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Donald M. 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 2012; Proposed Rule; 76 *Fed. Reg.* 42,772 (July 19, 2011); CMS-1524-P

Dear Administrator 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 calendar year 2012. Our detailed comments are set forth below and our principal recommendations are as follows:

Physician Quality Reporting System

- **CMS should allow physicians to provide feedback on the format and content of interim feedback reports in the Physician Quality Reporting System (PQRS) once CMS has developed the prototype for these reports.**
- **The AMA urges CMS to immediately rectify the separate certification requirements for PQRS and the Medicare and Medicaid Electronic Health Record (EHR) Incentive Program.**
- **We urge CMS to identify measure clusters up-front and not leave physicians guessing as to the specific requirements for successful participation in the PQRS.**
- **We urge CMS to ensure that all measures in measures groups are also reportable as individual measures.**
- **At least for the first year a measure is proposed, it should be reportable via claims-based reporting AND registry-based reporting. It is critical to offer the claims and registry option at least for the first year a measure is in the program, in case no registries adopt a certain measure.**

- **The AMA fully supports the addition of more measures groups to the PQRS program, yet we urge CMS to ensure that there is an analytically sound method for reporting measures groups when denominators differ.**

Electronic Prescribing

- **In order to better align the e-prescribing incentive program with the e-prescribing penalty program, we urge CMS to only require the reporting of at least 10, rather than 25, G8553 codes for electronic prescriptions per year for the 2012 and 2013 e-prescribing incentive programs.**
- **We support CMS' decision to make a reporting option available for group practices, and allowing physicians a choice to submit e-prescribing data through Medicare Part B claims or a qualified registry or EHR product.**
- **We oppose CMS' proposal to require reporting on e-prescribing activity the year before the penalty program begins. We previously have called on CMS to take such steps as establishing a new reporting period in 2012 and to refrain from applying the penalty until 2013. We also strongly urge CMS to establish an additional reporting period in 2013 to avoid 2013 penalties and in 2014 to avoid penalties in 2014.**
- **We strongly recommend that CMS add more exemption categories so that more physicians facing hardship will be eligible for an exemption from e-prescribing penalties in 2013 and 2014.**
- **We also recommend that CMS provide feedback reports to physicians and establish a process to allow physicians to appeal decisions.**
- **CMS should take appropriate measures to ensure the accuracy of the list of successful e-prescribers and eligible professionals (EPs) participating in the EHR incentive program and to provide the appropriate disclaimers for the Physician Compare website listing.**

Confidential Feedback Reports

- **If coming up with an attribution method that creates credible feedback reports for *all* physicians treating Medicare patients proves to be impossible, CMS should inform Congress that this is the case and recommend modifications in the Patient Protection and Affordable Care Act's (ACA) value-based modifier requirements.**
- **The AMA strongly supports CMS' proposal to investigate the possibility of stratifying physicians by specialty and the conditions they treat, and we would like to work with CMS to develop an improved physician specialty and sub-specialty list that could be applied consistently across many Medicare programs, including the value-based payment modifier, Physician Compare, and the Medicare Provider Enrollment, Chain and Ownership System (PECOS).**
- **If ongoing efforts produce reliable Medicare-specific groupers for at least a limited set of conditions, CMS should adopt them in lieu of the per capita data as soon as possible.**

Value-Based Payment Modifier

- **The AMA strenuously opposes CMS' plan to truncate an already inadequate preparation period by basing the 2015 value-based payment adjustments on performance in calendar year 2013.**
- **The AMA cannot support the imposition of a value-based payment modifier on any physicians unless and until there is evidence that it is possible to accurately measure value without penalizing those physicians who treat the most difficult cases. If CMS is compelled to initiate modifiers despite the many remaining barriers to accurate measurement, we recommend that the program be limited to large integrated health systems.**

Medicare Economic Index

- **The AMA is disappointed that CMS has not yet convened the MEI technical panel. We understand from CMS staff that the agency still intends to convene this technical panel, and we urge CMS to move forward quickly on this front.**

Geographic Practice Cost Indices Proposals for 2012

- **An impact table should be made available separately showing the impact of the different CMS proposed revisions to the geographic practice cost indices (GPCIs) for 2012.**
- **CMS' proposal to switch from one source of apartment rental data to another source of apartment rental data is a substitution of one office rent proxy for another, and a far better solution would be for the government to develop actual data on the cost of renting medical office space.**

Consolidating Reviews of Potentially Misvalued Codes

- **We urge CMS to ensure rigorous agency review of public comments and supporting documentation when determining whether a publicly nominated code should be reviewed as a potentially misvalued code, especially when a code is nominated by only a few commenters or even a single commenter.**

Multiple Procedure Payment Reduction

- **CMS should withdraw its proposal to apply a 50 percent multiple procedure payment reduction to the professional component of some 119 imaging procedures and drop consideration of other even broader versions of this proposal.**

Codes with "23-Hour+" Stays

- **The AMA urges CMS to accept the RUC-recommended values and physician time for all site-of-service anomaly codes, including codes relating to stays of 23+ hours (observation care services), which should be valued the same as an inpatient visit.**
- **We also urge CMS to accept the RUC recommendation and restore the time data for all services for which claims data indicate that the service is performed in the inpatient setting. At least three years of consecutive data should be available indicating a site-of-service anomaly before a review and adjustment is considered.**

Annual Wellness Visit

- **The AMA urges CMS to ensure Medicare coverage for a physical exam as part of the Annual Wellness Visit (AWV).**
- **The AMA urges CMS to issue clear guidance to beneficiaries and their physicians on what is and is not covered in the "free" preventive service visit that is part of the AWV.**

PHYSICIAN QUALITY REPORTING SYSTEM

Interim Feedback Reports

The AMA applauds CMS' proposal to provide interim feedback reports to physicians and other EPs participating through the claims-based reporting mechanism under the PQRS for 2012 and beyond. These reports will be based on claims for dates of service occurring on or after January 1 and processed by March 31 of the respective program year. Reports will be available in the summer of the respective program year.

The AMA has long been working with CMS to improve the feedback process, and the proposed interim reports are a good step in the right direction. Currently, incentive payments and feedback reports are distributed seven or eight months after the reporting period has ended. This lag time makes it difficult for physicians to improve their understanding of program criteria or participation and respond in a timely manner. The proposed interim reports will alert physicians to potential problems in their PQRS reporting and enable them to revise and correct their reporting practices, if needed, to be a successful participant. They will also help promote internal quality improvement within a practice. **We urge CMS to allow physicians to provide feedback on the format and content of these interim feedback reports once CMS has developed the prototype.**

Qualified Registries

CMS proposes to post on the PQRS section of the CMS Web site a list of qualified registries for the 2012 PQRS, including the registry name, contact information, and the 2012 measure(s) and/or measures group(s) for which the registry is qualified and intends to report. Additionally, CMS will provide information regarding the cost of the registry to physicians and other EPs.

