the RVUs for new and established office visits and initial hospital and facility visits as well as incorporate the increased use of these visits into the PE and Professional Liability Insurance (PLI) RVU calculations.

While there may be both advantages and disadvantages to this proposal, the AMA has strong concerns about moving forward with the consultation code proposal on January 1, 2010. It would be impossible to educate all physicians who currently report consultation codes in such a short period of time, which means there would be a flood of claim denials and appeals. Further, at a time when the President and Congress are seeking administrative simplification as part of health care reform, this new policy would undermine this goal by setting up a different standard for Medicare versus other payers that will still be using consultation codes. This would create new burdens, rather than eliminate them.

The AMA, therefore, strongly urges CMS to refrain from finalizing the consultation code proposal in November and instead develop possible revisions to use the consultation codes after a more thorough consideration of the key issues involved with use of the consultation codes, as well as the impact of elimination of the use of these codes. For example, CMS should consider whether additional payment should be made to consulting physicians for providing a thorough report back to the patient's referring physician. This report is critical for incentivizing more coordination of care. It is unclear how this proposal could adversely affect care coordination and the communication that currently exists between referring and consulting physicians. In addition, the AMA CPT Editorial Panel recently adopted a new definition of "transfer of care" that goes into effect January 1, 2010, largely in response to the Department of Health and Human Services Office of Inspector General and other concerns that the consultation proposal attempts to address. CMS should allow time to determine whether this new definition appropriately addresses issues with use of the consultation codes. While policymakers are looking for ways to improve coordination of care, it seems counter-intuitive that CMS would move forward with this proposal without understanding the implications for the impact on care coordination.

Further, consulting specialists should be appropriately compensated for the expertise they provide. The discussion in the "telehealth" section of the proposed rule, where CMS proposes to continue separate coverage for consultations, acknowledges the value of this expertise. **Accordingly, we urge CMS to work with the CPT Editorial Panel to explore alternative options for addressing its concerns about consultation coding before moving forward prematurely with a plan that will put Medicare and CPT at odds with one another and with other payers.**

POTENTIALLY MISVALUED SERVICES

Contributions of Organized Medicine to Address Potentially Misvalued Services

The AMA does not believe that CMS and other policymakers have sufficiently recognized the major contributions that organized medicine has made over the past few years in identifying and addressing potential misvaluation within the Resource-Based Relative Value Scale (RBRVS) payment system. After several failed attempts by CMS to objectively identify services, the RUC established a Five-Year Review Identification Workgroup to develop objective screens that may indicate potential misvaluation in individual CPT codes. The RUC has identified nearly 550 services to date and has completed review of 346 services, recommending decreases in more than 100 services. Most of the services identified have required some analysis by the CPT Editorial Panel to either clarify codes, bundle services into fewer codes, or provide clarification via the CPT Assistant newsletter. This work has been extensive, and many physician volunteer hours have been expended to ensure that the process is fair, objective, and based on clinical expertise. The AMA is disappointed that CMS has proposed to distort this work based on a flawed method to revalue certain services for which the agency had initially accepted and implemented the RUC recommendations. We understand that the RUC and several specialty societies will provide detailed comments discussing the multitude of flaws in the CMS proposal to alter

the RUC recommendations for codes listed in Table 8 on page 33555 of the proposed rule. **The AMA would urge CMS to not implement this proposal and instead work with the RUC to address the specific concerns that led to this proposal.** We also urge CMS to rely on CPT and the RUC for the clinical expertise required to review services reported on the same date by the same physician. A consultant will not have the institutional knowledge or expertise to provide a correct interpretation regarding current valuation of these services.

High-Cost Supplies
The AMA is disappointed that CMS has not proposed new methodologies to address high-cost supplies, after not implementing their proposed process outlined in the 2008 proposed rule. Although CMS initially determined that repricing of these high-cost supplies would be burdensome on certain physician groups, it later concluded that the burden would be minimal and that the repricing process would afford better results to ensure CMS is paying properly for these supplies. Yet, in the 2009 final physician fee schedule rule, CMS stated it would not implement this proposal. **The AMA encourages CMS to develop a process that will use all available resources to ensure that these supplies are priced correctly, including the consideration of paying for high-cost disposable supplies using J codes.**

REVIEW OF POTENTIALLY MISVALUED CODES

CMS is requesting public comment on the concept of an expert panel separate from the RUC to ensure that the relative valuation within the RBRVS is appropriate. **An expert panel is unnecessary, and the AMA does not support this concept.**

This concept was initiated by MedPAC recommendations from March 2006 and March 2008, including:

> *We also recommended that CMS establish a group of experts, separate from the AMA RUC, to help the agency conduct these and other activities. This recommendation was intended not to supplant the AMA RUC but to augment it. To that end, the panel should include members who do not directly benefit from changes to Medicare's payment rates, such as experts in medical economics and technology diffusion and physicians who are employed by managed care organizations and academic medical centers.*

The AMA does not believe that the MedPAC recommendations recognize the improvements made in the RBRVS by the AMA RUC, particularly regarding primary care, and this has led to a misperception that there remains significant misvaluation in the RBRVS that would be better directed to E&M services. Yet, proposed 2010 national payment rates for E&M services are significantly higher than the 1992 payments, while most other services will be paid less in 2010 than in 1992. For example, assuming no change in the 2010 conversion factor, a mid-level office visit (99213) will increase from $31 in 1992 to $69 in 2010. In comparison, payments for cataract surgery (66984) will decrease from $941 to $725 and payments for MRI of the lumbar spine (72148) will decrease from $485 to $306.

We appreciate CMS' acknowledgement in the proposed rule of the recent improvements to primary care as a result of the RUC's and CMS' efforts. In addition to these significant improvements to payment for primary care services, the RUC unanimously approved monthly payment rates for the Medicare Medical Home Demonstration project under development. This is consistent with the RUC's ongoing recommendations to value physician services that describe care coordination, including telephone calls and team conferences.

Further, the RUC is a voluntary expert panel comprised of individuals who have acquired the necessary experience to evaluate the resources utilized in the provision of physician services. All of the complex rules and methodologies that comprise the RBRVS have been developed and maintained by CMS and are subject to public rulemaking. However, there are few clinicians, or other individuals, who have acquired the technical knowledge to assist in the maintenance of this payment system. The AMA and the national medical specialties, through the RUC and its Advisory Committees, have developed this unique expertise. The RUC's work is based on a review of data and clinical expertise to develop consensus. The MedPAC recommendations and the comments made by some specialties and other policymakers fail to recognize the importance of this institutional knowledge in ensuring that the RBRVS remains a fair system for all specialties.

In addition, the RUC process, meetings, and decision-making are transparent, and CMS allows for public comments before any final implementation of relative values. More than 250 individuals, representing medical specialty societies, other health care organizations, MedPAC, the General Accounting Office, international delegations, and CMS, attend the RUC meetings. Any individual interested in attending a RUC meeting may be invited upon petitioning the Chairman of the RUC. The RUC has a strict conflict-of-interest policy and makes every effort to ensure that those with a financial interest in medical devices and technology are not present in a capacity to influence decision making. All RUC recommendations are included in CMS rulemaking, published in the *Federal Register* and additional detail regarding RUC rationale and the resource inputs are available in the AMA's RBRVS Data Manager**.**

CMS has had little success in the past in relying on the expertise of consultants and in coordinating expert panels to review resource relativity. The key illustration of a failed effort to develop an external panel was the Clinical Practice Expert Panels (CPEPs) used to evaluate the direct practice costs associated with individual physician services. The process led to exaggerated practice costs and overall distortions that prevented CMS from utilizing the data directly in computing practice expense RVUs. CMS ultimately asked the RUC to engage in an intensive review to correct the anomalies created in the CPEP process. The RUC, and its Practice Expense Advisory Committee, spent several years reviewing each individual CPT code to ensure that the itemization of resource costs was based on rules and standards that could be applied consistently across all physician services.

