



Michael D. Maves, MD, MBA, Executive Vice President, CEO

August 24, 2010

Donald Berwick, MD
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 2011; Proposed Rule; 75 *Fed. Reg.* 40,040 (July 13, 2010).

Dear Dr. Berwick:

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 CY 2011. Our detailed comments are set forth below and our principal recommendations are as follows:

- **The AMA strongly supports the proposed comprehensive review of the Medicare Economic Index (MEI). The MEI needs to reflect the realities of medical practice in the 21st century and the AMA welcomes the proposed review. Until this review of the MEI is completed, CMS should withdraw the changes it has proposed to the MEI for CY 2011, as well as the revisions to the relative value units (RVUs) and geographic practice cost indexes (GPCIs) that arise from the proposed changes to the MEI.**
- **CMS should revise the Physician Quality Reporting Initiative (PQRI) feedback report proposal to ensure that this process improves successful participation in the PQRI program.**
- **To implement a successful informal PQRI appeals process, CMS should significantly improve the Quality Net Help Desk by adding more telephone lines and hiring more trained and experienced, qualified staff.**
- **The AMA applauds CMS' decision to change the definition of group practice from 200 to 2, as it will allow more physician practices to participate in the group practice reporting option (GPRO) for 2011.**

- **CMS must publish detailed specifications for individual measures and measures groups for the PQRI November 15, 2010.**
- **The AMA applauds CMS' decision to reduce the PQRI reporting sample requirement from 80 percent to 50 percent for FY 2011. The AMA urges CMS to also use its existing authority to apply the new 50 percent threshold retrospectively to the 2010 reporting year.**
- **The AMA supports enhancing the measures and methods used in the resource use Physician Resource Use Measurement and Reporting Program (RUR). Under this program, CMS must adequately prepare for handling additional feedback report requests and distribution techniques, and until adequate risk adjustment and attribution models are widely tested and applicable, these reports should not be publicly reportable.**
- **We strongly support CMS' proposed requirements for the 2011 electronic prescribing (e-prescribing) incentive payment program, which is to require reporting on only 25 services involving electronic prescriptions.**
- **We strongly oppose CMS' proposal to impose financial penalties in 2012 and 2013 against physicians based on their e-prescribing activity during the first six months of 2011. Instead, we strongly urge CMS to review 2012 and 2013 e-prescribing activity (not 2011 e-prescribing activity) in order to assess penalties in 2012 and 2013.**
- **We strongly recommend that CMS add more exception categories so that more physicians facing hardship will be eligible for an exemption from e-prescribing penalties in 2012 and 2013.**
- **We also recommend that CMS provide feedback reports to physicians and establish an appeals process to allow physicians to appeal decisions that affect their eligibility to take part in the e-prescribing program or that affect their ability to get e-prescribing incentives.**
- **CMS should take appropriate measures to ensure the accuracy of the list of successful e-prescribers and to provide the appropriate disclaimers for the website listing.**
- **The AMA strongly supports better coverage for preventive care. CMS should work through the established Current Procedural Terminology (CPT) Editorial Panel and the Relative Value System Update Committee (RUC) process to adopt existing CPT codes for the annual preventive visits rather than establishing separate Healthcare Common Procedure Coding System (HCPCS) G-Codes for these services.**

- **CMS should expand the availability of the primary care incentive payments by interpreting “allowed charges” as charges under the physician fee schedule, and not as all Part B charges.**
- **CMS should ensure that the general surgery bonus payments promote access to these important services for patients by modifying the Health Professional Shortage Area (HPSA) criteria to allow a non-HPSA hospital to be part of a HPSA if: (i) the hospital is adjacent to a HPSA; (ii) the patient resides in a HPSA; or (iii) the general surgeon maintains an office in a HPSA.**
- **CMS should seek input from the RUC and its Health Care Professionals Advisory Committee on the efficiencies or reduced resources involved in services provided to the same patient in the same session or on the same day rather than implementing arbitrary multiple procedural payment reductions for imaging and therapy services.**
- **The ACA contained a number of provisions that apply retroactively, which requires CMS to re-process claims for various physicians’ services. CMS should issue guidance to its contractors about reprocessing these claims in a manner that minimizes the burden on physicians and avoids further confusion and payment delays. CMS should also make this guidance publicly available so that physician organizations can disseminate it to our members.**

MEDICARE ECONOMIC INDEX

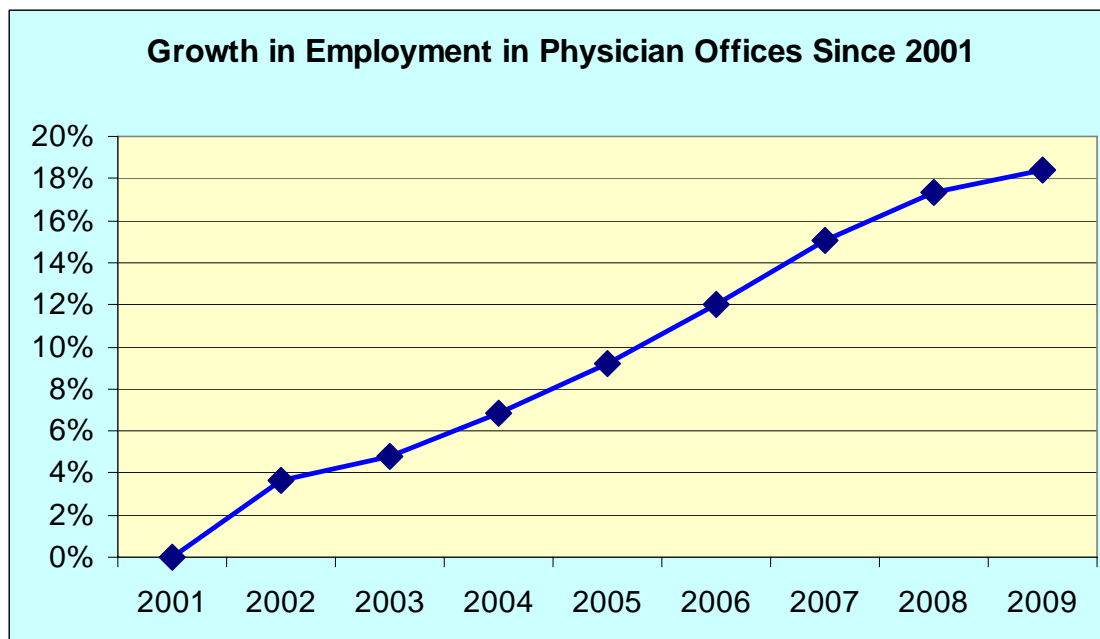
CMS proposes to convene a technical panel later this year to review all aspects of the MEI, including the inputs, input weights, price measurement proxies, and productivity adjustment. The panel’s analysis and recommendations will be considered in future rulemaking. The AMA has long requested that CMS address the problem that the “market basket” of inputs whose prices are measured in the MEI is outdated and, despite periodic rebasing, has not been comprehensively revised since it was originally developed in 1973.

Accordingly, the AMA welcomes the proposal for a technical panel to review all aspects of the MEI. At the same time, we are puzzled by the CMS proposal to reconfigure the office expense element of the MEI before the panel has even begun its work. Instead, we urge CMS to withdraw its proposal to rebase and revise the MEI in 2011 and develop a new MEI proposal after the panel conducts a comprehensive review.

CMS proposes to separate out and price nine new MEI components, including chemicals, paper, rubber and plastics. Although it references data on these components derived from the Bureau of Economic Analysis (BEA), no rationale has been provided for separately pricing these components. The AMA has long argued that the factors (or inputs) involved in 21st century medical practice are vastly different than when the MEI was first developed, and additional inputs are needed to ensure that the current MEI adequately measures the costs of practicing medicine. Today’s physicians must comply with an array of government-imposed regulatory

requirements that did not exist in 1973, including those relating to: Medicare prescription drug plans and formulary compliance; compliance with rules governing referrals and interactions with other providers; detailed coverage policies including requirements for particular tests to be completed at specific intervals; advanced beneficiary notices; certificates of medical necessity; rules governing Medicare and Medicaid dual eligible patients; limited English proficiency rules; Medicare audits; the Health Insurance Portability and Accountability Act, Clinical Laboratory Improvement Act, Americans with Disabilities Act, and Emergency Medical Treatment and Labor Act; billing errors; quality monitoring and improvement; and patient safety. CMS is also promoting the use of electronic medical records and other new health information technology systems that facilitate physician participation in quality improvement initiatives.

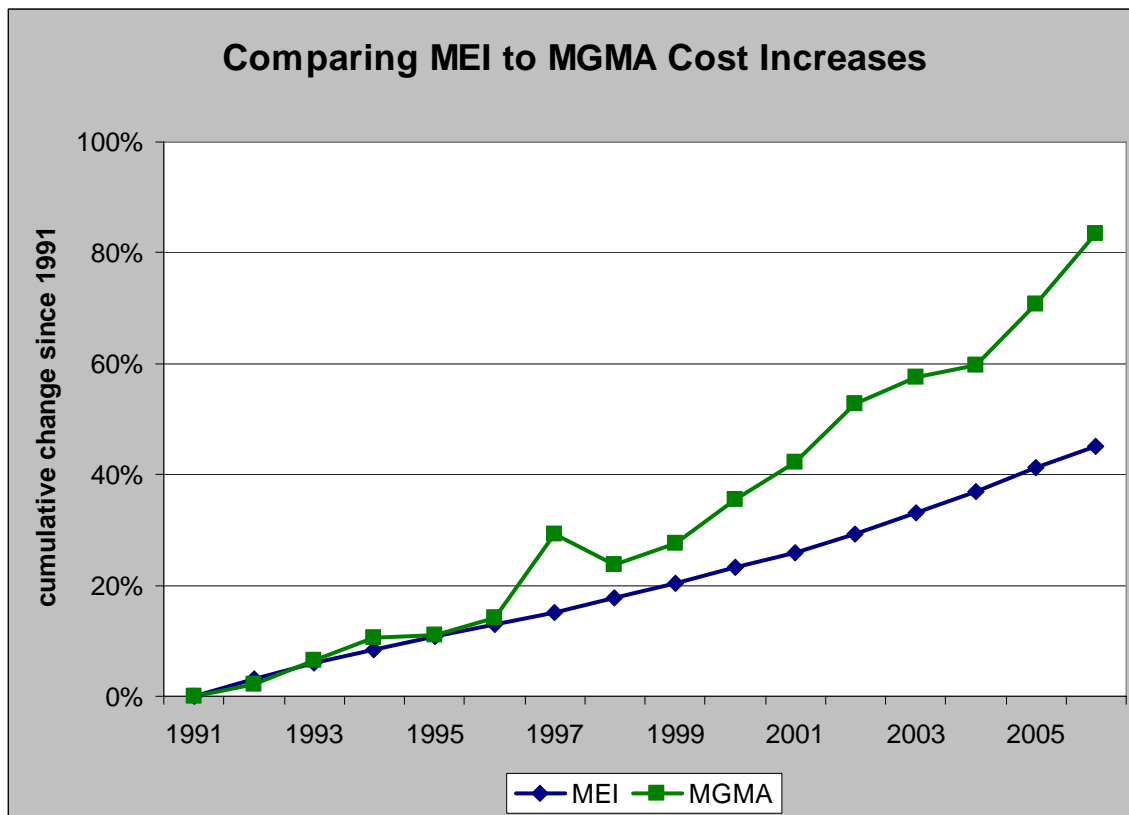
To ensure compliance with these requirements, physicians often must take actions that increase their practice costs, including hiring additional office staff, attorneys for legal and regulatory compliance, as well as accountants and billing companies to ensure proper billing of claims to handle these additional responsibilities. These types of inputs are not currently taken into account for purposes of measuring the MEI, and therefore the MEI undervalues actual medical cost increases. Data from the Bureau of Labor Statistics show an increase of more than 18% in the number of people employed in physician offices since 2001. The MEI does not account for this increase.