The AMA is pleased that CMS will provide this additional cost information for 2012, and we continue to recommend that CMS post additional registry information as well, including number of past or current participants, frequency of registry feedback reports, and the overall success rate of participants. These additional topics of information will better assist physicians in selecting a registry most appropriate for their practice.

EHR-Based Reporting

CMS is proposing for 2012 and beyond, to allow physicians and other EPs who participate in the PQRS via the EHR-based reporting mechanism to have the option of submitting quality measure data obtained from their PQRS-qualified EHR to CMS either directly from the EP's qualified EHR or indirectly from a qualified EHR data submission vendor on the EP's behalf. Physicians and other EPs would be required to have a separate PQRS-qualified EHR product, despite the fact that physicians and other EPs may have already purchased Certified EHR Technology for purposes of reporting under the Medicare and Medicaid EHR Incentive Programs, i.e., meaningful use (MU) program. **The AMA urges CMS to immediately rectify these separate certification requirements. Physicians have invested significant amounts of money in purchasing Certified EHR Technology for the Medicare and Medicaid EHR Incentive Programs. Physicians should not have the added burden of verifying whether their current EHR technology is also qualified for purposes of reporting under the 2012 PQRS. Moreover, they should not have to purchase additional technology to participate in the PQRS via EHR-based reporting simply because these programs have not been aligned.**

The AMA believes it is critical that the measures and format for reporting measures under the PQRS and MU programs are aligned. This requires:

- Establishing common program objectives;
- Aligning the measures and establishing a common format for reporting;
- Testing the common "measures" and "reporting format" to see if they can be implemented in an EHR system;
- Piloting the measures in an actual clinical environment once system testing is completed to provide real world results and feedback in a selected and controlled environment; and
- Evaluating results of pilot testing to determine that the results meet the original program objectives.

These alignment efforts must be initiated immediately, or physicians will have a huge incentive not to report under the PQRS program via the EHR-based reporting mechanism, and this will have a significant chilling effect on the progression of the PQRS program toward the more accurate and efficient EHR reporting.

In a further effort to align the PQRS and MU programs, CMS is proposing that physicians and other EPs specializing in internal medicine, family medicine, general practice, and cardiology report: (i) all PQRS core measures (in the proposed rule); and (ii) report each measure for at least 80 percent of the EP's Medicare Part B fee-for-service patients for whom services were

furnished during the reporting period to which the measure applies. Since not all of the proposed PQRS core measures will apply to all of these specialties, CMS proposes to allow the reporting of these proposed PQRS core measures with a zero percent performance rate. **While the AMA is a proponent of meaningful reporting, we support allowing reporting on these measures with a zero percent performance rate. It is only equitable for these physicians and other EPs to get credit if they are making an effort to meet the program reporting requirements, but are not able to do so if certain measures do not apply to their practice.**

Physician Quality Reporting System-Medicare EHR Incentive Pilot

CMS is proposing that EPs may demonstrate meaningful use by participating in a Physician Quality Reporting System–Medicare EHR Incentive Pilot that relies on the infrastructure of the PQRS. EPs who choose to participate in this voluntary pilot would be required to electronically report the Clinical Quality Measures (CQMs) using certified EHR technology via one of two options:

1. *EHR data submission vendor-based reporting option*: EPs participating in this option would submit CQM data from their certified EHR technology to a PQRS qualified EHR data submission vendor. The vendor would submit calculated results to CMS on behalf of the EP. The EPs who elect this option would submit data on the same CQMs as required under the EHR Incentive program, but the data for this pilot would be limited; and

2. *EHR-based Reporting Option*: EPs would submit CQM data directly from their EHR to CMS via a secure portal using the infrastructure of the PQRS EHR reporting system. The EHR technology used for this option must also be a 2012 PQRS qualified EHR. CMS will include an additional vetting process for EHR vendors wishing to participate in the Pilot. Under this option, the data submitted would be slightly different than that for the EHR Incentive program, in that it will:

    - Include Medicare patients only;
    - Consist of patient level data, which CMS will calculate, rather than using aggregate results calculated by the EP's certified EHR technology; and
    - Be based on one calendar year regardless of their year of participation in the EHR Incentive program.

EPs who successfully submit all required CQM data from their certified EHRs (which also must be PQRS-qualified) directly to CMS would also meet the criteria for satisfactory reporting under the 2012 PQRS.

The AMA recognizes that this pilot will allow CMS to gain experience with collecting quality measurement data directly from an EHR, as well as an EHR vendor. This experience is essential to better understand and improve upon the functionality of electronically capturing quality data. **However, for this pilot to be successful for both physicians and the Medicare program, CMS must further clarify the requirements of this new pilot.** We support efforts to integrate

these two programs, but the technology and processes by which physicians report on CQMs to qualify for both programs must be more intuitive and adaptable for a diverse number of physician offices. Moreover, as mentioned above, the burden of two **s**eparate technology certification requirements for PQRS versus the EHR Incentive program creates barriers to those physician practices interested in pursuing robust electronic reporting of quality measures.

The AMA urges CMS to clearly state in the final rule how participation in the PQRS-Medicare EHR Incentive Pilot and the proposed PQRS EHR reporting option for 2012 will allow physicians to successfully satisfy the CQM reporting requirements for the EHR Incentive program and PQRS reporting requirements.

Claims-Based Reporting

CMS is proposing, with respect to claims-based reporting, that if an EP reports on fewer than three measures in 2012 and reports on a measure that is part of an identified cluster of closely related measures, but does not report on any other measures in the identified cluster, then the EP would not qualify as a satisfactory reporter in the 2012 PQRS or earn an incentive payment. This is an onerous and vague requirement since CMS has not identified any "clusters of closely-related measures." It will cause significant confusion considering that physicians likely will have different views about what constitutes a "cluster of closely-related measures." Further, it would be extremely unfair for physicians to report data in good faith to the PQRS only to find out after-the-fact that they did not meet a requirement that was not specified up front. **We urge CMS to identify these clusters up-front and not leave physicians guessing as to the specific requirements for successful participation in the PQRS.**

Also, CMS sets forth various requirements that EPs specializing in internal medicine, family medicine, general practice, and cardiology must meet for satisfactory reporting of PQRS measures groups via claims-based reporting. One of these requirements is to report at least one PQRS measures group. If the measures group does not contain at least one Physician Quality core measure, EPs must report one Physician Quality core measure. **The AMA urges CMS to clearly identify in the final rule which measures groups contain core measures. This will clarify for EPs which measures groups have a core measure, and whether reporting is needed for a separate core measure.**

Physician Compare Website

In implementing section 10331 of the ACA, the Physician Compare Internet website, CMS is proposing during 2011 and 2012 to continue developing and improving the existing Physician Compare website, including providing monthly data refreshes and a semiannual website release to incorporate updates and improvements to the website. The AMA supports these improvements to Physician Compare. **To achieve the goal of monthly "data refreshes," we urge CMS to require contractors to provide CMS with monthly updates in a standardized format.** This is critical because, unless contractors provide updated information to CMS, the monthly "refreshes" still will not contain up-to-date Medicare enrollment information. Further,

as in the past, the AMA would welcome the opportunity to work with CMS on reviewing draft website disclaimers or participate in focus groups to ensure that the information on the Physician Compare website is accurate, and not subject to misinterpretation.