Accordingly, the AMA does not agree with the MedPAC recommendation to create an expert panel because: (i) the premise that MedPAC utilized is flawed—the RUC and CMS have addressed primary care payment improvements and the significant redistribution from other services leaves few services overvalued; (ii) the RUC has the unique skills required to assist in the identification of misvalued services and the maintenance of the RBRVS; and (iii) CMS has been unsuccessful in coordinating expert panels.

PHYSICIAN QUALITY REPORTING INITIATIVE

The AMA supports the agency's efforts to expand the Physician Quality Reporting Initiative (PQRI) reporting options to improve participation. Further, we support streamlining reporting periods and criteria for these options to reduce reporting burden and confusion. In moving forward to implement these changes to the PQRI, it is critical that CMS initiate a strong educational program aimed at helping participating physicians successfully report data under the 2010 PQRI. We urge CMS to work with the AMA and other physician organizations to educate physicians about the requirements that must be met to successfully report under the various reporting options in 2010. Further, CMS must provide more detailed education resources on its PQRI web site well in advance of the 2010 PQRI's January 1, 2010 effective date.

Below are more specific comments regarding suggested improvements to the PQRI that we strongly feel are needed to improve the program and better engage physicians and other health care professionals about participation in quality improvement programs like the PQRI.

Intent to Limit Claims-Based Reporting

Regarding the proposal to significantly limit claims-based reporting after 2010, we recommend that CMS move cautiously and not remove the claims-based mechanism for reporting in the PQRI until such time that registries and electronic health records (EHRs) have been widely implemented, with the majority of physicians able to report on quality measures from these data sources. Currently, claims remain the only mechanism that enables a majority of the physician community to participate in the PQRI without incurring additional significant costs to their practices. Further, the PQRI program is less than four years old. Significantly changing how physicians participate in the program, without adequate transition time to ensure most specialties have the capability to report on quality measures through other mechanisms like registries or EHRs, will negatively impact participation in the program. If the goal is to improve overall quality for Medicare beneficiaries through a continuum of care, flexibility in how all physicians report on quality measures should be exercised.

In addition, the current requirement that physicians must be able to report on at least three measures when participating through a registry may unintentionally exclude some specialties and subspecialties from participating in the PQRI in the future. **For this reason, we encourage CMS to consider adding the measures listed below (beginning at the bottom of page 15), as this expansion would enable additional specialties to participate through registries and, in the future, through EHRs.**

EHR Reporting Option

To date, little information has been provided on testing the EHR reporting option in the PQRI, and we strongly encourage CMS to make the results available as quickly as possible. We strongly support the implementation of quality measures into EHRs and support CMS' move toward this method of reporting. At the same time, this implementation—the process by which measures will be reported and what EHR systems will be approved for reporting to the PQRI—should be made publicly available well in advance of January 1, 2010.

Requirements for Qualified Registries

It is unclear why CMS is restricting a single practice site or solo practitioner from becoming a qualified registry. Given that in the current environment there is progressive movement towards the use of registries and EHRs, single practice sites or solo practitioners should not be prohibited from becoming a qualified registry if they are able to meet the requirements. We also note that providing incentives for the development of registries and registry reporting is imperative for advancement of comparative effectiveness research.

We strongly support inclusion of feedback reports as a requirement in qualifying as a registry. However, issuance of the feedback report should occur at a point in time during the year so as to allow practices to assess their performance both on reporting and performance. These reports should be confidential and can be a first step toward promoting internal quality improvement within a practice and ensuring that physicians are reporting correctly early in the program. Moreover, feedback reports should be timely for all physicians and other health professionals that participate in PQRI, regardless of their reporting option. Confidential interim and final feedback reports must be provided so that physicians have timely, actionable information on potential problems in their PQRI reporting. Without timely feedback, physicians are unable to improve care at the point of care, which is the ultimate goal behind quality measurement. In addition to timely and accurate feedback reports for physicians, measure developers are also in need of detailed information on reporting patterns. This will help identify areas for education and allow for appropriate maintenance of the measure specifications.

Measures Groups and Expansion of PQRI Measures

We support the change that CMS has made regarding the removal of the "consecutive method" requirement for reporting measures groups. We also agree that the minimum sample requirement is reasonable and appropriate.

With the goal of providing a more comprehensive picture of the quality of care provided to patients, we recommend that CMS continue to explore the inclusion of additional measures across the various methods of reporting to increase the number of measures for a clinical condition. **In addition, we strongly urge CMS to consider reducing the number of measures required for inclusion in a measures group to a minimum of three measures.** If this criterion were to be changed, the number of measures groups could be expanded. As the PQRI advances, we support flexibility to allow participants to report on sets or groups of measures, as well as individual measures.

We also recommend that CMS continue to explore how to implement the reporting of measures groups with complex denominators (e.g., multiple diagnoses in one denominator). While it may be ideal for measures to be simplistic in their parameters and coding for the purposes of reporting, patient care for many clinical conditions is complex and involves many factors and co-morbidities. For this reason, we believe that to achieve the goal of developing and reporting on measures that have an associated impact on patient care and positive outcomes,

quality measurement will not become more simplistic, but rather will become more complex in the future. **With this evolution of measures in mind, we strongly encourage CMS to explore ways to enable the PQRI to capture and calculate groups of measures containing complex denominators.** We acknowledge that system changes and identification of strategies and solutions will be required for this evolution to occur. We are committed to assisting CMS in developing solutions to these issues.

Public Reporting

CMS intends to make public the names of eligible professionals and group practices that satisfactorily submit quality data for the 2010 PQRI on the "Physician and Other Health Care Professionals Directory," as required under Medicare Improvements for Patients and Providers Acts of 2008 (MIPPA). It is important that CMS be clear in its definition of "satisfactorily submit." While we propose that "satisfactorily" be linked to the receipt of an incentive payment, we recommend that CMS exercise flexibility until the agency can guarantee its systems can accurately collect and analyze the submission of quality data codes. We eagerly await the distribution of the 2008 feedback reports and incentive payments planned for October 2009, as it will allow the agency and physician community to determine whether recent corrections to the algorithms used to analyze successful participation were indeed improvements to the program.

CMS proposes to publish both the names of the group practices that satisfactorily submit quality data as well as their performance results. **We have strong concerns about reporting performance results at both the individual physician and group practice levels.**

First, CMS currently does not have the statutory authority to publicly report performance data gathered under the PQRI. MIPPA only authorizes CMS to post on the Internet the list of names of eligible professionals or group practices that satisfactorily submit data on quality measures. This provision shows Congress' intent that only limited information can be made public under the PQRI. If Congress intended broad scale performance data under the PQRI to be made publicly available, it would have provided the HHS Secretary with the authority to do so. Moreover, if Congress had already conferred CMS with the authority to act on this goal, Congress would not have needed to provide authority to CMS to post on its web site the names of those who satisfactorily submit data.