Data published by the Medical Group Management Association (MGMA) in 2003 indicated that, between 1992 and 2002, the number of staff per full time equivalent physician increased by 18.8%.

CMS recently incorporated findings from the new Physician Practice Information (PPI) survey into the Practice Expense (PE) relative values; before that it relied on data from the AMA

Socioeconomic Monitoring System (SMS). With the time gap between the two surveys, the PPI and SMS surveys may not be directly comparable, but a comparison of the two indicates that medical practice costs increased 79% from 2000-2006. Looking at the SMS alone, the SMS indicated a 35% increase from 1994-2000. The MEI, however, only increased 18% from 2000-2006. As shown below, MGMA data also show higher growth than the MEI.



Clearly, every other available measure of physician expense growth shows faster growth than the MEI. In addition to providing no rationale for the revisions it proposes in the MEI inputs, such as rubber and plastics, these revisions do not do anything to improve the adequacy of the MEI. In the proposed rule, CMS estimates the 2011 MEI at just 0.3%, and the addition of the new components that CMS has proposed based on BEA data do nothing to increase it. With the MEI shrinking to nothing while their costs continue to rise, today's physicians can detect no resemblance between the MEI and the costs they face every day in practice.

In addition to the new office expense inputs, CMS proposes to re-weight the work, PE and liability expense components of the MEI to match the data from the PPI survey. It further proposes to increase the PE and liability expense RVUs and decrease the conversion factor so that the relative value scale will match the new MEI weights. Finally, as discussed below, CMS proposes a number of changes to the GPCIs in order to make the GPCIs match the new weights

in the MEI and to make the inputs in the PE GPCI match the revised office expense inputs in the MEI.

We urge CMS to delay all of these proposed changes until CMS has had an opportunity to convene the technical panel and thoroughly review the needed changes in the MEI. Implementation of changes to the MEI, the RVUs, the conversion factor and the GPCIs in 2011 would play havoc with 2011 payments for many physician specialties and localities based on proposed MEI changes that may change again, perhaps substantially, after the technical review panel is convened. At a time when physicians are already facing enormous pay cuts due to the Sustainable Growth Rate (SGR) formula, it does not make sense to move forward with proposed changes until CMS has a complete MEI proposal.

GPCI UPDATE

CMS proposes a number of changes to the GPCIs, including those that are pursuant to the “Patient Protection and Affordable Care Act”(ACA), as well as other changes due to the use of more recent data, while still others would result from proposed revisions to the MEI:

- The work GPCI floor of 1.0 would be extended only through 2010, as required by the ACA, and thus is not reflected in the proposed 2011 work GPCI.
- The PE GPCI would reflect only one-half of the geographic differences in employee wages and office rents for each of 2010 and 2011, as required by the ACA, increasing payments in localities with a PE GPCI below 1.0. The ACA requires that each locality be held harmless so that the PE GPCI in localities with a PE GPCI above 1.0 are not reduced as a result of the change in the methodology for the PE GPCI.
- A permanent, non-budget neutral floor of 1.0 for the PE GPCI will be implemented for five “frontier” states (MT, WY, ND, SD, and NV), as required by the ACA.
- The ACA requires CMS to evaluate certain aspects of the PE GPCI and implement indicated revisions in a budget neutral manner no later than January 1, 2012. Specifically, CMS is required to analyze the office expense component of the GPCI, including the extent to which types of office expenses are determined in local markets instead of national markets, the weights assigned to each of the components of the PE GPCI, and the feasibility of using actual data, for example, physician office rent data, in place of proxies like apartment rental data. Instead of waiting until the proposed payment rule for 2012, CMS has completed this ACA-required review of the PE GPCI and proposes to implement the indicated changes in 2011.

- As required under longstanding existing law, CMS proposes its every three-year GPCI update, including use of 2006 through 2008 Bureau of Labor Statistics (BLS) Occupational Employment Statistics data in place of the professional earnings data from the 2000 Census. Also as required by existing law, this will be phased in over two years, in 2011 and 2012.
- As discussed above, CMS has also proposed a number of changes to the MEI which, if adopted, would significantly affect the GPCIs. CMS proposes to rebase the MEI to 2006 using data from the PPI survey, which decreases the weight for the work component of the physician payment schedule and increases the weights for the PE and liability insurance cost components. When these MEI changes are applied to the GPCIs, they apply less weight to the work GPCI and more weight to the PE and professional liability insurance (PLI) GPCIs in each locality.
- CMS proposes to use BEA data to disaggregate the office expense component of the MEI by creating separate categories for utilities, chemical, paper, rubber and plastics, telephone, postage, “all other labor-related” expenses, fixed capital, and moveable capital. When these MEI changes are applied to the PE GPCI, it leads to different weights being assigned to different components of the PE GPCI.

Impact of revising the PE GPCI in accordance with proposed MEI revisions

The large number of changes in the GPCIs that are being proposed simultaneously make it difficult to sort out the impacts of specific elements of this proposed rule. The AMA is concerned, however, that the proposal to revise the PE GPCI in accordance with the proposed revisions to the MEI would lead to cuts in a number of localities in 2011, one year earlier than Congress had called for budget neutral changes to the PE GPCI in the ACA.

Many of the new categories that have been separated out in the MEI office expense category are being grouped with medical equipment, materials and supplies which are treated in the GPCI as having national prices rather than local prices. As a result, a major change that occurs in the translation of the MEI changes to the PE GPCI is that the portion of the PE GPCI that is the same everywhere in the country instead of varying by locality grows from 29% currently up to 42% in the proposed rule.

These changes in the MEI and GPCI components, their weights, and the proportion of national vs. local pricing in the GPCI heighten the 2011 impact of the ACA requirement that only one-half of the geographic differences in rent be recognized. Localities with a PE GPCI below 1.0 see payment increases in 2011 because only half the geographic differences in rent are recognized, and these localities see further increases because the weight assigned to rent is reduced. The ACA holds harmless localities with PE GPCIs above 1.0 because they would see payment cuts if only half the geographic differences in rent were recognized. **Under CMS’ proposal, however, these localities, which are primarily large metropolitan areas, will face cuts in 2011 due to the reduced weight for physician office rent. These cuts appear to**

contradict Congress' intent as shown in the hold-harmless provision that applies to the PE GPCI provisions of the ACA for 2010 and 2011.

CONSULTATION CODES

In the proposed rule, CMS requests input on Medicare coding and payment policies, including the discontinuation of CPT consultation codes this year. As conveyed in a June 18 letter signed by the AMA and 33 medical specialty organizations, the policy has forced some physicians to cut back services to Medicare patients and discouraged communication between clinicians at the very time CMS is looking for ways to improve care coordination. A survey of affected specialties suggests that continuation of the current policy will lead to additional cutbacks in care and make it impossible for many specialists to purchase electronic medical records systems and adopt new technologies required to launch the transformation envisioned in the ACA.

Specific Survey Findings include:

- Twenty percent of the 5,500 physicians who completed the survey have reduced the number of new Medicare patients in their practice, 12% have reduced time spent with Medicare patients and 10% have reduced or eliminated consultations on hospital inpatients.
- Thirty-nine percent say they will defer purchase of new equipment and/or information technology to compensate for lost revenues. More than a third (34%) are eliminating staff.
- Six percent have already followed CMS's suggestion that they no longer need to send a written report back to the referring physician and 19% plan to stop providing a report.
- Although CMS predicted that no specialty would see Medicare revenues decline by more than 3%, nearly three-fourths (72%) of survey respondents saw declines of more than 5% and 30% faced losses greater than 15%.

These findings confirm the AMA's view that CMS should reverse its current policy and resume payment for consultation codes in Medicare. If the agency declines to adopt a complete solution, it should, at the very least, modify two other policies—involving prolonged services and new patient definitions—that have compounded the problem caused by elimination of the consultation codes.

As laid out in the previously-mentioned letter, in determining whether a service meets the prolonged service criteria, CPT stipulates that, for the inpatient setting, in addition to time spent "face-to-face" with patients, physicians can include time spent on the patients' floor or unit performing other tasks related to their care. Were CMS to apply the same definition as CPT, consulting specialists could use the prolonged services to obtain fairer reimbursement for particularly long and challenging cases they previously would have billed as consultations. CMS only recognizes the face-to-face time, however, and further discourages coordination of care by essentially denying payment for activities such as creating and reviewing charts, communicating with the family and coordinating with other health care professionals.

Cases where it would benefit a physician to use the prolonged service code are relatively limited and their use could be monitored through claims edits. Consequently, it does not appear that conforming to CPT policy on these codes would lead to large increases in Medicare expenditures and **the AMA is again requesting that CMS modify its interpretation of the prolonged service codes to match the CPT descriptors.**

The issue involving new patient definitions occurs because unlike the consultation codes, visit codes distinguish between new and established patients. The difference can be significant—about \$60 for the most complex office visits—and it affects a substantial number of specialist physicians. In the aforementioned survey, for example, 33% of all respondents and more than 70% of some specialties said that more than 25% of their consultations in 2009 were with patients who had been seen previously by another member of the same specialty and group within the past three years.

In CPT, new patients are defined as those who have not been seen by the same physician or another member of the same group and **sub-specialty** within the last three years. In Medicare, however, a new patient is one “who has not received any professional services, i.e., E/M service or other face-to-face service (e.g., surgical procedure) from the physician or physician group practice (same physician **specialty**) within the previous 3 years. The problem is that physicians often focus on a narrower range of services than are recognized in Medicare’s current list of 42 medical specialties. Thus, for example, if an electrophysiologist treats a particular patient and two years later, the patient is seen by an interventional cardiologist in the same group, the patient will be viewed as an established patient even though the two cardiologists have different areas of expertise.

The current situation is inequitable and the AMA believes that Medicare should comply with the CPT policy of identifying patients seen by physicians in a different sub-specialty as “new” patients. As pointed out in the June 18 letter, correcting its budget neutrality assumptions would provide some additional funding CMS could use to offset or partially offset any cost associated with this change. We recognize, however, that due to variations in the way that different specialties have dealt with the issue of extended training and focused expertise, **setting the criteria for determining Medicare-recognized sub-specialties or equivalent expertise will require some further analysis. The AMA would be pleased to assist CMS in identifying affected specialties and creating a work group that could help with this analysis.**

PHYSICIAN QUALITY REPORTING INITIATIVE

CMS proposes a number of changes to the PQRI, including changes required by the ACA. The AMA supports many of these changes, but we also have strong concerns and recommendations regarding other PQRI proposals, as specifically discussed below.

Feedback Reports

Section 3002(e) of ACA requires the Secretary to provide timely feedback to physicians on their performance with respect to satisfactorily submitting data on quality measures. CMS proposes to

meet this ACA requirement by providing 2011 feedback reports on or about the time of issuance of the 2011 incentive payments, consistent with current practices. **This proposal is unacceptable and falls well short of the statutory requirement and intent; we urge CMS to revise it to ensure that the feedback process improves successful participation in the PQRI program, as is intended by section 3002(e).**

Under current practices, CMS has not distributed incentive payments and feedback reports until seven or eight months after the reporting period has ended. Seven or eight months is not timely. Physicians cannot improve their understanding of program criteria or participation in a timely manner when there is such significant lag time between participation and distribution of feedback reports. To be effective, reports must be distributed at a point during the reporting period so as to allow physicians to assess their reporting and performance status, and revise their reporting practices, if needed, to be a successful participant. 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. They are also needed to provide physicians with 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.