Maintenance of Certification Program

The AMA supports CMS' proposal to more broadly interpret the "more frequently than is required" standard for successful participation in a Maintenance of Certification (MOC) program. Specifically, in meeting the "more frequently" standard to be eligible for the additional PQRS incentive payment of 0.5 percent, an EP would be required to "more frequently" meet at least one element of an MOC program, as determined by the MOC, rather than meet all elements of the MOC program more frequently than is required. This broader interpretation is more consistent with the statutory intent and will allow EPs more flexibility in meeting this standard.

Definition of Group Practice

CMS is proposing to change the definition of a group practice through consolidating the existing GPRO I (200 or more EPs) and GPRO II (2-199 EPs) options. Under the proposal, a group practice would be 25 or more EPs. According to data from the Medical Group Management Association (MGMA), 66.56 percent of physicians are from practices of 25 doctors or fewer. Therefore, under the proposed definition of a group practice, a significant percentage of physicians will no longer be able to participate in the PQRS on a group practice basis. We recognize that CMS is moving to this proposed revision due to the lack of GPRO II participants and to align the PQRS group practice definition with other Medicare programs involving group practices. On the other hand, we do not believe that the opportunity for smaller groups of physicians to exercise this option has been in place long enough to draw any conclusions about its potential value and appeal. Moreover, as the penalties for non-participation in PQRS approach, we expect that more and more physicians will want to participate and to report their data as a group rather than as individuals. **Therefore, we urge CMS to retain the opportunity for groups of fewer than 25 physicians to participate in the PQRS GPRO option.**

Proposed 2012 PQRS Quality Measures and Measures Groups

To keep PQRS measures current and to maintain consistency, the AMA has a number of recommendations intended primarily to ensure that the PQRS program incorporates the most recent measures adopted by the AMA-Physician Consortium for Performance Improvement.

1. We suggest retiring the following measures from PQRS in 2012 to reflect PCPI's retirement of these measures.

    - PQRS Measures #135 Chronic Kidney Disease: Influenza Immunization; #79 ESRD: Influenza Immunization in Patients with ESRD; #175 Pediatric End Stage Renal Disease: Influenza immunization. These measures have been retired from the PCPI portfolio of measures and participants are now directed to use the general PCPI influenza measure

PQRS #110. PQRS measure #110 has been updated to apply to all patients aged 6 months and older, is proposed for reporting in PQRS 2012 via Claims, Registry, EHR, and several measures groups. Please note that in the Chronic Kidney Disease measures group, PQRS measure #135 should be removed and replaced with PQRS measure #110.

- PQRS Measure #153 Chronic Kidney Disease. This measure has been designated as Quality Improvement Only with the 2011 PCPI updates to the Kidney measures. This measure is no longer appropriate for PQRS as it is no longer an accountability measure. This measure should also be removed from the Chronic Kidney Disease (now renamed Adult Kidney Disease) measures group.
- PQRS Measure #200 Heart Failure: Warfarin Therapy- Patients with Atrial Fibrillation has been retired in favor of the PCPI measure "Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy" in lieu of this measure. The PCPI submitted the broader Atrial Fibrillation measure during the 2011 CMS call for measures for PQRS 2012. Although PQRS measure #200 is no longer consistent with the evidence-based clinical guidelines, we recognize the need to retain PQRS #200 for the PQRS 2012 program year in order to align with the Meaningful Use program. As a result, we have since made a modification to PQRS measure #200 to allow for the use of additional therapies consistent with the updated guidelines.

2. PQRS measure #199 "Heart Failure: Patient Education" has been updated to be quality improvement only, and is not intended for accountability reporting. Therefore, this measure should be removed from the program.

3. The PCPI has combined the clinical topics of Chronic Kidney Disease and End Stage Renal Disease into one measure set, and the new clinical topic name is Adult Kidney Disease. Therefore, the clinical topic on the Chronic Kidney Disease measures group should be changed to "Adult Kidney Disease." Further, the clinical topic should be changed on the following individual measure numbers: 81, 82, 121, 122, and 123.

4. There is an error in Table 321, page 42,872 of the proposed rule, which should be corrected. Measure #117 for (E) is listed with AMA-PCPI as the measure developer, yet this is an NCQA measure.

5. PQRS measure #108 is listed as an NCQA measure, yet this is a joint AMA-PCPI/NCQA measure, and it should be listed as such in the final rule.

6. PQRS measure #196 is a paired measure with proposed measure M14 "CAD: Symptom Management"; one measure should not be reported without the other. Therefore, measure M14 should be added to the CAD Measures Group in addition to proposing it as a new individual measure for PQRS 2012.

7. The following measures have updated titles that should be incorporated in PQRS:

    - #7; the new title is "Coronary Artery Disease (CAD): Beta-Blocker Therapy- Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40 percent)
    - #53, the new title is "Asthma: Pharmacologic Therapy for Persistent Asthma"
    - #64; the new title is "Asthma: Assessment of Asthma Control"
    - #81; the new title is "Adult Kidney Disease: Hemodialysis Adequacy: Solute"
    - #82; the new title is "Adult Kidney Disease: Peritoneal Dialysis Adequacy: Solute"
    - #32; the new title is "Stroke and Stroke Rehabilitation: Discharged on Antithrombotic Therapy"
    - #36; the new title is "Stroke and Stroke Rehabilitation: Rehabilitation Services Ordered"
    - #224; the new title is "Melanoma: Overutilization of Imaging Studies in Melanoma"
    - #121; the new title is "Adult Kidney Disease: Laboratory Testing (Lipid Profile)"
    - #122; the new title is "Adult Kidney Disease: Blood Pressure Management"
    - #123; the new title is "Adult Kidney Disease: Patients on Erythropoiesis-Stimulating Agent (ESA) Hemoglobin Level > 12.0 g/dL"
    - #197; the new title is "Coronary Artery Disease (CAD): Lipid Control"
    - #110; the new title is "Preventive Care and Screening: Influenza Immunization"
    - #186; the title is not new, but the clinical topic is not accurately reflected; the title should read "Chronic Wound Care: Use of Compression System in Patients with Venous Ulcers."