Further, in establishing a quality reporting program for hospitals and ambulatory surgery centers (ASCs) under the Tax Relief and Health Care Act of 2006 (TRHCA), Congress specifically granted the HHS Secretary the authority to "establish procedures for making data submitted under [the quality reporting program] available to the public." Congress has not provided such authority for the PQRI. If CMS plans to make performance data publicly available for group practices or individuals under the PQRI, Congress would likewise have to provide CMS with the statutory authority to do so, as it did with hospitals and ASCs under TRHCA. Indeed, legislation considered by Congress in prior years that would have authorized establishment of a physician value-based reporting program for physicians under Medicare included provisions addressing a number of critical issues that must be resolved in developing a public reporting program.

In addition, public reporting for group practices is premature given that the program is still in its early stages of development and is being accepted and adopted by physicians, and will be a new option for group practices. Further, according to some of those group practices who participated in the Physician Group Practice (PGP) demonstration, no specific performance results were ever made public. Rather, CMS presents each year's results to the 10 PGPs via a conference call, in which the 10 groups have agreed to share their results with each other. While some of the PGPs may have published their results within their local communities, this information was not made public through CMS. The agency must define what it means by "performance results," as currently only general information related to the number of measures a particular PGP successfully reported on is shared.

Public reporting of performance information, if not approached thoughtfully, can have unintentional adverse consequences for patients. For example, patient de-selection can occur for individuals at higher-risk for illness due to age, diagnosis, severity of illness, multiple co-morbidities, or economic and cultural characteristics that make them less adherent with established protocols. Further, health literacy may not be adequate to comprehend basic medical information. Programs must be designed so that appropriate and accurate information is available to patients to enable them to make educated decisions about their health care needs.

If done correctly, public reporting has the potential to help provide such appropriate and accurate information to patients. There remain, however, several critical issues that must be resolved before public reporting provisions can be implemented. There must be a method for ensuring that any publicly reported information is: (i) correctly attributed to those involved in the care; (ii) appropriately risk-adjusted; and, (iii) accurate, user-friendly, relevant and helpful to the consumer/patient. Moreover, as CMS acknowledges in the proposed rule, an important aspect of a quality reporting program is that physicians (and other eligible professionals) have the opportunity to review their data on reporting rates on PQRI quality measures. We strongly agree. **Physicians and other providers involved in the treatment of a patient must have the opportunity for prior review and comment and the right to appeal with regard to any data that is part of the public review process. Any such comments should also be included with any publicly reported data.** This is necessary to give an accurate and complete picture of what is otherwise only a snapshot, and possibly skewed, view of the patient care provided by physicians and other professionals or providers involved in the patient's care.

Other factors that must be considered as part of any initiative to make performance data available to the public are as follows:

- To date, there has been no formal, rigorous evaluation of the PQRI to determine such factors as: its impact on quality of care, whether it allows for fair and meaningful comparison of performance among physicians and other eligible professionals, and whether the data on physician participation is valid and can be verified.

- A detailed educational program for the public should be undertaken to explain the PQRI and openly address its limitations, including barriers to physician participation and the fact that quality measures used in the program take into account only a small fraction of all dimensions that explain overall physician performance.

- CMS should provide physicians an opportunity to explain why they did not participate in the voluntary PQRI and detail any quality improvement initiatives in which the physician is participating. This information should be provided to the public by CMS. Many physicians are participating in health care quality improvement projects conducted by Medicare's Quality Improvement Organizations, CMS' Coverage with Evidence Development mandates, health plans and various other quality initiatives. Physicians should have an opportunity to highlight these quality improvement efforts.

- As discussed above, CMS should provide the AMA and medical specialty societies access to aggregate PQRI participation data so these groups can analyze data to ensure accuracy, improve upon identified quality gaps in specialty care and work with physicians to increase participation.

- CMS should provide information on year-to-year changes in measures included in the program, as well as changes to the specifications of measures that would impact participation in PQRI.

Group Practice Reporting Option

The AMA supports the addition of a group practice reporting option. Allowing group practices to collectively report on measures helps eliminate duplication and confusion between individual group practice physicians who participate in PQRI. However, the AMA is disappointed that the group practice reporting option is defined as 200 physicians or more. With such a high threshold, small and mid-size practices are excluded from electing this option – those very practices that expressed interest in utilizing a group practice option to promote efficient quality measure reporting. **We recommend CMS explore the development of an appropriate group practice reporting option that recognizes small and mid-size practices.**

The agency proposes to incorporate some characteristics and methods from the PGP and Medicare Management Performance demonstration projects into the PQRI group practice reporting option. Improvements should be made to the patient selection methodology utilized in assigning Medicare beneficiaries to a PGP. The AMA understands that the patient assignment methodology used in the PGP demonstration was at times problematic,

as beneficiary assignment was based on the plurality of care to any provider type regardless of specialty. For example, beneficiaries assigned to a physician group practice that only came for cancer care, but had documented during their treatment that they had a history of heart failure, would fall in the PGP's sample, and so the PGP would be held responsible for reporting the heart failure quality measures for that patient. CMS should look to assigning beneficiaries to a PGP based on a plurality of a particular specialty. This would allow the physician to validate that the patient actually had the condition, and should therefore be included in the sample size for the PGP.

CMS proposes to not only publicly report the names of successful PQRI group practices, but also their performance results. Performance results were not publicly reported under the PGP demonstration project. Rather, information was shared regarding the number of measures the PGP successfully reported on—detailed information regarding scores or figures were not released by CMS. It is premature to publicly report performance results associated with this new PQRI reporting option. CMS must define "performance results," and whether this information is determined by a national benchmark or is derived from individual group practice quality improvement that compares yearly progress. These issues, along with the development of an appropriate risk adjustment model and improved education of Medicare physicians and beneficiaries about the detailed make-up of "performance results" must be addressed before moving forward.

The AMA understands that the data collection tool used in the PGP demonstration project was helpful in capturing and sharing data with CMS. The AMA urges that the tool also allow practices to verify their data after CMS has determined incentive calculation. All data should be verifiable and accurate prior to making incentive payment determinations, and the ability to review and verify the data should extend until after an incentive determination is made. Further, CMS should explore making the data collection tool a secure web-based application rather than free-standing at each practice.

Regarding Group Practice Reporting Option Measures – Table 34: The ACC/AHA/AMA-PCPI Heart Failure (HF) measures are currently undergoing maintenance and update by the work group. The HF: Weight Measurement measure that is proposed for inclusion in the Group Practice Reporting option is being recommended for retirement from the HF measurement set and we request that the measure be removed from the Group Practice Reporting Option.

The Preventive Care: Blood Pressure Management measure is not an AMA-PCPI-developed measure. We request that the measure developer listed be corrected in the Final Rule.

Proposal to Remove Measures from the PQRI
We recommend that the following measures listed in Table 16—*2009 PQRI Quality Measures Not Proposed for Inclusion in the 2010 PQRI*, be considered for registry only, rather than be removed from the program:

- Measure #143-Oncology Medical and Radiation-Pain Intensity Quantified
- Measure #144-Plan of Care for Pain

These measures address a key quality of life issue for patients with cancer, and we believe that the analytical challenges can be addressed through implementation in a registry.

Proposal to Make Certain Measures Registry Only
We recommend that the following measures listed in Table 18—*Proposed 2010 Measures Selected from the 2009 PQRI Quality Measure Set Available For Registry-Based Reporting Only*, be considered for claims and registry, not registry only:

- Measure #139-Cataracts: Comprehensive Preoperative Assessment for Cataract Surgery with Intraocular Lens (IOL) Placement
- Measure #141-Primary Open Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15 percent or Documentation of Plan of Care

These measures can be implemented using the claims option and would expand the number of measures on which eye care professionals can report using that data source.