The AMA has long been working with CMS to improve the feedback report process. Yet, feedback reports have not been distributed in a timely way, and therefore Congress enacted section 3002(e) to ensure timely reports. If Congress had intended that CMS simply continue with its current feedback practices, it would not have enacted section 3002(e). Thus, it is clear that to meet the intent of this section, CMS must propose a feedback report process that improves current practices.

CMS also proposes to provide interim feedback reports for physicians reporting 2011 measures groups through the claims-based reporting mechanism. **The AMA supports additional feedback, but we urge CMS to improve upon the aggregate quality data error reports by individual measure, which are currently distributed approximately four times per year. It would be helpful if these reports were generated monthly to help physicians identify common errors in reporting, e.g., incorrect gender, diagnosis code, CPT code. Further, these reports should not only be posted on the CMS PQRI Web site, but also distributed to medical specialty organizations in advance to ensure this information is available for educating specialties about measure reporting errors. The AMA would be happy to help CMS facilitate improved distribution of the aggregate feedback reports.**

The AMA appreciates CMS' intent to continue to explore methods to facilitate PQRI feedback report distribution. We support the agency's consideration of a process by which CMS could respond to interim feedback report requests at the individual level for claims-based submission, based upon first quarter claims data for the applicable program year. This additional feedback could help inform physicians as to errors in claims-based quality data code submission while the reporting period is ongoing and prior to the start of the 6-month reporting period.

Appeals Process

Sec. 3002 (f)(2) of ACA requires the Secretary to establish by not later than January 1, 2011, an informal appeals process so that physicians can seek review of the determination that the physician did not satisfactorily submit data on quality measures under the PQRI. CMS proposes to base the informal process on its current inquiry process whereby a physician can contact the Quality Net Help Desk (via phone or e-mail) for general PQRI and e-prescribing incentive program information, information on PQRI feedback report availability and access, and/or information on PQRI Portal password issues.

The AMA supports a PQRI appeals process, which is critical for re-evaluating the participation status of a physician who may have been incorrectly deemed not successful. **We have strong concerns, however, with use of the current structure of the Quality Net Help Desk.** Physicians have had many difficulties in accessing and obtaining reliable information from the Quality Net Help Desk. At times, they could not get through, or worse, the Help Desk representative was ill-equipped to answer their specific questions, which has led to frustration among physicians who are attempting to successfully participate in the PQRI. **Therefore, the AMA urges that CMS significantly improve the Quality Net Help Desk by adding more telephone lines and hiring more trained and experienced, qualified staff. If the Quality Help Desk is not adequately resourced to handle the additional processes related to an informal PQRI appeals process, CMS' efforts will not be viewed as sincere in trying to add a successful informal PQRI appeals process. We also urge that CMS post on its Web site the names of physicians who have been determined to be a successful participant upon appeal.**

Reporting Periods

AMA supports the agency's proposal to retain 2010 PQRI reporting periods for FY 2011. CMS proposes to retain the claims-based reporting mechanism for 2011, but notes that the agency continues to consider significantly limiting the claims-based mechanism of reporting clinical quality measures in future program years. This limitation continues to be contingent upon there being an adequate number and variety of registries available and/or the continuation/expansion of the electronic health record (EHR) reporting option. Potentially, CMS would continue to retain claims-based reporting in years after 2011 principally for the reporting of structural measures and in circumstances where claims-based reporting is the only available mechanism for certain categories of physicians to report PQRI quality measures. **The AMA encourages CMS to be cautious in how it determines to phase-out the claims-based reporting option until it is abundantly clear that all physicians understand and are able to consistently and accurately capture quality measures using EHRs or registries.**

CMS must also consider whether the eventual elimination of claims-based reporting would unnecessarily penalize physicians who do not own an EHR or participate in a registry because of extenuating circumstances, e.g., small, rural providers lacking digital connection. The availability of a claims-based reporting option enables most physicians to participate in the PQRI without incurring significant technology. Transitioning away from claims-based reporting too

quickly, without consideration of the small or rural provider, could inappropriately burden physicians who are making a good faith effort to report measures for quality improvement.

Regardless of the reporting mechanism, CMS should provide developers of measures utilized in the PQRI with support to carry out validity and reliability testing of measures. The AMA Physician Consortium for Performance Improvement (PCPI) has significant experience in testing quality measures in various platforms and would be a valuable resource as CMS continues to evaluate all reporting options for the PQRI.

Qualified Registries

CMS proposes to post on the PQRI section of the CMS Web site a list of qualified registries for the 2011 PQRI, including the registry name, contact information, and the 2011 measure(s) and/or measures group(s) and e-prescribing reporting (if qualified) for which the registry is qualified and intends to report. At the February 2, 2010, PQRI Listening Session, the AMA and other attendees recommended that CMS post additional registry information including cost to participate; number of past or current participants; frequency of registry feedback reports; and success rate of participants. **CMS did not reflect these comments in the proposed rule, and the AMA urges CMS to seriously consider these recommendations and include these additional topics of information to better assist physicians in selecting a registry most appropriate for their practice. In addition, the AMA recommends that PQRI participants have an opportunity to file complaints directly with CMS regarding particular registries.**

As discussed in the proposed rule, CMS continues to be concerned that an individual physician or a small practice does not have either the resources or the capabilities to successfully submit quality measures results and numerator and denominator data on PQRI individual measures or measures groups through the registry data submission process. The AMA shares this concern, which is why we continue to have reservations about the requirement that physicians must meet all 15 core measures (including clinical quality measure reporting) and five additional measures from a defined menu in order to qualify for meaningful use (MU) program incentives.

The PCPI seeks to test its measures across a variety of Medicare incentive programs using different data sources, and has a long-established protocol to conduct such testing. Our difficulty has been identifying practice sites that participated in PQRI claims reporting for a complete year on specific measurement sets, and who have the capacity to participate in a testing project. It appears the qualified registries may have such information readily available and be in a position to collaborate with the PCPI on testing quality measures. The AMA welcomes an opportunity to discuss quality measures testing with CMS and the qualified registries.

Integration of PQRI and EHR reporting

Section 3002(d) of the ACA requires CMS to move toward integration of EHR measures with respect to the PQRI program. **The AMA strongly supports efforts to streamline the clinical quality measures used in both the PQRI and EHR reporting programs. We encourage**

CMS to work with the PCPI to improve the development, and accelerate the testing, of clinically relevant measures for all Medicare physician specialties.

In order to align the two programs, clear program objectives must first be established. Currently, PQRI is a pay-for-reporting program and the CMS EHR Incentive Program is to demonstrate meaningful use of a certified EHR system. After the program objectives have been established and aligned, the measures and format for reporting the measures must then be aligned. **The steps that the AMA recommends to achieve alignment of the PQRI and EHR Incentive program include:**

- **Establish common program objectives;**
- **Align the measures and establish a common format for reporting;**
- **Once the "measures" and "reporting format" have been finalized and are aligned, the measures should be tested to see if they can be implemented in an EHR system; and**
- **Upon completion of system testing, the measures should be piloted in an actual clinical environment. Pilots are very common in information technology. In fact, any technology implementation or rollout typically has a pilot test completed. Pilot testing provides real world results and feedback in a selected and controlled environment. Upon completion of pilot testing, an evaluation will need to be performed to determine that the results meet the original program objectives.**

Public Reporting of PQRI Data

The ACA requires the Secretary of HHS to develop a Physician Compare Internet Web site by January 1, 2011, on which information on physicians enrolled in the Medicare program and who participate in the PQRI program would be posted. CMS proposes for the 2011 PQRI to use the current Physician and Other Health Care Professional Directory as a foundation for the Physician Compare Web site. As with the 2010 PQRI, CMS will continue to make public the names of physicians and group practices that satisfactorily submit quality data for the 2011 PQRI. Specifically, CMS proposes to post the names of physicians who: (1) submit data on the 2011 PQRI quality measures through one of the reporting mechanisms available for the 2011 PQRI; (2) meet one of the proposed satisfactory reporting criteria of individual measures or measures groups for the 2011 PQRI as described above; and (3) qualify to earn a PQRI incentive payment for covered professional services furnished during the applicable 2011 PQRI reporting period, for purposes of satisfying the requirements on the Physician Compare Web site.

Similarly, for purposes of publicly reporting the names of group practices, on the Physician Compare Web site, for 2011, CMS proposes to post the names of group practices that: (1) submit data on the 2011 PQRI quality measures through one of the proposed group practice reporting options; (2) meet the proposed criteria for satisfactory reporting under the respective group practice reporting option; and (3) qualify to earn a PQRI incentive payment for covered professional services furnished during the applicable 2011 PQRI reporting period.

CMS also discusses that it is not proposing that performance information be made publicly available at either the group practice or individual level as a condition of participation in the 2011 PQRI. The AMA agrees with and supports CMS' determination in this regard.

CMS discusses that section 10331 of the ACA, however, requires that not later than January 1, 2013, and with respect to reporting periods that begin no earlier than January 1, 2012, CMS must implement a plan for making publicly available through Physician Compare, information on physician performance, including measures collected under the PQRI. CMS will expand the information that is publicly posted on the Physician Compare Web site in future years and will be further described in future rulemaking.

The AMA looks forward to providing input into the design of the Physician Compare Web site. It is important to promote physician engagement in quality improvement through such factors as accurate benchmarking and other beneficial functions. We also suggest a process by which a physician or group can review and update their demographic information. The AMA understands this was a major challenge when the CMS Hospital Compare Web site was initiated.

Further, 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 has acknowledged, an important aspect of a quality reporting program is that physicians have the opportunity to review their data on reporting rates on PQRI quality measures. **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 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.

Maintenance of Certification Reporting Option

Section 3002(c) of the ACA requires a mechanism under which a physician may provide data on quality measures through a Maintenance of Certification Program (MOCP) operated by a specialty body of the American Board of Medical Specialties (ABMS), with an additional 0.5 percent incentive payment for years 2011 through 2014 if certain requirements are met. These requirements include that the physician must satisfactorily submit data on quality measures under the PQRI for a year and have such data submitted on their behalf through the MOCP. Physicians must also more frequently than is required to qualify for or maintain Board certification status, participate in an MOCP for a year, and successfully complete a qualified MOCP for a year.

CMS must provide further clarification on the requisite interconnected steps and processes for participating in the PQRI and MOCP to qualify for the additional 0.5 percent incentive. Without clearer articulation, physicians will not be able to understand the necessary processes to qualify under what is already a detailed and at times overwhelming incentive program. Further, requiring physicians to interact with both CMS carriers and the Medical Boards on an added PQRI reporting option allows for confusion and duplication of effort. If this additional reporting option is to succeed, CMS and the Boards must work together prior to January 1, 2011, to clarify the parameters and processes of this added reporting option, and communicate PQRI MOCP reporting option requirements clearly and often to physicians.

Further, to engage in an MOCP "more frequently" in the current health care environment, comprised of new requirements and programs, e.g., RUR meaningful use, will severely deter or even prevent many physicians from electing the MOCP option in 2011. The AMA understands that most Boards do not have a fully developed and tested Part IV MOCP, which is referred to as "practice assessment." Therefore, if most Boards do not have operational and tested "practice

assessment” capability, it is not possible for physicians participate in the program at all, much less “more frequently.” We look forward to working with CMS and the Boards to improve the availability of operational and tested practice assessment programs, such as condition-specific Practice Improvement Modules (PIMs). These modules incorporate quality measures that permit physicians to complete the module using their own patient population to produce a quality improvement score.