8. The following measures now have joint copyright between the AMA-PCPI and ACC (American College of Cardiology), and these measures should be corrected to reflect this: 5, 8, 198.

9. The following measures now have joint copyright between the AMA-PCPI and NCQA, and these measures should be corrected to reflect this: 53, 64, 224, 225, 231, 232, M01, M02, M08, M10, M57, M58, M59, M60, M141.

10. The following measures now have joint copyright between the AMA-PCPI, ACC, and AHA, and these measures need to be corrected to reflect this: 6, 7, 118, 196, 197, M18.

11. The clinical topic is missing from the title of the following measures: 67, 68, 69, 70. The clinical topic of "Hematology:" should be added prior to the actual measure title.

12. There are nine Dementia measures proposed only as a measures group and only reportable via registry-based reporting. The AMA believes these measures are extremely applicable to the Medicare population and therefore should also be reportable as individual measures. Having to report all nine measures might be too administratively burdensome for some practitioners, and it would be beneficial to increase the potential of providers who report on

these measures by making them available as either a measures group OR as individual measures. We also advocate that these measures be reportable via claims-based reporting OR registry-based reporting. There is no guarantee that a registry will pick up these measures, and if not, then providers will not be able to report on these measures. In general, we discourage making new measures only reportable via registry unless there is already an established registry in that clinical topic area; otherwise at least for the first year of reporting, an EP should have the option of claims-based reporting. **Accordingly, we urge CMS to allow the nine Dementia measures to be reportable as individual measures both for claims-based and registry-based reporting.**

13. On page 42,879 of the proposed rule, CMS states that: "Measures selected for inclusion in all other 2012 Physician Quality Reporting System measures groups would be reportable either as individual measures or as part of a measures group." This is inaccurate based on the reporting modalities specified by the PQRS contractor for several measures groups that are NOT listed also as individual measures that can be reported, for example, the Dementia MG and the Epilepsy MG. **We urge CMS to ensure that all measures in measures groups are also reportable as individual measures.**

14. The AMA supports the variety of reporting modalities for the quality measures that are included in the proposed rule. It is important to retain claims-based reporting in the PQRS program since numerous physicians and other EPs do not yet have certified EHR systems in place. We also support the large number of measures and measures groups that are reportable via registry-based reporting. Many measures groups and some individual measures proposed for 2012, however, are reportable by registry only. The AMA is concerned about whether these measures groups will in fact be adopted by a registry. If a registry does not adopt these measures, they will have to be removed from the program. **Accordingly, at least for the first year a measure is proposed, it should be reportable via claims-based reporting AND registry-based reporting. It is critical to offer the claims and registry option at least for the first year a measure is in the program, in case no registries adopt a certain measure.** Examples of registry-only measures groups include: Dementia Measures Group; Parkinson's Measures Group; Inflammatory Bowel Disease; Elevated Blood Pressure; and Cataracts. An example of an individual measure proposed for registry-only reporting is measure M18. This measure is an update of former measure #235 (from the 2011 PQRS). Measure #235 was reportable either via claims or registry, but measure M18 has only been proposed as reportable through registry. We urge CMS to re-designate measure M18 to be reportable either via claims or registry reporting.

15. Measure M18 has an updated title of "Hypertension: Blood Pressure Management," and combines 2010 PQRS measures #235 - Hypertension: Plan of Care and #237 - Hypertension: Blood Pressure Measurement. This reflects an update by the Hypertension Workgroup and the updated measure now combines the blood pressure value recorded (PQRS measure #237) and a plan of care component (PQRS measure #235). At the time the CPI submitted its cardiovascular measures to NQF for maintenance of endorsement, Hypertension: Blood Pressure Management (PQRS proposed measure M18) was submitted as an update to NQF

measure number 0013. The PCPI will maintain the specifications for the Hypertension: Blood Pressure Measured measure (the 0013 currently in Stage I MU and PQRS #237), and will recommend it for continued use as a core measure and a measure reportable via EHR (only) in PQRS to ensure alignment between the two programs. The PCPI did not submit the measure Hypertension: Blood Pressure Measured for continued NQF endorsement. The rationale for this decision is that in the update of the PCPI Hypertension Measurement Set, the "Hypertension: Blood Pressure Measured" measure was revised to become Hypertension: Blood Pressure Management.

16. The AMA is also concerned that some measures are grouped together in a measures group when they have different denominators. **We fully support the addition of more measures groups to the PQRS program, yet we urge CMS to ensure that there is an analytically sound method for reporting measures groups when denominators differ.** This is particularly important since CMS states in the proposed rule that if an EP reports a measure contained within a measures group with a zero percent performance rate, the EP will fail to meet the criteria for the satisfactory reporting of measures groups. If denominators for measures within a measures group differ, an EP may not have an opportunity to report on all measures in the group, and it would be inequitable for physicians to be deemed to have unsatisfactory reporting on the measures group.

17. **We support CMS' efforts to align the MU and PQRS programs. Specifically, we support the alignment of the reporting periods and attempts to begin aligning the quality measures reportable in the two programs. However, during the period of alignment, there should be flexibility with respect to the quality measure specifications published for the two programs.** It is nearly impossible to achieve alignment of the two programs when the cycles for updating the measure specifications are not aligned. For instance, the PQRS quality measure specifications will be finalized in October and the MU measure specifications are currently undergoing revision suggestions via the NQF, and those suggested changes are anticipated to be published in December of 2011. Unless changes to the MU measures are not applied until Stage 2, if any changes are made for 2012, the specifications for the PQRS and MU programs will not be aligned. In this event, an EP could not successfully qualify for both programs (where the same measures are reportable for each program) if the specifications are not aligned. **Moving forward, the AMA strongly urges CMS to ensure that updates to specifications for MU and PQRS occur at the same time.**

18. For 2012, CMS is proposing 26 new individual measures for inclusion in the Physician Quality Reporting System, of which two are NQF-endorsed and 24 are either pending NQF endorsement or would have to be adopted under the exception to NQF endorsement provided under existing law. The AMA is pleased that CMS is proposing measures that are "in the process" pending NQF endorsement. This allows use of standardized measures, yet retains flexibility to use a measure while it is pending final NQF endorsement.

19. The proposed rule states that CMS does not believe there needs to be any special restriction on who can develop measures. We disagree. Physicians must develop the quality measures

used for collecting and reporting data. This ensures that the 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; American Board of Medical Specialties 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 tested for inclusion in the PQRS 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 PQRS. 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.