By only allowing the reporting of the measures listed below through registries, it limits the ability of physicians (particularly dermatologists) to participate in the PQRI. Additionally, changes to the denominator coding for measure #138 were made by the measure developer for the 2009 program, based on feedback received from CMS, thereby addressing some of the analytical challenges with this measure.

- Measure #136-Melanoma: Follow-Up Aspects of Care
- Measure #137-Melanoma: Continuity of Care – Recall System
- Measure #138-Melanoma: Coordination of Care

Comments on Specific Measures:
Measure 34-Stroke and Stroke Rehab-tissue Plasminogen Activator Considered. It is unclear what measure CMS will use to replace measure #34, and we request that CMS not replace this measure until clarification is provided.

The following measures from Table 19 were Ambulatory Care Quality Alliance (AQA) selected prior to January 31, 2009, and have not been declined endorsement by the National Quality Forum (NQF). We, therefore, believe they meet the requirements for inclusion in the program, and we strongly encourage CMS to include them in 2010 PQRI:

- Cataracts 20/40 or Better Visual Acuity Within 90 Days Following Cataract
- Cataracts Complications Within 90 days

In addition, these two measures are currently under consideration by NQF and were recommended by the Steering Committee to move forward for an NQF member vote. We anticipate that these measures will receive NQF endorsement well before the end of 2009. As they are outcome measures addressing physician performance of cataract surgery, we believe that they address important areas of clinical care.

Measure #46-Medication Reconciliation. CMS proposes to make this measure available for either claims-based reporting or registry-based reporting in the 2010 PQRI. For the 2009 PQRI, registries have reported difficulty capturing the required information since the measure requires the inpatient discharge to be correlated to the outpatient visit. We support that this measure is being proposed for claims and registry reporting in 2010. In order to minimize the reporting burden for physicians who choose to report on this important measure, we recommend that CMS use the same approach for measure calculation as was used in the 2007 and 2008 PQRI program years, in correlating the inpatient discharge to the ambulatory visit.

Selection of Measure Topics
The AMA is disappointed that CMS did not include several measures that the AMA-convened Physician Consortium for Performance Improvement (AMA-PCPI) submitted in February 2009 for consideration during the request for comments on the measure selection process for 2010. We believe that the following measures meet the qualifications listed for inclusion in the program:

Chronic Wound Care (all AQA-selected 10/1/2008)
- Use of wound surface culture technique in patients with chronic skin ulcers (overuse measure)
- Use of wet-to-dry dressings in patients with chronic skin ulcers (overuse measure)
- Patient education regarding long term compression therapy
- Patient education regarding diabetic foot care

Endoscopy and Polyp Surveillance (all AQA-selected 10/1/2008)
- Appropriate follow-up interval for normal colonoscopy in average risk patients
- Comprehensive Colonoscopy Documentation

Melanoma (AQA-selected 10/1/2007; currently under NQF Review)
- Appropriate Use of Imaging Studies in Stage 0-IA Melanoma

Oncology (NQF-endorsed 7/31/2008; AQA-selected 10/1/2007)

- Treatment Summary Documented and Communicated – Radiation Oncology

Radiology (NQF-endorsed 10/30/2008; AQA-selected 10/1/2008)

- Reminder system for mammograms

Substance Use Disorders (AQA-selected 10/1/2008)

- Counseling regarding psychosocial and pharmacologic treatment options for alcohol dependence
- Counseling regarding psychosocial and pharmacologic treatment options for opioid addiction
- Screening for depression among patients with substance abuse or dependence

Corrections to Measure Titles

The following AMA-PCPI measures titles have been updated to provide additional detail. We request that the titles be updated in the PQRI.

- #24-Osteoporosis: Communication with the Physician Managing Ongoing Care Post-Fracture of Hip, Spine or Distal Radius for Men and Women Aged 50 Years and Older
- #40-Osteoporosis: Management Following Fracture of Hip, Spine or Distal Radius for Men and Women Aged 50 Years and Older
- #41-Osteoporosis: Pharmacologic Therapy for Men and Women Aged 50 Years and Older
- #30-Perioperative Care: Timely Administration of Prophylactic Parenteral Antibiotics

VALUE-BASED PURCHASING

The AMA appreciates the agency's summarizing of comments received from its December 9, 2008, physician Value-Based Purchasing (VBP) Listening Session, and looks forward to the agency maintaining an open dialogue as it moves forward in developing a VBP plan for Congress. The AMA submitted extensive comments to the CMS VBP Issues Paper and Listening Session last year, and we ask that the agency continue to review these comments as it works on a VBP Plan for physicians. Recognizing the agency's current interest in the issues of accountability and appropriate data submission, we have highlighted our earlier comments regarding these important areas below.

Accountability

VBP programs must recognize that physician practice arrangements vary by size, specialty mix, structure (e.g., use of information technology systems). Thus, it will be difficult for a VBP program to meet the needs of all. A series of "pilots" or "demonstration projects," therefore, would help develop those aspects of a VBP program that help varying physician practice arrangements enhance the quality of care for all patients. These pilots will also help to develop a reporting infrastructure that supports accurate data collection, which is critical for increasing the rate of those who successfully participate in a program.

Appropriate Data Submission

An interoperable health information technology (HIT) system is critical for the success for a VBP data infrastructure and reporting system. When implemented properly in a connected environment, widespread HIT adoption will transform the practice of medicine and provide physicians with a powerful tool that puts real-time medical information in physicians' hands at the point of care. To achieve this reality, a comprehensive HIT environment will need to be highly connected, secure, and affordable. To truly ensure success, HIT must be able to integrate into the typical workflow of medical practices as diverse as those where patients receive care, including large hospitals, community health centers, and small or solo physician practices. Further, it is imperative that CMS link the development of a physician VBP plan with the work underway at the Office of the National Coordinator to define "meaningful use" as it relates to the adoption and use of HIT. CMS must keep in mind that the capability to capture quality measure reporting to assess performance will require significant EHR use, programming, training, and information exchange.

The AMA supports the use of registries and EHRs as reporting mechanisms. Use of registries and EHRs will allow data capture and submission to move beyond the use of administrative claims data alone, along with real time quality improvements. The AMA is working closely with the EHR vendor community and others to influence increased functionality in EHR systems that facilitate physician use of measures for quality improvement and reporting. The AMA, with the National Committee for Quality Assurance (NCQA), and the Health Information Management Systems Society's Electronic Health Record Association, continues to co-sponsor the Collaborative for Performance Measurement Integration with EHR systems (Collaborative). The Collaborative is focused on facilitating the integration of performance measures into EHR systems to enable accurate translation of measures and to promote quality improvement.

Procedural protections are needed, however, under a VBP program, to ensure the accountability of the registry or EHR product vendor for successful submission of data to CMS from physicians and eligible professionals. CMS should specify procedures and requirements that registries (and EHR product vendors) must meet to minimize errors in the registry or EHR reporting process during the reporting period, including interim and final feedback reports, as well as procedures to be followed to correct errors that may occur when the registry or vendor submits the data to CMS.

INCENTIVES FOR ELECTRONIC PRESCRIBING (E-PRESCRIBING)

The Medicare e-prescribing incentive program reporting requirements must be broad-based and achievable to encourage the widest possible adoption and use of e-prescribing, even among low-volume prescribers. Prior to the issuance of the proposed rule, the AMA informed CMS of the results of a brief online survey of physicians about the Medicare incentive payments for e-prescribing, that was conducted by the AMA. Here is a summary of our survey results:

390 physicians responded to the survey:

- One-third of the respondents are solo practitioners and 29 percent are in 2-4 physician practices.
- 36 percent are primary care physicians and 64 percent are specialists.
- 12 percent of respondents practice in rural areas.