Physicians will further have difficulty meeting the “more frequent” standard because, as we understand, some practice assessment activity must be completed every one to four years. “More frequent” compliance could occur every two years, for example, and therefore, would not align with current PQRI reporting periods. In addition, meeting the “more frequent” standard in these instances may not yield meaningful learning from the collection and reporting of quality measures because evidence-based medicine, although a dynamic process, may not have substantially changed.

Even if a physician has the ability to participate in a practice assessment on a “more frequent” basis, issues of accurate data capture and transmission to CMS remain questionable. If practice assessment data for a physician were submitted through an MOCP that meets the criteria for a registry under the PQRI, the only PQRI qualified Board registry currently available, according to the 2010 PQRI Qualified Registries, would be the American Board of Family Medicine. Since no other Board registries exist under the PQRI, it is questionable whether they would have the capability to submit data for the 2011 PQRI (and beyond). While more Boards may request to qualify as a registry in 2011 or satisfy the rule by “meeting the criteria for a registry,” as noted in the proposal, most Boards will not be able to do so, preventing most physician specialties from electing to participate in the PQRI MOCP reporting option.

Additionally, the AMA believes there is inadequate time to test whether MOCPs have the capabilities to collect and transmit quality data to CMS accurately and consistently. Testing must occur first. If MOCP or CMS systems are faulty, CMS must provide a formal opportunity for physicians to file a complaint.

To qualify for the additional incentive payment, the MOCP should submit to CMS in a form or manner specified by the Secretary, that the physician has successfully completed a qualified MOCP practice assessment for such year, as well as the methods, measures, and data used under the MOCP and qualified MOCP practice assessment. Only “if requested by the Secretary,” does information on the survey of patient experience need to be provided. **The AMA urges patient experience information not be submitted, as the collection methods and data accuracy associated with patient experience lack uniformity and validity.**

Under the ACA, the Secretary has the discretion to incorporate participation in an MOCP and successful completion of a qualified MOCP practice assessment into quality composite measures for purposes of the physician fee schedule payment modifier under section 3007 of the ACA. **Considering incorporation of MOCP as part of the physician fee schedule payment modifier is premature. The Secretary should not adopt this approach until there is ample time to understand and act upon lessons learned with the PQRI MOC reporting option.**

In addition to requiring Boards to either operate a qualified PQRI registry or to self-nominate to submit MOC data to CMS on behalf of their members, CMS is also considering requiring the various Boards to submit data to ABMS and ABMS would then channel this information from the Boards to CMS. The AMA understands that the medical Boards and their representative organizations do not have the tools or resources to facilitate this type of data transfer. While this may be a temporary option for handling the data transfer from smaller Boards, it is an inefficient, piecemeal approach which places unnecessary data transfer burden and additional costs on the larger Boards that have not yet proven they can manage submission directly to CMS. The AMA remains concerned about the integrity of physician quality data, and it is critical that CMS not focus on data transfer for the sake of data transfer, but on adopting structured and understandable objectives for transferring and interpreting health care quality data.

Group Practice Reporting Options (GPRO)

CMS proposes for the 2011 PQRI to change the definition of “group practice” to allow a minimum group size of 2 (in contrast to the 2010 minimum group size of 200) to enable more group practices to participate in the PQRI GPRO. **The AMA applauds CMS’ decision to change the definition of group practice from 200 to 2, as it will allow more physician practices to participate in the GPRO for 2011.**

We are also pleased that CMS has called for deeming eligible group practices participating in the Physician Group Practice (PGP), Medicare Care Management Performance and Electronic Health Record demonstrations to be participating in PQRI. As such, all eligible professionals participating in these demonstrations automatically receive PQRI bonus payments. Adopting this proposal will help reduce the reporting burden for physicians.

CMS proposes for the 2011 PQRI GPRO I (large group practices) that it will validate that the group practice consists of a minimum of 200 NPIs and will supply group practices with this list. **This is a change from 2010, and the AMA seeks clarification on how it will validate NPIs.**

The AMA supports CMS’ decision to allow those group practices selected to participate in the 2010 GPRO to automatically participate in the 2011 PQRI GPRO, without being required to complete the 2011 GPRO I self-nomination process.

CMS invites comments regarding its proposal to publicly report GPRO II information with respect to satisfactory PQRI participation. The AMA seeks clarification on what the agency means by “information.” “Performance” information would be problematic, considering 2011 would be the first year for the GPRO II. **GPRO II information for public reporting must not include performance information.**

Measure Development

CMS states in the proposed rule that it does not believe there needs to be any special restriction on who can develop measures. We disagree. Measure development requires specific expertise and stringent processes to assure that the measures used are yielding the

results expected without unintended consequences. Therefore, physicians must lead quality measure development to ensure measures are accurate and clinically relevant to patients.

In 2000, the AMA convened the PCPI to develop clinical performance measures that are patient-focused and that can be implemented to improve patient outcomes. The PCPI actively engages all stakeholders including payers, patient advocates and other organizations that are committed to high quality care. The PCPI is comprised of over 170 member organizations, including: national medical specialty and state medical societies; other health care professional organizations; the Council of Medical Specialty Societies; ABMS and its member-boards; experts in methodology and data collection; the Agency for Healthcare Research and Quality; and CMS.

As the leading developer of physician-level measures, we urge that the PCPI be recognized as such in CMS' plan to ensure that clinically relevant quality measures are accurately specified and adequately testing for inclusion in the MU program. The PCPI incorporates all critical factors in the measure development process and is also committed to maintaining its portfolio of measures. It operates through a transparent, consensus-based process for developing physician-level measures, and has worked aggressively in developing to date more than 250 physician performance measures and specifications covering 40 clinical topics and conditions. These measures are available for implementation and many have been adopted by CMS for use in CMS quality improvement demonstration projects and the PQRI. In addition, the PCPI ensures that measures: (i) are evidence based and developed with cross-specialty representation and consensus; (ii) include enhanced relevance to clinical practice; and (iii) that the measure developer is committed to maintaining its measures. Any incentive program must use measures that meet these criteria.

Proposed 2011 PQRI Quality Measures and Measures Groups

Table 51- 2010 PQRI Measures Not Proposed for Inclusion in PQRI 2011

- The AMA supports the proposal to retire measures #114 and #115 and replace these retired measures with the new measure PCPI measure-Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention.
- Measure # 135: Chronic Kidney Disease-Influenza Immunization. The AMA respectfully requests that CMS reconsider measure #135 for inclusion in PQRI 2011. The proposed rule states that this measure was considered for National Quality Forum (NQF) Endorsement, but ultimately not NQF-endorsed. This is incorrect. Measure #135 has not yet been reviewed by NQF, and therefore still meets the requirements for inclusion in the CMS PQRI program.

Tables 52 & 53- Proposed 2011 Measures Selected from the 2010 PQRI Program

- The AMA supports the continued inclusion of the measures listed in Table 52. However, CMS should be aware that the PCPI has received inquiries from various stakeholders related to Measure #193 – Perioperative Temperature Management. Based on inquiries received, which questioned how the process component of the measure is defined, the PCPI work group that developed the measure reconvened in 2010 to review the evidence base. Upon reviewing updated guidelines and other changes to the evidence base, the work group convened a webinar inviting open presentations from interested stakeholders in measure #193. The work group considered the relevance of evidence and information presented during the webinar to the existing definitions in the process component of the measure (i.e., definition of active warming). Additionally, the work group directed PCPI staff to draft for its consideration a potentially more clinically-relevant version of the measure focused on the outcome component only (i.e., maintaining normal intraoperative temperature). The revision of the measure is ongoing, and will require the development of detailed specifications, an open public comment period, and PCPI approval upon work group review of comments and final consensus on the measure.

Table 54: Proposed New Individual Measures for PQRI 2011

- Care Transitions Measures: The AMA appreciates that CMS recognizes the importance of the four Care Transitions measures and for this reason has included them in the measures proposed for PQRI 2011. While the AMA looks forward to implementation of these measures in a national program, the Care Transitions measures were not designed for individual physician level measurement. These measures are specified at the facility (hospital) level, using the UB04 administrative data to identify the denominator population. Given that one of the PQRI program requirements is that the measures are for services covered by the Physician Fee Schedule, it does not seem feasible to include these in the PQRI program. The AMA will work with the Society for Hospital Medicine to determine whether these measures would be appropriate for a hospital-level quality reporting program. As a point of clarification, the National Committee for Quality Assurance is incorrectly included as a joint measure developer on these measures. The measures were developed by the PCPI in collaboration with the American Board of Internal Medicine Foundation, the American College of Physicians, and the Society for Hospital Medicine.
- Hypertension: Plan of Care- The AMA-PCPI, in collaboration with the American College of Cardiology Foundation/American Heart Association (ACCF/AHA) recommends that this measure not be finalized for inclusion in PQRI 2011 individual measures (claims or registry) Hypertension-Plan of Care. When this measure was originally developed, it was developed as a “test measure” and was not designed for individual physician accountability, but rather internal quality improvement. The CAD/Hypertension measurement set is currently undergoing full maintenance and update by the PCPI/ACCF/AHA Measure Development work group. The expert work group has recommended that this measure be retired and will be replaced with another measure.

The updated Hypertension measurement set is in its final stages of development, and the PCPI anticipates to have a new measure for consideration in PQRI 2012.

- **Melanoma: Overutilization of Imaging Studies in Stage 0-IA Melanoma:** this measure is proposed for either claims or registry reporting. The AMA would like to propose that the existing Melanoma measures #137 and #138 (currently registry only) also be proposed for either claims-based or registry-based reporting. This will provide consistency in reporting for dermatologists reporting on the Melanoma measures. In PQRI 2010, measures #137 and #138 are only available for registry-based reporting.
- **Radiology: Reminder System for Mammograms;** the AMA supports the inclusion of this new measure.
- **Asthma: Assessment of Asthma Risk- Emergency Department (ED)/Inpatient Setting and Asthma: Discharge Plan- Emergency Department/Inpatient Setting**
The AMA does not recommend these two measures be finalized for PQRI 2011 because they both are for the ED/Inpatient setting only and are not aligned in terms of care setting with the existing Asthma measures (#53, #64) in PQRI. CMS proposed an Asthma Measures Group for 2011 comprised of these two measures and the two existing Asthma measures in PQRI (#53, #64). However, as noted in comments for Table 70, these measures are not appropriate for inclusion in the Asthma Measures Group due to the varying settings of care. The AMA recommends that CMS consider adding the following Asthma measures for inclusion in PQRI 2011 for individual reporting (claims and registry) 1) Asthma: Tobacco Use: Screening- Ambulatory Care Setting; 2) Asthma: Tobacco Use: Intervention- Ambulatory Care Setting. The inclusion of these AMA proposed measures would enable CMS to proceed with creating an Asthma Measures Group unique to one setting of care.
- **Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention;** the AMA supports the inclusion of this updated PCPI measure for tobacco use.

Tables 55 & 56: Measures Available for EHR Reporting

The AMA commends CMS for expanding the measures available for EHR reporting and specifically supports inclusion of PCPI measures for EHR reporting.

Tables 57-69

The AMA supports the continued inclusion of the proposed measure groups for PQRI 2011.

Table 70: Proposed Measures for the Asthma Measures Group

The AMA supports the proposed addition of an Asthma Measures Group. However, the measures proposed for inclusion in the Asthma Measures group do not lend themselves to a measures group, due to the fact that measures #53 and #64 are for the ambulatory setting, and the two new proposed measures (Assessment of Asthma Risk and Asthma: Discharge Plan) are for use in the ED or inpatient settings only. Because of the variation in care setting among the measures, the AMA does not recommend these four measures be included in a measures group.