ELECTRONIC PRESCRIBING

Penalty Program Overview

As noted elsewhere in these comments, the AMA has very serious concerns with CMS' habit of effectively "back-dating" the imposition of Congressionally-mandated penalties by basing the penalties on performance before the penalty was to take effect. The policy first appeared with CMS' plan to base 2012 e-prescribing penalties on whether the physician met e-prescribing requirements in 2011 and would be continued in future years covered under this rule.

We are aware that this proposed rule does not address the 2012 penalty program. However, we believe that 2012 will set a precedent for how the program operates in future years and that unless CMS modifies its current plan, a significant number of physicians will be subjected to the 1 percent penalty a year earlier than called for by Congress. We recognize and appreciate the steps that have been taken to provide more flexibility to the program but without additional modifications, large numbers of physicians will be penalized for failing to adhere to a requirement that they reasonably assumed was not effective until next year. We strongly believe that this would violate Congressional intent and have urged CMS in a variety of forums, including a sign-on letter with 92 states and specialty societies, to create more mechanisms to assist physicians in avoiding the e-prescribing penalty. **We have called on CMS to take such**

steps as establishing a new reporting period in 2012 and to refrain from applying the penalty until to 2013.

Instead, CMS is proposing in this rule to continue this objectionable policy and require that in order to avoid e-prescribing penalties in 2013 and 2014, physicians and other EPs must have reported on e-prescribing activity in the first six months of the previous year. **We strongly oppose this proposal to back-date the 2013 and 2014 penalty programs which exposes physicians to financial penalties in 2013 and 2014 based on their e-prescribing activity in the previous year.** We also recommend that CMS add more exemption categories so that physicians who face hardship could apply for an exemption to avoid penalties in 2013 and 2014. In addition, the agency should provide feedback reports so physicians can assess their prospects for incentives or penalties and establish an appeals process to contest inaccurate data.

2012 and 2013 E-Prescribing Incentive Program Requirements

CMS is proposing to continue the 2010 and 2011 e-prescribing requirement that in order to qualify for incentives, eligible physicians and other EPs must report on 25 services involving electronic prescriptions in each calendar year. This differs from the 10 reports required to avoid a penalty and has created confusion and educational challenges regarding the programs' requirements. We appreciate CMS' consideration of the AMA's recommendation to minimize the e-prescribing reporting burden. **However, we believe that in order to eliminate confusion and reduce administrative complexity, the incentive program reporting requirement should be matched up to the penalty program requirements by only requiring the reporting of the G8553 code 10 times. In addition, EPs and group practices should be able to report the G8553 code without tying the e-script to a particular visit/service given that physicians do not always e-prescribe on the day of a patient visit/service.** Both of these steps are consistent with President Obama's January 18, 2011, Executive Order calling on federal agencies to reassess and streamline regulations in order to reduce the financial and administrative hardships created by these programs

CMS is proposing to expand the definition of a "qualified electronic prescribing system" to also include certified EHR technology. **We support CMS' proposal to also recognize certified EHR technology certified under the Medicare/Medicaid EHR incentive program under the e-prescribing incentive and penalty programs.** This recognition is an example of the importance of synchronizing the overlapping e-prescribing and EHR programs.

In addition, the AMA agrees with CMS' proposal to allow a group reporting option and several mechanisms for physicians to submit e-prescribing information (e.g., vis-à-vis Medicare Part B claims, a qualified registry, or a qualified EHR product). Please also refer to our comments on requirements for group practice reporting, qualified registries and the EHR reporting option under the PQRS section of this comment letter. We remain committed to working with CMS to pursue significant outreach to the physician community on the 2012 and 2013 e-prescribing incentive program details.

2013 and 2014 E-Prescribing Penalty Programs

As noted earlier, CMS is also proposing criteria for applying penalties in 2013 and 2014 for EPs and group practices who are eligible for e-prescribing incentives but choose not to participate or do not successfully participate in the e-prescribing program. 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 2013 or 2014 Medicare e-prescribing incentive program and do not qualify for a hardship exemption would be subject to penalties (one and a half percent payment reduction based on the 2013 Medicare fee schedule amounts during the year and 2 percent payment reduction in 2014). MIPPA also provides the Secretary of HHS with the authority to exempt physicians from penalties for hardship reasons.

CMS is proposing that EPs can avoid an e-prescribing penalty in 2013 if they successfully participate in the 2011 e-prescribing incentive program or e-prescribe and report on at least 10 e-scripts during the first six months of calendar year 2012. To avoid the 2014 e-prescribing penalties, EPs would have to successfully participate in the 2012 e-prescribing incentive program or e-prescribe and report on at least 10 e-scripts during the first six months of calendar year 2013. **As we have previously conveyed, the AMA strongly objects to levying financial penalties in 2013/2014 based on physicians performance during the first six months in 2012/2013.**

The law states that the penalty would apply "with respect to covered professional services furnished by an EP during 2012, 2013, or 2014." Congress clearly intended to provide CMS as much flexibility as possible to come up with a penalty program that is fair and reasonable. **We insist that CMS revise the 2013 and 2014 penalty criteria by adding additional reporting periods. For example, physicians should be able to report on 10 e-scripts during the first six months of 2013 to avoid the 2013 e-prescribing penalty and report on 10 e-scripts during the first six months of 2014 to avoid the 2014 e-prescribing penalty. In addition, since CMS pays out e-prescribing incentives following the conclusion of the reporting period, penalties should only be imposed after and not before the conclusion of the e-prescribing penalty reporting period.** In other words, a physician who does not successfully e-prescribe in 2013 and does not apply for an exemption should not be financially penalized until 2014.

The application of the e-prescribing penalty is the first of several penalty programs (e.g., meaningful use of EHRs and PQRS programs include penalties), so this approach of back dating the reporting periods to the year prior to the penalty year will become even more confusing for physicians who may be subject to multiple, overlapping penalties. Multiple adjustments would have to be made to their claims payments and cost-sharing amounts would be fraught with errors causing confusion to physicians and their patients.

CMS is also proposing to allow several reporting mechanisms to report e-prescribing activity in order to avoid a penalty. Physicians must report the G-code (G8553): (1) to CMS on their Medicare Part B claims; (2) to a qualified registry; or (3) to CMS via a qualified EHR product to avoid penalties. Physicians must select one mechanism and can not report the e-prescribing measure by using more than one reporting mechanisms. **We support CMS' proposal to allow multiple mechanisms to report the e-prescribing measure for the penalty program.** It will be important to educate physicians on the different reporting periods associated with the use of a qualified registry or EHR.