About 30 percent said that their practice uses an e-prescribing system, and of this group, 60 percent said they are familiar with the details of Medicare e-prescribing incentive payments. Of respondents overall, 37 percent were familiar with the Medicare incentive program details.

Asked if 10 percent of the Medicare services they provide are included in the specifications for e-prescribing, which is the threshold to be eligible for the incentive payments, 27 percent said they are but nearly two-thirds said they do not know.

Respondents suggested several improvements to the e-prescribing incentive program:

- 43 percent of all respondents said the e-prescribing incentive program is confusing, so Medicare should try to offer more outreach and education to physicians.
- Half the physicians who use e-prescribing reported that some of the pharmacies their Medicare patients use do not accept their electronic prescriptions, so Medicare should work to get better compliance.
- Half said that they cannot tell if their contractor is processing the e-prescribing codes correctly, so feedback reports would be helpful.
- 35 percent of the e-prescribing physicians indicated that, because nearly all the services they provide are included in the e-prescribing measure, the requirement to report these codes 50 percent of the time is too burdensome.

We are very pleased that CMS' proposals for 2010 are very responsive to the findings from our survey. We agree with CMS' proposal to keep the 2009 reporting period duration for 2010 (reporting period would be for the entire year) in order to help maintain program consistencies and to avoid potential confusion among eligible professionals. We also support CMS' proposal to recognize more than one mode of reporting the e-prescribing measure. We anticipate that allowing multiple reporting mechanisms (i.e., claims-based, qualified registry-based, or qualified EHR-based reporting) will increase opportunities for eligible professionals to successfully

report the e-prescribing measure. As for the proposed group practice size and reporting option, please refer to the comments and concerns that we raise above under the PQRI section of our comments.

We strongly agree with CMS' proposal to modify the current requirement to report on at least 50 percent of applicable e-prescribing cases. The proposed adjustment for the 2010 reporting period, which would require the modified G8443 code to be reported at least 25 times during a reporting period, is less burdensome to meet. We do, however, strongly urge that CMS allow for alternative reporting in order to accommodate eligible professionals who use an e-prescribing system but may not meet the 25-count requirement due to state or federal law or regulations that require physicians to phone in or print prescriptions (i.e., prescriptions for narcotics or other controlled substances). We also urge CMS to apply a similar adjustment to the 2009 incentive payment reporting period so that eligible professionals who e-prescribed in 2009 and reported appropriate G codes at least 25 times are also able to receive 2009 incentive payments.

We are supportive of CMS' proposal to add home visit codes to the denominator of the e-prescribing reporting measure. However, a subset of home care physicians remains unable to participate under CMS' proposal, so we recommend that CMS add codes for domiciliary care visits. Both home and domiciliary care visit codes are valued the same, and because some physicians exclusively make domiciliary care visits, we recommend that both families of codes be included in the e-prescribing incentive program.

We do have concerns regarding CMS' plan to publicly report the names of successful e-prescribers on the CMS web site. Although MIPPA authorizes CMS to post the names of successful e-prescribers, we urge CMS to take appropriate measures to ensure the accuracy of the list of successful e-prescribers before any information is released publicly. CMS should also consider delaying the posting, given that almost half of the physicians that responded to our survey do not fully understand the details surrounding the e-prescribing incentive program, and patients may not understand the purpose for the posting, given the fact that this incentive program just started in 2009.

Based on our survey results, we strongly recommend that CMS pursue significant outreach to the physician community on the 2010 e-prescribing incentive program details and variances from the 2009 program. In addition, CMS should display on its web page the lists of qualified registries and EHR vendors and products well in advance of the 2010 reporting period. We look forward to working with CMS on developing reasonable, achievable reporting measures to further the goal of widespread adoption and use of e-prescribing and EHRs.

PHYSICIAN RESOURCE USE REPORTS (RURs)

General Comments: While the AMA appreciates and supports CMS' efforts to phase in the Congressionally-mandated use of confidential feedback reports to physicians, we are concerned that the agency is under enormous pressure to use the information they contain for public reporting and payment purposes. In our view, **CMS needs more time, as well as additional resources, to construct a fair and workable system and conduct an adequate cost-benefit analysis before undertaking any significant expansion of the scope and uses of the feedback reports.** A number of studies or pilots, in addition to this one, offer opportunities to refine resource measurement over the next few years. At this time, however, many questions remain and to move ahead too rapidly could discredit a potentially useful cost-control method, as well as jeopardize care for some of Medicare's sickest patients.

Two concerns most frequently mentioned by physicians are the need to adjust for differences in patient mix and to factor quality and outcomes into any resource use analysis. While we appreciate CMS' recognition of the need to integrate quality and resource data in the next phase of the resource use project, experience with the PQRI suggests the need for considerable caution and a limited application as this work proceeds. Any credible system will require improvements in current risk-adjustment tools, employ outcome measures developed by the physician community, and avoid the use of any measurement tools that have not been open to review by practicing physicians. **We are particularly troubled that despite the acknowledged need for better risk adjusters, the Notice of Proposed Rule-making (NPRM) does not suggest that CMS is making a serious effort to address this problem.**

The 2010 Plan: For 2010, CMS is proposing to continue its current approach with several modifications, the most significant of which is the addition of quality data and group reporting. The AMA solicited input from physicians on the confidential feedback program and on the resource use report that CMS' contractor, Mathematica, posted on its web site. The following comments on the 2010 plan reflect the input of these physicians, as well as national medical specialties and AMA staff.

- **Unit of Measurement:** Citing support for both per capita and per episode measurement in comments on the 2009 rule, CMS is proposing to "finalize both methodologies as options for use in future phases of the program." It appears that the intent here is not to rule out either option at this time, while still reserving the right to choose one over the other in the future. We would like some clarification on this point and also would like some assurance that there will be additional opportunities to comment on the merits of the two methodologies once more experience is gained through the CMS pilot and other public and private initiatives. Several of the concerns laid out below would apply to both methodologies but are potentially even more problematic in a system that measures per capita use than one that looks at episodes of care.

- **Cost of Service Categories:** Several of the physicians who reviewed the resource use report on Mathematica's web site wanted more detail in some of the categories. No one suggested that any of the current categories be eliminated. Possible categories suggested for addition in the future included prescribed drugs (once this data becomes available) and infection-related costs.

- **Data Set:** The resource reports distributed this year involved four years of Medicare claims data (2004 through 2007) with the 2004 data used only for the purposes of risk adjustment. CMS states that comments on last year's rule favored the use of three years of data and that it will therefore continue to rely on three-years of claims data. There is no discussion either in the rule or Mathematica's sample report of what constitutes a sufficient number of cases for measurement. This raises several issues:

    1. Shouldn't the agency define a minimum number of cases and should this minimum vary by condition? CMS asked for comments on this issue in the 2009 rule but fails to address it in the 2010 NPRM. The sample report says that only "statistically reliable cost information" was included but does not identify the number of patients included in various categories or lay out its criteria for determining statistical reliability. Studies by J. William Thomas and others have shown that the number of episodes used in a physician's profile is the most important determinant of cost efficiency score reliability and validity. Some experts suggest that at least 50 cases are needed for reliability and at least one of the government's approved Charter Value Exchanges (CVEs) required a minimum data set of 50 cases. Physicians know intuitively that case size matters and are not likely to respond to data based on an inadequate or unspecified sample of patients. We strongly believe that both CMS and the RURs need to provide greater transparency on this issue and suggest that Mathematica be asked to evaluate the cost distribution and efficiency score reliability associated with different patient sample sizes.
    2. Is three years the right time frame? Some experts prefer and many private plans have adopted shorter time frames because they provide more current and therefore more actionable information to physicians. In fact, a study funded by the Massachusetts Medical Society recommended that the data-set used by plans insuring state employees should be reduced from three years to two years. Since the rule does not address the pros and cons of longer versus shorter time frames, CMS' rationale for using three years is unclear and should be further discussed in the final rule. If the contractor found it necessary to include three years of data in order to have adequate numbers of cases for each physician, CMS should look for alternative ways of expanding the number of cases per physician, including selecting a more limited set of conditions or scoring physicians in groups (as proposed in the rule) instead of as individuals.