One alternative would be to consider the following measures for individual reporting (claims, registry) and for the Asthma Measures Group that were submitted to CMS for consideration during the “Call for Measures for PQRI 2011”:

- Asthma: Tobacco Use- Screening -Ambulatory Setting.
- Asthma: Tobacco Use- Intervention -Ambulatory Setting.

In addition to the measures that were proposed for PQRI 2011, we respectfully request that CMS consider the following measures for inclusion in the PQRI 2011 program:

These measures were submitted to CMS for consideration during the call for measures, but were not included in the measures proposed for PQRI 2011. All three of these measures are being recommended for NQF Endorsement:

- Otitis Media with Effusion: Antihistamines or Decongestants- Avoidance of Inappropriate Use.
- Otitis Media with Effusion: Systemic Microbials- Avoidance of Inappropriate Use.
- Otitis Media with Effusion: Systemic Corticosteroids- Avoidance of Inappropriate Use.

The AMA urges publication of detailed specifications for individual measures and measures groups by November 15, 2010. The agency has until December 31, 2010 to post detailed measure specifications. To ensure physician practices have the requisite time to identify clinically relevant measures and understand their specifications before day one of the program (January 1, 2011), detailed measure information must be posted by November 15, 2010.

Qualification Requirements for EHR Vendors and Products

CMS proposes that previously qualified vendors and new vendors will be required to incorporate any new EHR measures (measures electronically-specified) added to the PQRI for the reporting year in which they wish to maintain their PQRI qualification. Vendors must also update their electronic measure specifications and data transmission schema, should either or both change.

The AMA urges that CMS work to align measure specifications across programs and vendors, so that physicians feel comfortable with their ability to accurately and consistently report quality measures.

The AMA applauds CMS’ decision to reduce the reporting sample requirement from 80 percent to 50 percent for FY 2011. At the December 17, 2009, Practicing Physicians Advisory Council meeting, CMS discussed the PQRI reporting rate threshold options and presented data on the potential impact of a modified reporting threshold. According to the presentation, 82 percent of PQRI TIN/NPI participants in 2008 reported on at least 50 percent of their patient cases for at least one measure. CMS estimates that if a 50 percent reporting threshold had been applied for 2008, approximately 66 percent of PQRI TIN/NPI participants would have been incentive eligible. AMA also urged CMS, in a letter dated April 30, 2010, to use its authority to establish a 50 percent threshold for successful participation, as it would better reflect the current

realities of the PQRI reporting environment for participating physicians. **The AMA urges CMS to also use its existing authority to apply the new 50 percent threshold retrospectively to the 2010 reporting year.**

For registry-based reporting in 2011, in contrast to prior program years, CMS proposes to require that the minimum patient numbers or percentages must be met by Medicare Part B fee-for-service patients (FFS) exclusively and not non-Medicare Part B FFS patients. The rationale for this is the difficulty of analyzing data CMS receives from registries, which include patients other than Medicare Part B FFS patients. The AMA understands that the requirements for registries to be considered “qualified” include the ability to separate out and report on Medicare Part B FFS patients. The same requirement exists for qualified EHRs. If CMS requires that the minimum patient numbers or percentages be met by only Medicare Part B FFS, many specialties may not be able to meet the minimum patient numbers to be considered a successful PQRI participant. For hospital reporting, CMS receives data from all payers, which indicates that CMS should be able to capture data on both Medicare Part B FFS and non-Medicare Part B FFS. Limiting the patient population will skew the results for some physicians depending on their patient population and severely limit the value of the results for quality improvement and payment incentive. As a result, PQRI participation may be viewed as a “regulatory requirement” by physicians instead of a tool to support quality improvement.

CMS proposes that qualified registries use “PQRI measure specifications and the CMS- provided measure calculation algorithm to calculate reporting rates or performance rates ...if aggregated measures data is continued for 2011 PQRI registry reporting.” **The AMA recommends that CMS involve the measure developers who maintain the measures included in the PQRI program in this process.** This will ensure that the calculation of algorithms, including performance and exception (exclusion) rates are calculated consistently with the intent of the measure as originally developed and subsequently endorsed by the NQF. **CMS should work with measure developers, such as the AMA-PCPI, to solicit feedback on program algorithms.**

Throughout the proposed requirements for registries, CMS refers to the submission of numerator and denominator data. **The AMA recommends that exception data be added as a requirement and that registries be required to report to CMS a physician’s numerator, denominator, and exception data.** The addition of exception data is consistent with the approach included in the Final Rule for Stage 1 of the CMS EHR Incentive Program (meaningful use).

PHYSICIAN RESOURCE USE MEASUREMENT AND REPORTING PROGRAM

In January 2009, CMS implemented the RUR for purposes of providing physicians with confidential reports that measure resources involved in furnishing care to Medicare beneficiaries. CMS is continuing a phased implementation of the program, which is currently focused on 400 large physician groups and their 2000 affiliated physicians, but could eventually focus on other “group” definitions, including geographic units. Section 3003 of the ACA continues the RUR and requires CMS, beginning in 2012, to provide reports that compare patterns of resource use of

individual physicians to other physicians. Further, section 3007 of the ACA requires the Secretary to apply a separate, budget-neutral quality and cost payment modifier to the physician fee schedule payment formula. This modifier will be phased in beginning January 1, 2015 through January 1, 2017.

The proposed rule observes that throughout future phases of reports under the RUR program, CMS will continue to enhance its measures and methods and improve the content of the reports based on both agency research and the feedback of stakeholders before the payment modifier begins to affect physician payments in 2015.

The AMA supports enhancing the measures and methods used in the RUR program. We are pleased that the agency has called for development of a transparent, Medicare-specific grouper. However, in the context of a confidential feedback program, additional testing of the commercial groupers could improve our understanding of grouper methodologies without any of the significant concerns that would occur in a program where the data was made public and/or affected payment.

As we have previously stated, the AMA does not support the use of GEM measures, and we urge CMS to use PQRI measures and the most recent data available in Phase II of the Physician Feedback Program. The PQRI is a national program that offers several advantages over GEM measures. Unlike the GEM measures, physicians can self-select clinically-relevant measures. In addition, PQRI measures capture more robust clinical information through CPT category II codes, registries, and EHRs. Use of PQRI measures in Phase II also will facilitate greater harmonization with other quality measures across the continuum of care. We recognize that PQRI reporting problems remain, and we encourage CMS to work with the AMA and other physician organizations to resolve these problems. Even so, we believe that the standardization of measures will reduce physicians' reporting burden as well as providing more meaningful and actionable information for both Medicare and physicians.

Access to patient level data via a web-based tool for the population of patients represented in these reports should also be made available to physicians to aid in evaluating the reliability of reported data and to inform quality improvement. Data access must be available on a timely manner.

CMS proposes to distribute resource use reports electronically in Phase II, by leveraging the infrastructure used to distribute PQRI feedback reports. This infrastructure will enable groups to utilize an electronic portal to download their Phase II reports, while individual physicians must contact their Medicare contractor to receive a very truncated version of their own report. **The AMA cautions CMS that our experience with distribution of PQRI feedback reports has been problematic, and encourages CMS to adequately prepare for handling additional feedback report requests and distribution techniques. We are also concerned that reports to individual physicians may provide so little information that they may not be able to verify the report's accuracy. In addition, we wonder how this particular mechanism could be expanded to larger groups, such as all physicians in a particular geographic region, where there is no defined entity to query the portal and download a report.**

CMS intends to determine measures for use in the payment modifier to inform continued dissemination of confidential feedback reports to both individual physicians and physician groups. **The AMA supports providing feedback reports that include quality measures, but reminds CMS that until adequate risk adjustment and attribution models are widely tested and applicable, these reports should not be publicly reportable.**

CMS seeks input on risk-adjustment, attribution, benchmarking, peer groups, minimum case sizes, cost and quality measures, and compositing methods. **The attribution methodology, peer group identification, adequate case (sample) sizes determination should be assessed on a condition-specific basis, and should be based on physician and other expert input and transparent to all stakeholders.**

Currently, no single risk adjustment methodology is appropriate across a spectrum of conditions or episodes of care. As a result, risk adjustment model specifications (HCC model or other approaches) should be condition specific. The risk adjustment methodology should also adequately address the complexities which arise from the multiple chronic conditions of the population of Medicare beneficiaries. Sensitivity analysis of the results of the condition-specific models should be conducted and available for review. In addition, benchmarking must take sub-specialties into consideration.

The AMA believes that eliminating risk adjustment is less problematic for clinical process quality measures. Outcome measure results are a function of multiple risk and patient severity factors. The inclusion of exception in AMA-PCPI quality measures, which comprise over 70 percent of current PQRI measures, allows for patient stratification, and therefore is a form of risk adjustment.

The process of risk adjustment model selection should be based on physician and other expert input, and be transparent to all stakeholders. The AMA looks forward to reviewing and commenting on specific parameters of the RUR program, including details of data elements and data sources, and risk adjustment model specifications provided by CMS.

Finally, though we understand the need for a single attribution model to make comparisons within a national program, we believe it is premature to choose a particular model at this time. **CMS should test many models and continue to analyze the advantages and disadvantages of different methodologies.**

ELECTRONIC PRESCRIBING

2011 Electronic Prescribing Incentive Program Requirements and 2012 and 2013 Electronic Prescribing Penalty Programs

In summary, CMS proposes to continue with the 2010 e-prescribing reporting requirement in 2011, which is to require eligible physicians to report on 25 services in 2011 involving electronic prescriptions in order to qualify for incentives. CMS also plans to publicly report the names of 2011 successful e-prescribers on CMS' website.

In addition, CMS has provided and seeks input on the 2012 and 2013 penalty phases of the e-prescribing program. CMS' proposal is to levy financial penalties in 2012 and 2013 against physicians who fail to report the e-prescribing measure during the first six months in 2011.

We strongly support CMS' proposed requirements for the 2011 e-prescribing incentive payment program, which is to reduce the reporting burden from 50 percent of all applicable services, which was the requirement in 2009, to reporting only 25 services involving electronic prescriptions. We do however, strongly oppose CMS' proposal to impose financial penalties in 2012 and 2013 against physicians based on their e-prescribing activity during the first six months of 2011. Instead, we strongly urge CMS to review 2012 and 2013 e-prescribing activity (not 2011 e-prescribing activity) in order to assess penalties in 2012 and 2013. We also strongly recommend that CMS add more exception categories so that physicians who face hardship are exempt from penalties in 2012 and 2013. Finally, we recommend feedback reports from CMS to assess the incentive program, the establishment of an appeals process, and that CMS ensure that the posting of the names of successful e-prescribers is done correctly.

2011 E-Prescribing Incentive Program Requirements

CMS proposes to continue with the 2010 e-prescribing reporting requirement in 2011, which is to require eligible physicians to report on 25 services in 2011 involving electronic prescriptions in order to qualify for incentives. **We appreciate CMS' consideration of the AMA's recommendation to minimize the e-prescribing reporting burden. We support CMS' proposal that for 2011, eligible physicians report the e-prescribing G-code, G8553, only twenty-five times for applicable Medicare office visit and service codes in order to receive the e-prescribing incentive, which totals up to one percent of their Medicare allowable charges.** In addition, the AMA agrees with CMS' proposal to allow several mechanisms for physicians to submit e-prescribing information (e.g., via a vis Medicare Part B claims, a qualified registry, or a qualified EHR product). Please also refer to our comments on requirements for qualified registries and the EHR reporting option under the PQRI section. We remain committed to working with CMS to pursue significant outreach to the physician community on the 2011 e-prescribing incentive program details.