CMS is proposing that the 2013 and 2014 penalties would not apply to the following individuals:

- An EP who is not an MD, DO, podiatrist, nurse practitioner, or physician assistant as of June 30, 2012, for the purposes of the 2013 penalty and June 30, 2013, for the purposes of the 2014 penalty;
- An EP who does not have prescribing privileges and for the purposes of avoiding the 2013 penalty reports the G-code, G8644, on at least one Medicare Part B claim with dates of service during the six month reporting period (January 1, 2012 through June 30, 2012) and for avoiding the 2014 penalty reports the G-code, G8644, on at least one Medicare Part B claim with dates of service during the six month reporting period (January 1, 2013 through June 30, 2013);
- An EP's Medicare Part B allowed charges for covered services to which the e-prescribing measure applies is less than 10 percent of the total Medicare Part B Physician Fee Schedule allowed charges for all covered services furnished by the EP during the 2013 or 2014 penalty reporting period; and
- An EP who does not have at least 100 cases (that is Medicare Part B claims for patient services) containing an encounter code that falls within the e-prescribing requirements during the January 1, 2012 through June 30, 2012 reporting period (to avoid the 2013 penalty) and during the January 1, 2013 through June 30, 2013 reporting period (to avoid the 2014 penalty).

CMS is also proposing that EPs only have to report the e-prescribing measure, G8553, 10 times during the specified six month reporting periods (January 1, 2012 through January 30, 2012 to avoid the 2013 penalty and January 1, 2013 through June 30, 2013 to avoid the 2014 penalty), and that the 10 e-scripts do not have to be tied to a patient visit/service in order to be reported. **We strongly support CMS' proposal to only require the reporting of the G8553 code at the most 10 times for the generation and transmission of 10 e-scripts during the reporting period and not tying the e-script to a particular visit/service given that physicians do not always e-prescribe on the day of a patient visit/service.**

CMS is proposing several categories for exempting eligible physicians from the e-prescribing penalty: (1) EP/group practice in rural area without high speed internet access; (2) EP/group practice in an area without sufficient available pharmacies for e-prescribing; (3) inability to e-prescribe due to local, state, or federal law or regulation; and (4) EPs who has fewer than 100 prescriptions during the six month reporting period required to avoid the e-prescribing penalty.

We support these exemption categories, and recommend that CMS include the following clarification and/or examples in the final rule:

- Under the "Inability to electronically prescribe due to local, state, or federal law or regulation" exemption category, CMS should clarify that physicians who are unable to e-prescribe controlled substances because their e-prescribing application/software is not yet compliant with the DEA and/or state requirements are eligible to apply for this exemption.

We also strongly recommend that CMS add more exemption categories. Specifically CMS should:

- Add an exemption category for physicians who are currently eligible for Social Security benefits or will be eligible for Social Security benefits by 2014. It will be economically burdensome for physicians who intend to retire in the next several years to install and utilize an e-prescribing system. We are also concerned that many of these physicians may decide to close their Medicare fee-for-service 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.
- Allow physicians the opportunity to apply for an exemption if they did e-prescribe at least 10 times in accordance with the program requirements but their claim submissions were missing the G8553 code due to administrative or system errors.
- Retain the 2012 exemption category in 2013 and 2014 for physicians who have registered to participate in the Medicare/Medicaid EHR incentive program and have adopted certified EHR technology. Physicians who are registered to participate in the Medicare/Medicaid EHR incentive program should be exempt from the 2013 and 2014 Medicare e-prescribing penalties given that the EHR incentive program includes an e-prescribing measure.
- Include an exemption category for physicians who were able to e-prescribe 10 times or more during the calendar year of 2012 and 2013 but were unable to issue all of the 10 e-scripts during the first six months of 2012 and/or 2013 in order to avoid a penalty.

CMS is proposing to allow physicians to apply for an exemption request on-line during the relevant six month penalty reporting period (e.g., on-line request for an exemption from the 2013 penalty must be made between January 1, 2012 through June 30, 2012). We support CMS' decision to assess exemption requests on a case by case basis given that physicians have varying practices and must comply with varying state and local requirements. In addition, we support the use of a web-based tool or interface that physicians can log-on to in order to request an exemption and provide the reason(s) why a hardship exemption(s) should apply. Once CMS has completed its review of the physician's request for an exemption and made a decision, CMS should notify the EP or group practice within two weeks of CMS' decision to accept or reject the exemption request.

Feedback Report on E-Prescribing Incentive Program and Appeals Process

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 recommend that CMS establish an appeals process, similar to what was established for the PQRS program, to allow physicians to appeal decisions: that affect their eligibility to take part in the e-prescribing program; that affect their ability to get e-prescribing incentives; and that physicians believe erroneously subject them to penalties. **An appeals process is especially critical for EPs and group practices whose request for a significant hardship exemption is denied.** If CMS needs additional information from the physician to fully assess the physician's particular hardship, then CMS should request additional information from the physician to fully assess the physician's reasons for applying for the hardship exemption and not deny the exemption request based on a technicality.

Reporting of Successful E-Prescribers and EPs Who Participate in the EHR Incentive Program

CMS is planning to publicly report the names of successful e-prescribers and EPs who participate in the EHR Incentive Program on the Physician Compare website. **We urge CMS to take appropriate measures to ensure the accuracy of the list of successful e-prescribers and EPs participating in the EHR incentive program and to provide the appropriate disclaimers for the website listing.** As in the past, the AMA would welcome the opportunity to work with CMS on reviewing draft website disclaimers or participate in focus groups to ensure that the presentation of the information on the Physician Compare website is accurate, and not subject to misinterpretation. Please also refer to our comments on public reporting under the PQRS section of this comment letter.

CONFIDENTIAL FEEDBACK REPORTS

In this section of the proposed rule, CMS outlines its past, current, and anticipated future efforts to develop and disseminate confidential feedback to physicians on the cost and quality of their care to Medicare patients and how it compares to costs and quality for other physicians. This year the agency intends to send reports to 35 group practices and their physicians and up to 56,000 individual physicians treating Medicare patients in Iowa, Kansas, Missouri, and Nebraska. In 2012, the number of physicians receiving a report is expected to rise to 100,000. As called for in the ACA, information in the reports will be used to apply a budget-neutral, value-based modifier to some physician payments in 2015 and to all physician payments by 2017.

Cost data in the reports includes the average per capita cost of health care services for all Medicare beneficiaries whose care is attributed to the physician plus the per capita cost for patients with four conditions: chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), coronary artery disease (CAD), and diabetes. Four groups under contract to Medicare are currently developing Medicare-specific episode groupers for several prevalent, high cost conditions, and CMS says it "could" apply those on a "limited" basis in 2012 or 2013.

Quality data will vary depending on a physician's individual circumstances but could be based on 2010 PQRS data, preventable hospital admission rates for six ambulatory care sensitive conditions or 28 claims-based measures selected from among 70 endorsed by the National Quality Forum. Attribution methods and decisions regarding appropriate comparison groups also have varied in different phases of the demonstration and CMS is considering additional modifications in the future. The agency seeks input in each of these areas and is particularly interested in identifying measures and methodologies that are appropriate for surgeons.