3. How useful is data with a two-year time lag? As became apparent in the PGP demonstration, Medicare's failure to provide timely data hindered participants' ability to monitor the success of their quality improvement and cost-reduction efforts and make course corrections when needed. Does CMS have any plans in the works that will lead to speedier data feedback? If not, does the agency plan to ask Congress for funding to improve its capability to retrieve and report data more quickly?
4. How does CMS plan to address the limitations of a claims-based data system? Even if the risk adjustments used in the pilot were adequate (which they weren't), claims data often is missing critical pieces of the care delivery picture that would have justified higher expense patterns for some physicians that are likely to be labeled as overutilizers under the current scheme. A number of CVEs, often working in conjunction with Medicare Quality Improvement Organizations, are testing the use of electronic medical records or other alternatives to claims data and ultimately, this may greatly improve the timeliness and quality of the data available for physician. In the meantime, it will be important for CMS and/or Mathematica to lay out the shortcomings of a claims-based system as a consideration in the potential timing of any expanded use of feedback data and physician profiling.

- **Conditions and Specialties:** Currently, feedback reports are focused on eight conditions and ten specialties that typically treat those conditions. CMS' proposal to add diabetes to the list of conditions is consistent with recommendations from several of the physicians who provided the AMA with feedback on the report. Along with the addition of diabetes, however, CMS should consider expanding the list of specialties to include endocrinologists and possibly other specialties.

- **Demonstration Sites:** CMS is proposing to add a limited number of sites to the 12 it currently uses. The lack of any specifics on the number and location of these sites makes it impossible to comment on whether CMS and its contractor have chosen appropriate new sites. In the AMA's view, an expansion of the sites is probably not as important as expanding the number of physicians who receive the reports and enhancing the outreach to those physicians. Only 230 physicians—or about 20 per site and 20 per specialty—received a feedback report in 2009. CMS has not disclosed how many physicians responded to the contractor's request for input on their report but unless responses significantly exceeded typical physician survey response rates, Mathematica will have very little input from practicing physicians on the utility of the reports, accuracy of the data, and the process itself. **The AMA strongly believes that the sample of physicians who receive the prototype reports should be expanded and that this should take priority over expanding the number of sites.**

- **Benchmarks:** The AMA supports the agency's proposal to continue providing physicians with data on low-, median-, and high-cost benchmarks for comparison. Several of our reviewers thought that the decision to "flag" the high outliers but not the low ones, sends the message that the government is interested only in reducing costs and without regard for quality. We therefore recommend placing more emphasis on possible undercare by the low cost providers. We are also concerned that the benchmark groups are too broad and do not result in "apple to apple" comparisons. There are two problems with the current structure.
    1. As noted in the NPRM, several groups commented in 2009 that comparisons should be made at smaller geographical units than the hospital service area. CMS argues that this will lead to smaller sample sizes and adversely affect statistical precision, making it more likely that physicians will be erroneously identified as high or low outliers. While we recognize that smaller units create statistical issues that would need to be resolved, we also know that patient mix is an important factor in physician practice patterns and that patient mix varies significantly even within the same HSA as has been shown by an analysis Richard Cooper, MD, conducted on Dartmouth's conclusions regarding Medicare spending in Milwaukee. Ideally, these geographical patient mix differences could be dealt with through risk adjustment. However, we do not believe that the adjustments Mathematica is currently using (income, race/ethnicity and physician supply) are sufficient to capture all the factors that influence physician treatment and patient compliance. Physicians who practice in inner cities and safety-net hospitals are at risk of being branded as over-utilizers.

2. Many physician organizations are also troubled by the use of data that compares physicians at the specialty level. As Medicare has become more complex, care has become increasingly specialized and many medical specialties—including several of those covered in this phase of the feedback program—now have three or more sub-specialties. Often, sub-specialists treat a larger number of complex cases and are therefore likely to show up as high resource users when compared to their more generalized colleagues. Even where a new sub-specialty has not emerged, some physicians may tend to take on surgical cases while others specialize in conditions that are more frequently treated with drugs or other less invasive care. Physicians at large referral centers also are likely to see patients who are more expensive than average. We agree with those who argue that these concerns should be mitigated somewhat when physicians are compared by episode rather than on a per capita basis. However, private sector experience with the software Mathematica is using suggests that it does not sufficiently account for differences in patient mix and will discriminate against the sickest patients and the physicians who treat them.

So long as CMS is only using RURs to provide confidential feedback to physicians, the biggest danger is that physicians will simply ignore the reports and a potentially useful approach to quality improvement and cost restraint will be discredited. Any additional uses of the report—such as making them public or using them to adjust payments—would greatly exacerbate the problem, however, potentially leading physicians to avoid costly and/or difficult patients. Once again, the development of more sensitive risk-adjusters could alleviate our concerns and we strongly recommend that Medicare expedite efforts to develop and test a new generation of risk adjusters. In the interim, **we urge the agency to resist expanding the use of feedback report data and to work with the medical profession to ensure that sub-specialists, safety-net providers and certain other physician groups are not disadvantaged by the current comparison groups**.

- **Quality Improvement:** As previously noted, the AMA is very supportive of integrating quality indicators into RURs so long as those indicators are based on measures that have been developed and vetted by the physician community. Very little detail has been provided in the NPRM and we expect to have additional comments once the proposal has been fleshed out in the interim final rule. There are some significant technical issues to be resolved, including finding ways to ensure that the quality and resource data cover the same time period and that there are well-accepted quality measures available for the conditions covered in the RURs. Regarding the relative merits of using outcome measures and data from the PQRI versus the Generating Medicare Physician Measurement Results (GEM) program, we are inclined to support the PQRI **if** CMS' efforts to improve the administration of this program prove to be successful. It is our understanding that a number of the CVEs have considered and rejected the GEM data because they found it too old and because physicians could not validate the data.

- **Group Reporting:** The AMA looks forward to additional detail on the proposal to initiate reporting for "groups" of physicians. We have questions about exactly how these reports would work. For group practices, who would the reports go to? Would those who received them be able to drill down and look at data for individual members of the group? Would individual members of the group still receive a report on their individual services? We also wonder what the purpose of a geographic group report would be. Physicians receiving a RUR already can compare their resource use with the averages for their specialty in their local area and across the 12 demo sites. It should be possible to include a national average as well. What other information would be provided in a report on geographic groups of physicians? Who would receive the reports? Specialties? State medical societies? What sort of information would be shared? These questions should be addressed in the interim final rule and this proposal should not go forward until the questions have been addressed and affected parties have an opportunity to comment.