2012 and 2013 E-Prescribing Penalty Programs

CMS has also proposed criteria for applying penalties in 2012 and 2013 for physicians and group practices that are deemed to be unsuccessful e-prescribers. The law that established the Medicare e-prescribing incentive program, the "Medicare Improvements for Patients and Providers Act of 2008" (MIPPA) (P.L. 110-275), requires a penalty phase for eligible physicians who do not e-prescribe during 2012 through 2014. According to MIPPA, physicians who are eligible but choose not to participate in the 2012 or 2013 Medicare e-prescribing incentive program and do not qualify for a hardship exemption would be subject to a one percent Medicare payment reduction based on their Medicare Part B allowed charges (1.5 percent in 2013). MIPPA does provide the Secretary of HHS with the authority to exempt eligible physicians from

penalties for hardship reasons. CMS' proposal is to levy financial penalties in 2012 and 2013 against physicians who fail to report the e-prescribing measure ten times during the first six months in 2011.

We strongly oppose CMS' proposal to levy financial penalties in 2012 and 2013 against physicians who fail to report the e-prescribing measure during the first six months in 2011 (January 1, 2011 through June 30, 2011). CMS' proposal conflicts with the intent of the law, which clearly delays penalties until 2012. The law states that the penalty would apply "with respect to covered professional services furnished by an eligible professional during 2012, 2013, or 2014." Applying penalties to services rendered in 2011 conflicts with the above-mentioned language in the law. Congress clearly intended to provide CMS as much flexibility as possible to come up with a penalty program that is fair and reasonable. Reviewing e-prescribing activity during the first six months of 2011 in order to assess penalties in 2012 and 2013 is an imbalanced approach. CMS has yet to produce the 2009 e-prescribing data and to address whether there were any problems in e-prescribing reporting. Inflicting financial penalties in 2012 and 2013 based on 2011 e-prescribing activity without fully assessing the 2009 and 2010 program, including adoption and use rates, is unfair and unreasonable. **We insist that CMS revise the 2012 and 2013 penalty criteria. Financial penalties should only be levied in 2012 and 2013 against Medicare eligible physicians who fail to qualify for an exemption and fail to e-prescribe ten permissible prescriptions by the end of 2012 or by the end of 2013. Unlike CMS' proposal, our recommended approach is entirely consistent with the intent of the law.**

CMS proposes two narrow categories for exempting eligible physicians from the e-prescribing penalty: eligible physician/group practice practices in rural area with limited high speed internet access; and eligible physician/group practice practices in an area with limited available pharmacies for e-prescribing. Although we support these exception categories, we strongly recommend that CMS add more exception categories.

CMS has failed to consider that many physicians postponed purchasing an e-prescribing software or application in order to take advantage of Medicare and Medicaid EHR incentives prescribed by the "American Recovery and Reinvestment Act" (ARRA) (P.L. 111-5). ARRA was signed into law in February 2009, less than eight months after the enactment of the e-prescribing incentive program, and authorizes incentives for up to five years to eligible physicians who demonstrate meaningful use of an EHR, that includes e-prescribing functionality. The Medicare e-prescribing incentive program and the Medicare EHR incentive program are at odds with each other. According to ARRA, physicians who choose to participate in the Medicare EHR incentive program can not participate in the Medicare e-prescribing incentive program simultaneously. In order to avoid an e-prescribing penalty, physicians would have to invest in a stand alone e-prescribing application along with a certified EHR system which would pose a significant financial, administrative hardship on them. **Physicians should therefore, not be penalized because it makes more economic, practical sense to choose to participate in the EHR incentive program and for investing in an electronic system that performs more than just e-prescribing.**

There is also flexibility in the EHR incentive program on the start date for EHR use. Physicians are eligible for incentives even if they wait until 2014 to take part in the EHR incentive program. Another critical factor that needs to be considered is the fact that most physician practices are small and many of these physicians, like the rest of the population, are reaching retirement age in large numbers. It will be economically burdensome for physicians who intend to retire in the next five years to install and utilize an e-prescribing system as they continue to face looming Medicare payment cuts. We are also concerned that many of these physicians may decide to close their Medicare panels or opt out of Medicare to avoid penalties during the end stage of their clinical careers, which would adversely affect access to care for our nation's elderly and disabled. Physicians who are currently eligible for Social Security retirement benefits or will be eligible for Social Security retirement benefits by 2014 should have the opportunity to apply for an exemption. In general, a person must be at least age 62 to start collecting Social Security retirement benefits. Another exception category should be for physicians who prescribe controlled substances so that they have adequate time to purchase and install Drug Enforcement Administration (DEA) compliant e-prescribing applications, which are not yet readily available.

In addition to CMS' above-mentioned proposed exemption categories, we strongly recommend that CMS exempt other categories of eligible physicians from the 2012 and 2013 penalties, including: physicians who plan on participating in the EHR incentive program beginning in 2012, 2013, or 2014; physicians who are currently eligible for Social Security benefits or will be eligible for Social Security benefits by 2014; and physicians who prescribe controlled substances and are working to comply with the new DEA e-prescribing requirements. A "G" code should be designated for each of these additional exception categories and physicians should be able to report the applicable "G" code(s) once in 2012 and in 2013 in order to be exempt from the 2012 and 2013 penalty programs.

Feedback Report on E-Prescribing Incentive Program and Appeals Process

We also remain concerned that despite the AMA's numerous requests, CMS has not yet produced 2009 e-prescribing data or issued 2009 incentive payments. Assessing the 2009 e-prescribing data is essential for evaluating the success of the incentive program and for applying lessons learned to the e-prescribing as well as other related programs like the Medicare and Medicaid EHR incentive programs. **We urge CMS to provide feedback reports as soon as practicable so that physicians have timely, actionable information on potential problems in their e-prescribing reporting.**

We also urge CMS to include a mechanism for physicians to appeal any aspect of the e-prescribing incentive program (e.g., payments or eligibility). We believe it is critical that physicians have an opportunity to appeal decisions that affect their ability to get incentives. **Given the pitfalls experienced with the Medicare PQRI, we strongly recommend that a timely feedback loop and appeals process be built into the program to allow physicians to address reporting problems and appeal decisions that affect their eligibility to take part in the program or that affect their ability to get incentives.**

Reporting of Successful E-Prescribers

In accordance with the law, CMS plans to publicly report the names of 2011 successful e-prescribers on the CMS website. **We urge CMS to take appropriate measures to ensure the accuracy of the list of successful e-prescribers and to provide the appropriate disclaimers for the website listing.** CMS should consider delaying the posting until CMS is able to pursue an educational campaign and is able to post appropriate disclaimers along with the list of successful e-prescribers. Physicians and patients should understand: the purpose for the posting given that this incentive program just started in 2009; that adjustments to the program have been made since 2009; and that the law does not allow physicians to participate in this program and others (e.g., Medicare EHR incentive program) simultaneously so many physicians have to select one incentive program over another. Please also refer to our comments on public reporting under the PQRI section.

MEDICARE PREVENTIVE SERVICES

CMS is proposing to implement section 4104 of the ACA, which provides Medicare Part B coverage of an “Annual Wellness Visit Providing Personalized Prevention Plan Services.” CMS is proposing payment for these new Medicare services through the use of two new HCPCS G Codes. Yet, CPT already has codes that could be used for these services. **The AMA, therefore, urges CMS to work through the established CPT Editorial Panel and the RUC process to adopt these existing codes for these services.**

The AMA continues to have strong concerns about CMS’ development of HCPCS G codes instead of requesting the development and valuation of appropriate codes through the CPT Editorial Panel and the RUC. Development and valuation of codes through this regular process avoids massive billing confusion and ensures credibility of the coding process. There is an enormous amount of effort and expertise that is required by each specialty in developing coding proposals, conducting surveys to determine physician time and work, convening consensus panels, and determining appropriate direct PE inputs for each new CPT code that is created. The results of these efforts are then validated through multi-specialty groups of physicians, including CPT Advisors, the CPT Editorial Panel and the RUC. This process provides stability and credibility to the development of a code, and ensures that code descriptors and recommended RVUs are developed and maintained by physician experts who represent those providing these new services.

Further, the AMA strongly supports better coverage for Medicare preventive care, and we commend implementation of preventive care benefits. We urge CMS, however, to address several important issues related to implement of this ACA provision.

Screening and behavioral counseling in primary care to reduce alcohol misuse

The US Preventive Services Task Force (USPSTF) gives screening and behavioral counseling interventions in primary care to reduce alcohol misuse a B rating, and we urge CMS to cover

these services as part of the annual wellness visit/personalized prevention plan. The USPSTF states:

“Effective interventions to reduce alcohol misuse include an initial counseling session of about 15 minutes, feedback, advice, and goal-setting. Most also include further assistance and follow-up. Multi-contact interventions for patients ranging widely in age (12-75 years) are shown to reduce mean alcohol consumption by 3-9 drinks per week, with effects lasting up to 6-12 months after the intervention.”

Existing CPT Codes for this intervention fully describe these recommended actions, and we urge CMS to include these codes as a covered preventive care service in the final rule.

Smoking Cessation

The RUC has already developed CPT codes for smoking cessation, yet CMS is developing slightly different coding through the national coverage determination process (NCD). **We urge CMS to adopt the existing CPT Codes for smoking cessation and cover these services as part of the annual wellness visit/personalized prevention plan.**

Recommended Adult Immunizations

When the USPSTF ceased making recommendations with regard to vaccines after CY 1996, it demonstrated its support of the CDC’s Advisory Committee on Immunization Practices (ACIP) recommendations by including them in the USPSTF dissemination materials. **The AMA urges CMS to adopt the ACIP-recommended adult immunization schedule for adults 65 years and older. This would include, in addition to influenza, pneumococcal and hepatitis B vaccines, the vaccines for Herpes Zoster and Tetanus (Td).**

Additionally, as supported by a recent survey published in the *Annals of Internal Medicine* (Hurley et al, May 4, 2010 vol. 152 no. 9 555-560), payment for vaccines via Part D Medicare is a barrier to physicians administering the vaccine. **With the coverage for shingles vaccine (reimbursed via Medicare Part D) at an unacceptably low two percent rate, the AMA urges that all vaccines recommended by the ACIP and covered by Medicare be reimbursed via Medicare Part B.** This would bring all vaccines in line with the influenza, pneumococcal and hepatitis B vaccines, which are paid under Medicare Part B.