Attribution

We are unable to provide specific comments on the attribution methods that CMS has tested or plans to test without additional information. With only 30 percent of the 1,650 group practice physicians attributed enough patients to generate a feedback report in Phase II of the demonstration, we support CMS' proposal to continue testing different methods of attribution that might increase the number of physicians receiving reports. We also agree that it may be appropriate to use different attribution methods for different specialties. We would not support an approach that lowered the Phase II minimum thresholds (30 cases and 20 percent of Evaluation and Management (E/M) costs) for attributions in order to increase the number of reports because those thresholds are already lower than experts consider ideal. **In the end, coming up with an attribution method that creates credible feedback reports for *all* physicians treating Medicare patients may prove to be impossible. If so, CMS should inform Congress that this is the case and recommend modifications in the ACA's value-based modifier requirements.**

Comparison Groups

As we have previously commented, the AMA is concerned that in order to achieve comparison groups that are large enough to be statistically valid, CMS will have to create groups that are so broad they do not result in "apple to apple" comparisons. For example, experience in the private sector has shown that sub-specialty physicians frequently are identified as high-cost outliers, in large part because commercial episode groupers used to date do not adequately adjust for differences in severity and case mix. As a result, physicians with very specialized expertise and complex patients may be identified as high-cost in comparison to other members of their specialty who treat less difficult conditions or patients. This is further complicated by Medicare's specialty designations, which are inconsistent in their recognition of sub-specialized experience. (For example, CMS recognizes several sub-specialties of cardiology, but none in most others. It also recognizes just one of the several orthopedic subspecialties.) **According to the proposed rule, CMS is investigating the possibility of mitigating this problem by stratifying physicians by specialty and the conditions they treat. The AMA strongly supports this proposal, and we look forward to working with CMS to develop an improved physician specialty and sub-specialty list that could be applied consistently across many Medicare programs, including the value-based payment modifier, Physician Compare, and PECOS.**

Cost Data

The AMA concurs with CMS' conclusion that the current commercial episode grouper tools are inadequate for measuring costs in a Medicare population, and we support the agency's decision to pursue the development of a transparent Medicare specific episode grouper. As noted in the proposed rule, CMS found that commercial groupers did not "work well … for the significant number of Medicare beneficiaries with multiple chronic conditions." Therefore, it will be important to allow time for adequate testing of the new grouper on Medicare patients to determine whether this problem has been resolved.

In the meantime, CMS is proposing to base feedback reports, and potentially the value-based modifier, on per capita costs prior to the completion and testing of the new episode grouper. We realize that in addition to average per capita costs across all their Medicare patients, CMS also intends to compare physicians' per capita costs for certain conditions (COPD, CHF, CAD and diabetes), and we agree that the condition-specific data is likely to be more reliable than aggregate cost per capita. However, CMS has not laid out any plan for improving its current risk adjuster, which is not really precise enough to permit valid comparisons of per capita data at either the aggregate or condition-specific level. Consequently, we believe that there is a significant possibility that some physicians with high cost patients will be mislabeled as over-utilizers. In the context of a confidential feedback report, the biggest problem is that physicians will simply ignore the data due to their very legitimate concerns about its validity. In the context of a value-based modifier, however, there is a very real concern that physicians will avoid certain high cost patients in order to avoid being singled out for a negative payment adjustment. Therefore, as noted later in these comments, it will be important not to tie the modifier to feedback reports that are based only on per capita data. **We look forward to reviewing evaluations of the feedback reports going out in September and December of this year, and are reserving judgment until that time on how best to measure costs pending the availability of a Medicare-specific grouper. We are optimistic that the current work will produce reliable groupers for at least a limited set of conditions. If this proves to be the case, CMS should adopt them in lieu of the per capita data as soon as possible.**

Quality Measures

The AMA appreciates CMS' efforts to use a consistent set of measures across its various programs and agrees that it is important to ensure that appropriate and sufficient measures are available for all physicians subject to the value-based modifier during all phases of its implementation. To further that goal, it is imperative that CMS improve communications with specialties about what constitutes an acceptable, clinically relevant measure and why certain proposed measures have been rejected. Quality measures selected should also be aligned with cost measures. **At the same time, we continue to believe that CMS should require physicians to report on only a small set of core measures plus some limited number of applicable measures chosen by the physician or group practice**. While we do not have specific comments on the 28 claims-based measures the agency plans to use in feedback reports to Iowa, Kansas, Missouri, and Nebraska physicians, we have general reservations about the

claims system's ability to accurately capture all the critical information that may have influenced the care a physician provided. We will be interested in the views of report recipients on the accuracy and usefulness of these measures. We also look forward to reviewing the results of and reactions to the six preventable hospitalization measures being tested in the group practices.

VALUE-BASED PAYMENT MODIFIER

As previously noted, the ACA requires CMS to implement a budget neutral value-based payment modifier for some physicians by January 1, 2015, and for all physicians by January 1, 2017. The agency is required to publish no later than January 1, 2012, the quality and cost measures, implementation dates, and initial performance period to be used in the modifier and to begin implementing the modifier "through the physician rulemaking process during 2013." In this proposed rule, CMS announces its intention to use calendar 2013 as the performance year on which payment bonuses and penalties will be applied in 2015 even though many aspects of the modifier, including the attribution methodology, comparison groups, and affected physicians, have not yet been determined and are not likely to be finalized until November 2013.

Initial Performance Period

The AMA is well aware that this provision of the ACA asks CMS to work through a myriad of unresolved methodological issues and implement what may ultimately prove to be an unworkable proposal within an unrealistic time frame. As was recently confirmed in the Government Accountability Office's recent report entitled *CMS Faces Challenges with Methodology and Distribution of Feedback Reports*, the effort outlined in the rule to test different methodologies, feedback report formats, and measures is both necessary and extensive and will require considerable time to complete. According to the proposed rule, for example, the agency ***"could"*** begin testing the new Medicare episode grouper "on a limited basis" in 2012 or 2013 with additional work to follow over the next three or four years. It also is looking for ways to make reports and measures more applicable to specialty physicians and to introduce more outcome measures into the process. As laid out in the rule, other specific work still to be done includes:

- Investigation of alternative attribution methods that would expand the number and types of physicians who could be evaluated.
- Development and/or testing of various types of quality measures, including both self-reported and claims-based measures that are more outcome oriented and might focus on preventable hospitalizations, avoidable emergency room use, care coordination, and complications.
- Incorporation of feedback reports and value-based modifiers into CMS' information technology systems.
- Evaluation of other cost measures, such as one tied to the Medicare Severity. Diagnosis Related Groups (MSDRGs) now used to pay hospitals.
- Combining cost and quality data into a composite value-based modifier.