Other Issues:

- **Proprietary Software:** In response to CMS' request for comments on the use of proprietary products to measure episodes of care**, the AMA reiterates its concern that these products have not been adequately vetted with practicing physicians.** We are aware that Ingenix has posted background information and invited comments on its Episode Treatment Groups (ETGs) and know of several physicians/specialties that have attempted to work through the logic employed in the ETG groupers. In many instances, there was insufficient information to determine which/how services were incorporated into the ETGs and how co-morbidities were addressed. In addition, the process, even when looking at just a limited set of services, was extremely time-consuming. To our knowledge, Thomson Reuters has not released any background information on its Medical Episode Groupers(MEGs) for public review. We concur with the MedPAC view that Medicare should "use a Medicare-specific, transparent method" and we do not believe that either ETGs or MEGs meet that criteria at this time.

- **Electronic Versus Paper Reports:** CMS intends to continue providing paper reports due to concerns about the cost of initiating an electronic report. There are merits to both types of reports and the AMA would like for physicians to be able to choose how to receive the information. If the intent is to change physician practice, an electronic system that is frequently updated and allows physicians to drill down to get more detail will be required.

- **Validation of the Data:** To date, CMS and Mathematica have not addressed the crucial issue of how physicians can validate the data in these reports. The absence of any mechanism to validate the data will reduce physicians' ability and incentive to use the reports to modify their practice. In order to verify the data and in order to determine whether changes in their practice are warranted, **physicians will need to know the names of all the patients and other physicians whose costs were included in their reports. They will also need a formal mechanism to appeal and seek changes in the data**—especially once its purposes are expanded.

- **Attribution:** In this rule, CMS has not repeated its request for comments on methods of attribution but virtually every specialty that provided input to the AMA expressed concerns about holding physicians responsible for care that they had not provided and could not have controlled. In this demonstration, physicians are held responsible for any case/episode where they were responsible for at least 10% of evaluation and management services. **This is considerably lower than the 25% to 30% threshold recommended by the Leapfrog Group and NCQA and the 35% threshold MedPAC employed in its analysis.** We would appreciate some explanation for this decision in the interim final rule and a report on how this may have affected the usefulness of resource reports when Mathematica presents its final evaluation.

- **Structure of the Reports:** Our reviewers suggested that in addition to integrating quality data, the reports should include: more cost breakdowns, a summary sheet with suggestions on how physicians could improve their scores for those who do not want to wade through the detail, aggregate patient risk scores; information on how the scores were calculated, and information on how the physician can provide feedback and or appeal the reports findings to Medicare. Many suggested that more outreach and education will be needed to help physicians understand how the reports were constructed, what they mean, and what Medicare hopes to accomplish.

PROFESSIONAL LIABILITY INSURANCE RELATIVE VALUE UNITS (PLI RVU)

CMS is proposing its second five-year review and update of the PLI RVUs for 2010, and has requested comments on the proposed methodology for updating the PLI RVUs. The AMA appreciates that the proposal bases the PLI relative values on recent premium data. The current effort led to an expansion in the number of specialties and states that collected actual data. CMS compared the data collected by its contractor, Acumen, to the PLI premium data collected in the Physician Practice Information survey and determined that in most cases, the data were comparable.

The AMA recommends, however, that CMS round PLI relative values to .01 for those 36 physician services with physician work in which Addendum B lists a 0.00 PLI relative value.

COMPENDIA FOR DETERMINATION OF MEDICALLY-ACCEPTED INDICATIONS FOR OFF-LABEL USES OF DRUGS AND BIOLOGICALS IN AN ANTI-CANCER CHEMOTHERAPEUTIC REGIMEN

CMS proposes to establish new requirements whereby approved compendia must utilize a "publicly transparent process for evaluating therapies and for identifying potential conflicts of interest." The AMA generally supports efforts to promote transparency. Nonetheless, such efforts should not be utilized to limit the availability of compendia nor should requirements be prohibitively burdensome. As noted by CMS, the publishers of the four compendia that are currently recognized, have already adopted conflict of interest disclosure policies similar to the CMS proposal.

AVERAGE SALE PRICE ISSUES

CMS proposes to conform existing regulations to statutory provisions that have struck the one year limitation on coverage of immunosuppressive drugs following transplant. The AMA strongly supports this modification.

AMA remains concerned that smaller practices in particular continue to face challenges in recovering costs associated with Part B drugs under the average sale price (ASP) reimbursement methodology. This creates access barriers to some of the most vulnerable patients. We strongly urge CMS to carefully evaluate and take into consideration the impact of ASP methodology on smaller practices.

COMPETITIVE ACQUISITION PROGRAM ISSUES

The competitive acquisition program (CAP) was not offered last contract year. Thus, while it was to provide an alternative to ASP, practices, including smaller ones, did not have the CAP option. The AMA strongly supports efforts to reform CAP to garner greater support and participation by physicians. The AMA supports the decision to move to quarterly price adjustments to attract more vendor interest. The lack of vendor participation has limited the interest among physicians. The AMA questions the decision to limit the CAP payment amounts to ASP+6 percent since we have indicated that ASP does not adequately capture costs, particularly for smaller purchasers. While vendors might be able to obtain discounts, the ASP methodology has consistently posed problems for physician practices.

To the extent that CMS allows CAP vendors to delete drugs as proposed from the vendor's drug list during a contract, we strongly urge and support allowing physicians to change vendors outside of the election period. We also strongly support excluding CAP sales from ASP calculations because this leads to a deflation in prices that is not actually reflected in the market, particularly for physicians who do not participate in CAP and are part of a small practice. We also strongly support introducing flexibilities into the program that allow physicians to store CAP drugs in physicians' offices as well as the proposal to ease restrictions on physicians transporting CAP drugs. Despite the foregoing overall support for proposed CAP changes, the AMA does not support the proposed changes that would allow termination of CAP drug shipments to physicians who have been suspended from CAP after an initial determination by CMS, including in those instances where physicians are seeking reconsideration. This represents a denial of due process for physicians and such a termination should not be implemented until a final decision has been rendered.

MEDICARE ANESTHESIA TEACHING PROGRAMS

CMS is proposing to implement MIPPA section 139, which restores full Medicare payment to academic anesthesiology programs. Currently, Medicare payment to anesthesiology residency programs is cut in half each time a teaching anesthesiologist oversees two resident physicians on overlapping cases. Under section 139, as of January 1, 2010, full payment will be paid to teaching anesthesiologists involved in the training of physician residents in a single anesthesia case or two concurrent anesthesia cases if: (i) the teaching anesthesiologist is present during all critical or key portions of the anesthesia service or procedure involved; and, (ii) the teaching

anesthesiologist (or another anesthesiologist with whom the teaching anesthesiologist has entered into an arrangement) is immediately available to furnish anesthesia services during the entire procedure.

In the proposed rule, CMS provides that the section 139 payment rule for teaching anesthesiologists would apply in the following scenarios:

- The teaching anesthesiologist is involved in one resident physician case (which is not concurrent to any other anesthesia case);
- The teaching anesthesiologist is involved in each of two concurrent resident cases (which are not concurrent to any other anesthesia case); or,
- The teaching anesthesiologist is involved in one resident physician case that is concurrent to another case paid under medical direction payment rules.

The AMA joins the American Society of Anesthesiologists (ASA) in commending CMS for its interpretation and implementation of this part of section 139.

We have concerns, however, about CMS' proposal to require that only one individual teaching anesthesiologist be present during all of the key or critical portions of the anesthesia procedure in any of the above scenarios. In other words, CMS would not apply the new payment rule to "anesthesia handoffs." We agree with ASA that this narrow interpretation of section 139 exceeds CMS' statutory authority and is unjustified.