Assessment of individual functional ability and level of safety should include screening for visual acuity

The AMA applauds inclusion of functional status screening in the first annual wellness visit. However, we are concerned that CMS includes screening only for hearing impairment and not for visual impairment. While the USPSTF has removed visual acuity screening from a B to an I rating because of the lack of scientific research in this area, visual acuity is an important part of multi-factorial fall risk assessment and correction of visual problems is essential in fall prevention programs. The 2009 *Guideline for the Prevention of Falls in Older Persons*, a joint endeavor of the American Geriatrics Society, the British Geriatrics Society, and the American

Academy of Orthopaedic Surgeons, provides a thorough review of the evidence and recommends that physicians complete a multi-factorial fall risk assessment including: (i) history of falls; (ii) medications; (iii) gait, balance and mobility; **(iv) visual acuity**; (v) other neurological impairments; (vi) muscle strength; (vii) heart rate and rhythm; (viii) postural hypotension; (ix) feet and footwear; and (x) environmental hazards. **Clearly, the scientific evidence supports the recommendation to screen for and treat visual impairments, and we therefore urge CMS to include visual acuity services in the annual wellness visit.**

Health Risk Assessment

The ACA requires that a health risk assessment (HRA) be included in the new annual wellness visit benefit January 1, 2011. CMS acknowledges, however that the HRA guidelines (with standards for interactive telephonic and web-based HRAs) and the model HRA tool also required by the ACA are not yet available. CMS, therefore, has not included requirements related to the HRA in the proposed rule. **The AMA urges CMS to continue to develop the HRA guidelines, in consultation with the AMA and other relevant stakeholders representing physicians. These HRA program should also be pilot-tested before being widely imposed to determine such critical factors as the effectiveness of the guidelines and the administrative burden imposed on the physicians.**

BONUS PAYMENT FOR PRIMARY CARE AND GENERAL SURGERY SERVICES

Primary Care Bonus Payments

The proposed rule implements section 5501 of the ACA which provides a 10 percent incentive payment over five years for primary care practitioners for whom primary care services accounted for at least 60 percent of the allowed charges. This provision raises the question of what constitutes “allowed charges.” CMS is interpreting the legislative language to mean allowed charges under Medicare Part B. This would include a number of services that are not paid under the Part B Medicare physician fee schedule, such as clinical diagnostic laboratory services or drugs and vaccines furnished in a physician’s office, which would make it much more difficult for a physician to reach the 60 percent threshold. CMS’ broad interpretation of “allowed charges” would significantly narrow the number of primary care practitioners who would be eligible for the payment incentive.

The AMA urges CMS to narrow its interpretation of “allowed charges” consistent with both the intent and statutory language of this provision. The payment incentive is intended to promote primary care as a physician specialty. According to HHS’ most recent data, there are 6,204 primary care health professional shortage areas with 65 million people living in them. It would take 16,643 practitioners to meet their need for primary care providers (a population to practitioner ratio of 2,000:1).

The primary care incentive is intended to address both the shortage of primary care physicians and to promote preventive care and care coordination as a means to help reduce growth in Medicare services. CMS’ broad interpretation of “allowed charges” undermines the intent of this

provision since many physicians would not be eligible for the incentive payment. This would potentially affect both urban and rural physicians, but it would especially hurt patients living in rural communities. For example, a primary care physician practicing in a rural area, with few or no other primary care physicians and no physicians who specialize in services beyond primary care, is likely to furnish many types of services to patients (including clinical laboratory services and drugs and vaccines furnished in the physician's office) to which the patient may not otherwise have access. CMS proposes to include charges for all of these services in the 60 percent of allowed charges threshold, yet these services are not even paid under the physician fee schedule. The primary care bonus is especially intended to help support these primary care physicians, but under CMS' narrow interpretation, these physicians will be much less likely to be eligible for the incentive payment unless they discontinue offering certain services that patients may not be able to receive elsewhere. Further, if physicians in these areas are not eligible for the bonus, this will further damage recruitment efforts for these shortage areas.

Finally, we believe the statutory language in section 5501 requires only physician fee schedule services to be counted as "allowed charges." The language specifically provides that the incentive payment is for certain practitioners "for whom primary care services accounted for at least 60 percent of the allowed charges under this part for such physician or practitioner in a prior period as determined appropriate by the Secretary." (Emphasis added.) There are several uses of the phrase "under this part" in section 5501, and each time this phrase is used, it is in reference to services that are provided and paid under the Medicare physician fee schedule. For example, section 5501(a) uses the phrase "under this part" as follows—

"In the case of primary care services furnished on or after January 1, 2011, and before January 1, 2016, by a primary care practitioner, in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid (on a monthly or quarterly basis) an amount equal to 10 percent of the payment amount for the service under this part." (Emphasis added).

Here, "under this part" is referring to primary care services, as defined in section 5501, and all of these services are furnished under the physician fee schedule. Thus, it is logical to conclude that when this phrase is used in reference to allowed charges, it means allowed charges under the Medicare physician fee schedule. This conclusion is supported by Congressional Budget Office (CBO) scoring for this provision under the ACA. The CBO score for section 5501 is \$400 million for FY 2011, and \$3.5 billion over five years, which contrasts sharply from the CMS actuary estimate of \$170 million for FY 2011. Clearly, CBO and Congress anticipated that the primary care incentive payment would have a much broader application than CMS is proposing. **Thus, we urge CMS to interpret "allowed charges" as charges under the physician fee schedule, and not under Part B.**

General Surgery Bonus Payments

The AMA urges CMS to ensure that the general surgery bonus payments promote access to these important services for patients. The requirement that payment be tied to a geographic HPSA will result in very few general surgeons receiving the bonus payment. The HPSAs, as

currently defined, will not capture all the areas in which there is a shortage of general surgeons. The HPSA criteria should be modified to allow a non-HPSA hospital to be part of a HPSA if: (i) the hospital is adjacent to a HPSA; (ii) the patient resides in a HPSA; or (iii) the general surgeon maintains an office in a HPSA.

MULTIPLE PROCEDURE PAYMENT REDUCTION

CMS proposes to expand the existing multiple procedure payment reduction to computed tomography (CT) and computed tomographic angiography (CTA), magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA), and ultrasound services furnished to the same patient in the same session, regardless of the imaging modality, and not limited to contiguous body areas. CMS also proposes to apply this policy to multiple units of the same therapy service, as well as to multiple different services when furnished to the same patient on the same day.

The AMA has strong concerns about expansion of this policy, as proposed. When procedures are furnished across modalities, for example, these are separate procedures with little or no overlap, and therefore efficiencies cannot be achieved. The same is true for different types of therapy services provided to the same patient on the same day. An arbitrary reduction in payment for these services that has no relationship to actual efficiencies will only serve to reduce access for these services.

If CMS has identified a problem or believes there is an opportunity to achieve efficiencies when these imaging or therapy services are furnished to the same patient on the same day, we urge CMS to address this issue through the CPT/RUC process so that the physician community can appropriately address the matter as well as provide input and develop a reasonable solution that achieves its intended goal, while also preserving access for patients.

RESOURCE-BASED RELATIVE VALUE UNITS

The AMA appreciates the opportunity for physician input into the clinical resources required to provide services valued within the Resource-Based Relative Value Scale (RBRVS). The primary conduit for this practicing physician expertise is the RUC. CMS has proposed to accept the RUC's recommendations for several practice expense issues in 2011, including initiating a discussion on the how to best update high cost disposable supplies. We applaud the agency for proposing a process to ensure that high cost supplies are appropriately priced, but caution that the use of the United States General Services Administration (GSA) medical supply schedule should not be the sole determinant of the cost. The GSA list includes the lowest negotiated price by the United States government. Individual physician offices are not able to negotiate at this level and the RBRVS is intended to capture the "typical" or median price.

CMS acknowledges the efforts by RUC to identify, review, and re-value as necessary, physician services that may be inappropriately valued. Indeed the RUC's efforts have been substantial. The RUC has identified more than 850 services for review and submitted recommendations for

more than 600 services. The RUC's recommendations to decrease work relative values led to more than \$100 million in annual redistribution to other services via a small increase to the Medicare conversion factor in 2009 and 2010. A more substantial redistribution is anticipated in 2011 if CMS implements the pending RUC recommendations. The RUC has identified services in a fair and objective manner by first developing screens that generate lists of codes via review of claims data or other resources. While the three CMS-identified screens proposed for review in 2011 include several of the services that the RUC has identified, the AMA is concerned that the same objectivity was not applied when developing the list of codes in Table 9 (MPC), 10 (Low Work/Multiple Units), and 11 (Low Work/High Volume). It is critical that all specialties are treated fairly in this process, as reductions in payment for services must be justifiable from the initial identification to the time of implementation. **We urge CMS to carefully consider the RUC's review of these CMS proposed screens and the appropriate mechanism to address these issues.**

CMS has expressed concern that certain services remain misvalued after an initial RUC review. The AMA understands that the RUC has scheduled a re-review of approximately 40 physician services originally identified by the RUC for review as the Medicare claims data indicated a potential shift in the site-of-service from hospital inpatient to hospital outpatient. CMS acknowledges that "the AMA RUC's unique infrastructure and broad perspective permits the valuation of a code within the context of relativity to the entire relative value system." **We urge CMS to continue to place greater importance on relativity than arbitrary mathematical formulas that may ultimately result in negative relative values, as displayed in Table 15 of the proposed rule.** The importance of relativity cannot be emphasized enough. While the AMA agrees that valid extant data should be shared with the RUC to assist in discussion, the use to time and motion studies or journal articles to determine physician time is inappropriate unless the same methodology can be employed for all physician services. Time and motion studies for more than 7,000 physician services is neither feasible nor affordable. The use of physician surveys has provided a consistent, fair, and relative source of data for nearly twenty years and the AMA finds no justification to abandon this approach.

NEWLY "BUNDLED" SERVICES – NOT NEW SERVICES

CMS is in the process of transitioning new data from the PPI Survey into the existing services' PE RVUs. However, new codes are not transitioned as there are no historical PE RVUs to use in the computations. CMS should differentiate those codes that reflect new technology from those that have CPT modifications due to bundling efforts. **The AMA repeats its request for transition for all existing services that are now reported under a new bundled coding structure (e.g., myocardial perfusion image, CPT Codes 78451-75454).**

DISCLOSURE REQUIREMENTS FOR CERTAIN IMAGING SERVICES

The AMA is generally in agreement, with a few exceptions, to the proposed provisions to implement the written disclosure requirement for in-office ancillary services subject to a self-referral exception for certain imaging services. Specifically, the AMA strongly agrees with the proposal to limit the new written notice requirement to the category of services specified in the

ACA: MRI, CT, and PET services. We support the agency's decision to not expand this requirement to other radiology or imaging services included in the designated health services (DHS) category.

The AMA also agrees with the decision to apply the new disclosure requirement to services furnished on or after the effective date of the final implementing regulation. We would not have supported a retroactive application of this rule since it would not be possible for physicians to comply sans notice and guidance. We also agree with the determination that the written list should include suppliers only (and should not be expanded to include providers of service as defined by statute).

We also agree that it is not feasible or practical for a physician to prepare a separate list for every area in which his or her patient resides. This was a cause for considerable concern since patients may reside in many disparate locations and the staff resources required to fulfill this requirement would be significant. We support requiring physicians to develop a list with a specified number of suppliers within a 25-mile radius of the physician's office at the time of referral. The alternatives to this provision could be confusing and we agree with the agency that a bright line rule is preferable. We do have significant concerns that the number of suppliers the agency has indicated a physician must identify, ten, is not workable or helpful to patients. Maintaining an up-to-date list of ten suppliers is possible, but will consume staff time to regularly ensure that all of the contact information remains updated and accurate. In addition, a large list is more likely to overwhelm patients. Equally important, while a referring physician may have knowledge and confidence in two or three other suppliers providing the service, it is extraordinarily unlikely for a physician to have that level of information and confidence in ten. As we strive for continuity of care, enhanced communications among care providers, and integration of health care delivery, requiring physicians to potentially refer to suppliers with whom they have little contact or knowledge undermines the migration to greater care coordination. Two to three suppliers is a meaningful list in which a referring physician will have a far higher level of confidence as compared with ten.

Finally, we have very serious concerns and do not support the agency's decision to not include exceptions to the disclosure requirement. We strongly urge the agency to adopt exceptions to the requirement for services provided on an emergency or time sensitive basis or for instances when it would be difficult or impractical to provide the written disclosure prior to the provision of the imaging services. The agency could require physicians to document one of the foregoing reasons for not providing a written notification prior to rendering the service. This exception is essential in the context of an emergency. It is inconceivable that a physician would be required to demand that a patient sign a form prior to the rendering of the service when the patient's health is at-risk.

In addition, we strongly urge the agency to adopt other exceptions to account for situations in which the physician doing the test, such as a PET scan of a tumor, is also the physician who is treating the patient's cancer, such as through radiation treatment, chemotherapy, or surgical removal. For example, a surgical oncologist may want to do a PET scan of a tumor in order to ensure that the surgical procedure he/she is about to perform is very precisely and accurately

targeted. In these cases, the physician will be accountable for the outcome of care for the entire episode, including instances where the progression of the patient's condition must be carefully evaluated. Finally, in other circumstances it would be impractical to provide disclosure. For example, if there is a heart imaging center in an area, but no other orthopedic centers, it would not make sense for the orthopedic physician to be required to disclose the heart center to the patient. There should be an exception for these types of impractical circumstances as well.

AVERAGE SALES PRICE

Medicare Part B covers certain categories of prescription drugs and biologicals (hereafter both referred to as drugs) that are physician administered. Medicare has paid for Part B drugs using the average sale price (ASP) methodology. The reimbursement rate has been ASP plus six percent. In previous comment letters we have expressed concern that the methodology and process used to calculate ASP and the ultimate reimbursement has not covered actual costs, particularly for small physician practices that are not able to negotiate bulk discounts.

Nonetheless, we do appreciate and support CMS's judicious approach to proposing the use of the average manufacturer price (AMP) plus three percent in lieu of the ASP methodology plus six percent. To the extent it does not adversely impact the ability of small physician practices to receive reimbursement to cover costs, we support CMS's proposal to limit the effect of temporary price fluctuations. Also, we support the proposal to require ASP to exceed AMP by the specified threshold for two consecutive quarters or three of the last four quarters. We further support limiting the application of this policy to situations where the Office of Inspector General comparison is based on complete data for all of the National Drug Codes (NDCs) in a HCPCS code.

Despite our above support, our overriding concern remains: the payment methodology (whether utilizing AMP or ASP) for covered Part B drugs may not be sufficient to cover the actual cost of covered drugs, particularly to small physician practices and when there are significant price fluctuations. There was little mention in the proposed rule on the impact of small practices. In brief, we urge CMS to exercise its discretion to ensure that the payment for Part B drugs does not systematically short change small physician practices nor particular specialties.

RE-WEIGHT SGR TARGETS TO REMOVE DRUG PRICE CHANGE EFFECTS

In the final rule with the 2010 Medicare payment schedule, CMS adopted a policy of removing Part B drug costs from SGR actual and allowed spending in the base year and each year thereafter. However, there is still a substantial impact of Part B drugs having been in the SGR due to their effect on the weighting of the elements comprising the SGR targets. Specifically, in 2004-06, there were significant reductions in Part B drug prices due to the change to the ASP payment methodology. These price cuts were reflected in the fee component of the SGR, where the change in drug prices was weighted by the share of actual SGR spending attributed to drugs. With the removal of drugs from actual SGR spending, this share is now zero, but CMS has not adjusted the weights accordingly.

Using the 2005 SGR target as an example, the fee component of the target is a weighted average of the updates to the three major categories of SGR spending. In the Federal Register of December 1, 2006, p. 69759, the fee component of the 2005 SGR target is calculated as follows:

	<u>Weight</u>	<u>Update</u>
Physician	.842	3.1%
Lab	.070	0.0%
Drugs	.088	-21.0%
Weighted Average		0.8%

Each weight is defined as the percentage of actual SGR spending accounted for by that category for the year. Before the policy change made in the 2010 rule, drugs accounted for 8.8% of SGR spending in 2005. However, now that CMS has removed drugs from SGR, this category accounts for 0% of SGR spending. The revised calculation of the 2005 fee component would be:

	<u>Weight</u>	<u>Update</u>
Physician	.923	3.1%
Lab	.077	0.0%
Drugs	.000	-21.0%
Weighted Average		2.9%

Note that it is only the weights that need to be changed, but not the update values. The weights are changing based on the change in the definition of actual spending to remove drugs.

	SGR Fee Factor	Proposed Revised SGR Fee Factor
2004	1.3%	2.7%
2005	0.8%	2.9%
2006	2.1%	2.6%

To be consistent, this change could be made for every year's SGR through 2009, which is the last year in which CMS has included a weight for drugs, at 9.7% of actual spending that year. In the 2010 SGR, the weight for drug prices was zero.

HIGH COST SUPPLIES

The proposed rule provides an overview of the CMS contractor's efforts to identify pricing information for the 62 high-cost disposable supplies with prices of \$150 or more in the current PE input database. The CMS contractor was only able to obtain pricing for 37 of the supplies, and noted additional issues with the level of information obtained for these 37 services.

Inclusion of high-cost supply items within the relative values for physician services is not appropriate. **The AMA urges CMS to instead consider the addition of 62 new J codes to report the provision of these supplies to patients. The payment for these J codes should then be determined by CMS to reflect the average cost to physicians. The appropriate pricing should be determined on an annual basis.**

While the proposed use of the United States General Services Administration (GSA) medical supply schedule to augment the data collection process is understandable, CMS should use caution in using the GSA database as the sole source of information. CMS acknowledges that only nine of the 62 high cost suppliers could be found within the GSA list. In addition, the GSA reflects government negotiated prices, and it is unlikely that individual physicians would have the ability to negotiate prices from vendors at these rates. CMS has proposed or implied that vendors or “stakeholders” would ensure that each of the 62 high cost supplies are included on the GSA medical supply schedule by CY 2013. If the supply item was not placed on the list on or before this year of re-examination, CMS would reduce the price by 23 percent. **The AMA urges CMS to publish the analysis that led to the proposed 23 percent reduction.** CMS provides two examples of high cost supplies currently in the PE database and located on the GSA medical supply schedule. The endoscopy capsule or “pill cam” is nearly identical at \$450 in the PE database compared to \$444 in the GSA schedule. CMS notes that a jejunostomy tube ranges from \$60-\$83 in the GSA list, but is \$195 in the PE database. However, the PE database for jejunostomy tube (CPT codes 49441, 49446, 49451, and 49452) lists \$97.50 as the price. It is unclear if this apparent error impacted CMS’ analysis that led to the assertion that the GSA schedule includes prices for 9 codes that are 23 percent less than reflected in the current PE database. Regardless of the ultimate percentage difference between the two lists for the limited number of services, it would be inappropriate to extrapolate this difference to the remaining codes.

Each high cost supply, with 16 in excess of \$1,000, should be priced independently. The AMA urges CMS to reconsider the establishment of J codes for these services. **We agree that the pricing of these supplies should be based on a transparent process, and the most transparent method would be creation of J codes that are annually reviewed and updated.** CMS may wish to consider other dollar thresholds if 62 J codes would be too burdensome.

ENSURE ACCESS FOR MEDICARE BENEFICIARIES TO AAA SCREENING

Under current law, Medicare covers a one-time ultrasound screening for at-risk Medicare beneficiaries, including men who have ever smoked and men and women with a family history of Abdominal Aortic Aneurysms (AAA). Since this service is covered as part of the Initial Preventive Physical Exam (IPPE), however, it is only available during the first year of Medicare eligibility. Therefore, many at-risk beneficiaries are not getting screened. Less than 10,000 beneficiaries were screened in 2007 and approximately 18,000 in 2008.

The AMA urges CMS to remove the IPPE referral requirement for AAA. The Secretary has authority under Section 4105 of the ACA to do so. This provision authorizes the Secretary to modify Medicare coverage of certain preventive services, such as AAA, so long as the modification is consistent with the recommendations of the USPSTF. Screening for AAA is endorsed by the USPSTF. Yet, the requirement of a referral during the IPPE is not consistent with the USPSTF recommendation, which states the clinical need as being a one-time screening for at-risk individuals. It does not state that the screening must occur within 12 months of being enrolled in Medicare.

With the advent of the personalized prevention plan, the occurrence of this one-time AAA screening can be easily verified and not duplicated. It is estimated that over one million Americans have AAAs and at least 95 percent of these can be successfully treated if detected prior to rupture. Yet, because AAAs are almost always asymptomatic, the problem goes largely undetected and untreated, leading to needless loss of life. Lifting the IPPE referral requirement would provide much improved Medicare access to this important preventive benefit.

CANALITH REPOSITIONING

The AMA applauds CMS's proposal to acknowledge the distinct nature of CPT code 95992 from an evaluation and management (E/M) service by recognizing this CPT code for payment. We also agree with CMS's proposal to use the RUC-recommended values for work RVUs (0.75) and PE inputs for establishing payment for 95992 in CY 2011.

CODES WITH "23-HOUR+" STAYS

CMS discusses in the proposed rule its view that because 23-hour stays are billed as an outpatient service, the code should not incorporate physician work values for services that are typically associated with an inpatient service. We disagree with this regarding stays of 23+ hours.

The real issue CMS is addressing in the discussion is when patients are in observation status for 23+ hours, sometimes extending to 48 hours or beyond. The RUC identified this phenomena for a small number of surgical services, and recommended the following policy: *If a procedure or service is typically performed in the hospital and the patient is kept overnight and/or admitted, the RUC should evaluate it as an inpatient service or procedure using the hospital visits as a work proxy regardless of any status change made by the hospital.*

When the patient stays overnight in the hospital, the work value does not change, regardless of whether the status is changed by the hospital. CMS acknowledges that there has been a growth in the use of observation status by hospitals. In fact, physicians and patients may perceive the patient to be on inpatient status, but hospitals often arbitrarily change the status of a patient from in- to out-patient simply to conform to certain hospital policies or to avoid an audit by a recovery audit contractor (RAC). This change in status does not change the work involved.

The RUC has worked with the specialties and CPT to find a solution to this issue for 2011. We urge CMS to resolve this issue in a fair and consistent manner. The AMA supports the RUC in its continued use of magnitude estimation in developing relative value recommendations as it is the cornerstone of the RBRVS. When intra-work per unit time (IWPUT) or building block analysis are performed to augment this review, the RUC should then use the CMS policies that are finalized.

REPROCESSING OF CLAIMS FOR RETROACTIVE PAYMENT

The ACA contained a number of provisions that apply retroactively, which requires CMS to re-process claims for various physicians' services. **There has been significant confusion and**

delay in re-processing these claims, and therefore the AMA urges CMS to issue guidance to its contractors about reprocessing these claims, and in a manner that minimizes the burden on physicians. We further urge CMS to make this guidance publicly available so that physician organizations can disseminate it to our members.

**PHYSICIAN SIGNATURE FOR REQUISITIONS FOR
CLINICAL DIAGNOSTIC LABORATORY TESTS**

CMS is proposing to require a physician's signature on all requisitions for clinical diagnostic laboratory tests. The AMA urges CMS to reconsider this proposal. It will only lead to further confusion, a complicated and unnecessary administrative process, and potential harm to patients forced to wait too long for laboratory tests.

The conclusion that a physician's signature was not the only method for documenting the ordering of a test was the product of an extensive negotiated rulemaking involving 18 organizations representing physicians, laboratories, other health care stakeholders, and CMS. Changing this policy solely to establish "a less confusing process" is not an appropriate rationale because any existing confusion is largely due to confusing language in the CMS manuals.

The proposed policy will be even more confusing, will cause unnecessary administrative burden, duplicative record keeping (the physician would need to sign the requisition and the chart), and liability issues. It could also be harmful to patients, for example, in an emergency situation where a signature is missing, yet the laboratory tests is needed immediately. **Accordingly, we urge CMS to withdraw this proposal.**

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,

A handwritten signature in cursive script, reading "Mike Maves", written in black ink on a white background. The signature is positioned to the left of a vertical red line.

Michael D. Maves, MD, MBA