First, the legislation specifically recognizes current anesthesiology practice, which includes handoffs in that it provides full payment if: (i) the teaching anesthesiologist is present during all critical or key portions of the anesthesia service or procedure involved; and, (ii) the teaching anesthesiologist (or another anesthesiologist with whom the teaching anesthesiologist has entered into an arrangement) is immediately available to furnish anesthesia services during the entire procedure. (Emphasis added.)

Further, CMS discusses in the proposed rule that anesthesia handoffs create quality of care issues. We disagree, and we note that CMS acknowledges in the rule that it does not have data on the extent to which handoffs occur or whether they affect quality. Anesthesia handoffs allow smooth, seamless and safe treatment of patients and are essential to maintaining quality of care and patient safety. They are a common and necessary part of running a quality and efficient operating room, especially in academic settings where the cases are often longer and more complex than in smaller, non-teaching settings, and where medical expertise is often needed to teach a particular skill or to staff a particular case at any given time. If anesthesiologists are required to remain on a long case (up to and exceeding 12 hours, depending on the type of case) or after a 12-24 hour shift, this could adversely affect patient safety.

Further, handoffs are specifically conducted in the presence of anesthesiology residents, as a demonstration of professionalism and systems-based best practice, two core competencies required by the Accreditation Council for Graduate Medical Education (ACGME) for resident training. Because resident physician training is governed by ACGME rules regarding duty hours, there is a zero-tolerance for exceeding them. Therefore, early in their career, resident physicians must develop skills at complex handoffs for multiple patients, particularly in critical care units where they frequently brush up against duty hours restrictions.

Accordingly, we urge CMS in the final rule to permit different anesthesiologists in the same anesthesia group practice to be considered the teaching physician for purposes of being present at the key or critical portions of the anesthesia case.

Finally, CMS proposes to implement section 139(b) with respect to payment policy for anesthesia services furnished by a teaching nurse anesthetist (CRNA) with a student nurse anesthetist (SRNA), as well as for an anesthesiologist, or an anesthesiologist and nurse anesthetist jointly, with a SRNA. We support the CMS proposal as it recognizes the important distinctions between a teaching anesthesiologist and a teaching CRNA.

PAYMENT FOR INITIAL PREVENTIVE PHYSICAL EXAMINATION

CMS is proposing to increase the payment for an initial preventive physical examination (IPPE) furnished face-to-face with the patient through an increase in the work RVUs associated with CMS' Common Procedure Coding System (HCPCS) code G0402. The AMA had requested an increase in these RVUs for the IPPE, and thus we applaud and support CMS' proposal.

DIABETES SELF-MANAGEMENT TRAINING (DSMT)

The AMA supports the request of the American Association of Clinical Endocrinologists (AACE) and American Association of Diabetes Educators (AADE) that CMS re-evaluate the services described by HCPCS codes G0108 and G0109 (for individual and group training in diabetes management skills), and we urge CMS to ensure that payment for these services is appropriate.

Medicare reimbursement for these codes has declined more than 50 percent since 2002, while the cost of providing the same services has increased over 100 percent. Adequate payment for these services is critical to help curb the closure of diabetes education programs across the United States. Diabetes now affects nearly 24 million people in the United States, an increase of more than 3 million in approximately two years, according to new 2007 prevalence data estimates released recently by the Centers for Disease Control and Prevention (CDC).

It is important that patients have self-management training skills to better manage their disease and help avoid more costly complications. The physician work involved to help patients achieve these goals is time-intensive and occurs outside of the context of the E&M service. With adequate payment for these services, patients can maintain access to quality, cost-effective care, which will help reduce overall health care costs.

Further, we support the AACE's request that CMS change the status of certain CPT codes (98960, 98961, and 98962 relating to education and training for patient self-management) from "bundled" to "active" and designate them as separately payable under the Medicare physician fee schedule. The RUC-recommended RVUs could then be considered for assignment to these codes.

Education and training services for patients with conditions, such as diabetes and asthma, contributes to improved health outcomes and where such services have been incorporated into nationally recognized clinical practice guidelines, including some developed and disseminated by NIH. Coverage of codes 98960 – 98962 will support the implementation of this benefit through the physician office and will improve access to proper medical care and prevent delayed disease complications.

ACCREDITATION STANDARDS FOR ADVANCED DIAGNOSTIC IMAGING SERVICES

MIPPA requires that beginning January 12, 2012, Medicare payment may only be made for the technical component (TC) of advanced diagnostic imaging services to a supplier who is accredited by an accreditation organization designated by the HHS Secretary. In implementing this requirement, CMS proposes that the designated accreditation organization would apply standards that set qualifications for medical personnel who are not physicians but who furnish the TC. The standards would describe the qualifications and responsibilities of medical directors and supervising physicians including the following:

- Recognizing whether a particular medical director or supervising physician received training in advanced imaging services in a residency program; and
- Has attained, through experience, expertise to be a medical director or supervising physician; has completed any continuing medical education courses related to advanced imaging services; or has met such other standards as the Secretary determines appropriate.

CMS should not require that both of these criteria be met. Rather, CMS should require that one or the other of the above criteria be met. The first criteria is too restrictive and may exclude a number of accomplished physicians who have attained, through experience, the expertise to be a medical director or supervising physician, but who may not have acquired this expertise through a residency program.

With regard to CMS audits of an accredited organization, CMS is proposing to identify accreditation programs for which validation and audit results indicate a 10 percent rate of disparity between findings by the accreditation organization and findings by CMS (or its contractor) on standards that did not constitute immediate jeopardy to patient health and safety if not met. The AMA is concerned that the 10 percent threshold may be too stringent. We urge CMS to ensure that any final threshold is reliable enough so that if it were to be tested by an independent contractor, the same conclusion would be reached.

CMS also provides in the proposed rule that if CMS determines that an accreditation organization does not provide reasonable assurance that the suppliers accredited by the organization meet the applicable standards, then the accreditation organization is entitled to a reconsideration. In this case, the accreditation organization would have 30 calendar days of CMS' notice of an adverse ruling to file a request for reconsideration. CMS would then provide written notice of the time and place of the informal hearing at least 10 business days before the scheduled date. We urge CMS to apply the same 30 calendar-day time-frame to itself as it applies to accreditation organizations. Ten business days would not be enough time for an organization to prepare for and make logistical arrangements to attend the hearing.

Finally, we urge CMS to ensure that specialty organizations are involved in the development of appropriateness and accreditation criteria. With respect to criteria for medical directors and supervising physicians, specialty-specific requirements are critical. Multiple accreditation organizations should also participate in the process to provide different perspectives.

CANALITH REPOSITIONING

In the proposed rule, CMS continues to bundle payment for the canalith repositioning procedure based on the rationale that this is being paid as part of an E&M service. In the proposed rule, CMS changed its designator for canalith repositioning from "bundled" to "inactive" due to a concern for duplicate billing. We disagree.

The canalith repositioning treatment is neither history, exam nor decision-making. Canalith repositioning time does not count toward the "Counseling and Coordination of Care" basis for coding, using time as a measure of the service, because it is a treatment. Because time is not the typical basis of code selection, physicians cannot account for additional time to perform this procedure during an office visit. It is unfair to bundle the time for this procedure into an E&M service and provide no reimbursement for the extra time spent performing the procedure during this time period. Accordingly, the AMA urges CMS to adopt the RUC recommendation that CMS revise its determination to bundle this procedure into E&M or other services and accept the RUC recommendation for canalith repositioning, 95992 of 0.75 work RVUs.

The AMA appreciates the opportunity to provide our views on these critical issues, and we look forward to working with CMS to achieve resolution in each of the foregoing matters.

Sincerely,

Michael D. Maves, MD, MBA