- Determination of whether the modifier will be applied to individual physicians, groups of physicians, or regions of the country and whether comparisons will be made on a regional or national basis.
- Deciding how to make the modifier "systems-based," as required by the ACA.
- Evaluation of and potential improvements in risk adjustment tools.

What we cannot understand, and must strenuously oppose, is the agency's plan to truncate an already inadequate preparation period by basing 2015 payment adjustments on performance in calendar year 2013. In effect, CMS is proposing to cut or increase payments to some as-yet-unidentified physicians based on comparisons to a still-to-be-determined peer group using cost and quality measures, risk adjusters, and patient attribution methods that also have not been finalized. As has been the case with other payment penalties imposed by Congress, CMS is essentially pushing up deadlines for participation by a full year due largely to its own data processing limitations. We are sympathetic to the problem, but do not agree that there is no other solution.

In the ACA, Congress gave the Secretary of the Department of Health and Human Services (HHS) the authority to "specify an initial performance period for application of the payment modifier" which it was to "begin implementing…through the rulemaking process during 2013." In the rule, CMS says that it will in fact begin implementing the modifier "through the rulemaking process during 2013 for the physician fee schedule effective in 2014." The agency then proposes to base the 2015 payment adjustment on how physicians performed in 2013, rather than a later time period because some claims are not processed until the year following the year when the service was rendered. Therefore, the rule asserts, CMS must use an initial performance period that covers the calendar year two years in advance of the year when payments will be adjusted.

Using 2013 as an initial performance period is much too soon, and is not required by law. In fact, nothing in the law requires that the initial performance period be based on a calendar year or that it cover an entire 12 months. We see no reason for rushing the process and adjusting physicians' Medicare payments for how they performed during a time when they didn't even know what the rules would be. This kind of logic may drive physicians, especially those in solo practices or small groups, out of medicine, creating access problems for Medicare beneficiaries and defeating the ACA's promise of coverage for the uninsured.

<u>Selection of Physicians Subject to Modifier</u>

Among the many questions confronting CMS is which physicians will be subject to a payment adjustment in the two years preceding its application to all physicians. **To be clear, the AMA cannot support the imposition of a value-based payment modifier on any physicians unless and until there is evidence that it is possible to accurately measure value without penalizing those physicians who treat the most difficult cases. If CMS is compelled to initiate modifiers despite the many remaining barriers to accurate measurement, however, we recommend that the program be limited to large integrated health systems where**

physicians are financially affiliated with a hospital. Budget neutrality should be applied only among the covered systems. This is consistent with the ACA's goal of encouraging systems-based care and with CMS' interest in developing and testing measures related to excess hospitalizations, readmissions, emergency room visits, and care coordination. This would provide a large and therefore more statistically valid patient base for measurement. It would align hospital and physician incentives and apply the adjustments to the physicians most equipped to finance and participate in the quality and efficiency improvement initiatives envisioned in the law. It is also more reasonable to impose detailed care coordination activities, such as follow-up visits and consultation reports, in hospital-based systems than it is in traditional Medicare where CMS has declined to cover care coordination activities and eliminated payments for consultations on grounds that reports from consultant physicians are not really necessary.

MEDICARE ECONOMIC INDEX

In the proposed physician fee schedule rule for calendar year 2011, CMS announced its intention to convene a technical panel in late 2010 to review all aspects of the MEI, including the inputs, input weights, price measurement proxies, and productivity adjustment. 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 we are disappointed that this technical panel has not yet been convened to review the MEI. **We understand from CMS staff that the agency still intends to convene this technical panel, and we urge CMS to move forward quickly on this front because the MEI has not kept pace with increases in the cost of medical practice.**

GEOGRAPHIC PRACTICE COST INDICES PROPOSALS FOR 2012

The ACA included significant increases in the GPCI for work and practice expense in localities with GPCI values below the national average. It extended a floor of 1.00 on the work GPCI through 2010, and the Medicare and Medicaid Extenders Act of 2010 maintained this work GPCI floor through 2011. For 2010 and 2011, the ACA reduced by half the impact of practice expense GPCI values below 1.00.

Also in 2011, CMS implemented the Sixth GPCI Update, phasing in the revised GPCIs over two years. Besides using more recent data, the most significant change in the Sixth GPCI Update was that, for the physician work GPCI and the employee wage component of the practice expense GPCI, CMS used 2006-2008 Bureau of Labor Statistics Occupational Employment Statistics instead of 2000 Census data.

In the 2012 proposed rule, CMS is proposing to revise the Sixth GPCI Update by:

- Reweighting the work, practice expense and professional liability insurance GPCIs to correspond to new Medicare Economic Index (MEI) weights adopted in 2011;
- Replacing apartment rental data from the Department of Housing and Urban Development (HUD) with the 2006-2008 American Community Survey (ACS);

- Reducing the weight assigned to office rent from 12.209 percent to 10.223 percent;
- Revising the occupations used in calculating the employee wage component of the practice expense GPCI; and
- Developing a purchased services index for which the portion deemed by CMS to be labor-related is adjusted in the GPCI.

Impacts

An impact table should be made available separately showing the impact of the different CMS proposed revisions. It is difficult for physicians to assess the impact of the proposed changes on their payment rates because the impact tables that have been made available mix together the effects of different changes. For example, Column E of Table 66 of the proposed rule combines the impacts of the Sixth GPCI Update with the elimination of the work GPCI floor and the practice expense increases from the ACA that will expire at the end of 2011. Column F of this table shows the combined impact of five revisions that are proposed to the Sixth GPCI Update for 2012. Additional tables are provided in a report from Acumen, but even this report appears to combine different effects, such as the impact of shifting to the ACS from the HUD data and the impact of the reduced weight for office rent. Without more detailed impact tables, it is not possible to attribute the changes to specific CMS proposals.

One particular factor to isolate is the impact of the changes to the work and professional liability insurance (PLI) shares of the Geographic Adjustment Factor. These shares do not affect payment for individual services. The work and PLI RVU pools were adjusted to match the MEI weights in the 2011 Medicare physician payment schedule, so these changes have already impacted the physician community.

Reweighting

The benefit of reweighting the GPCI components to correspond with the 2011 MEI is that it makes use of more recent data on physicians' and other providers' practice expenses. However, the assignment of MEI weights to the 10 office expense subcategories outlined in the 2011 Medicare physician payment schedule Final Rule is complex. It is not clear that the AMA PPI survey expense categories match up with the industry-level data from the Bureau of Economic Analysis in a way that makes this assignment of subcategory weights possible. **The MEI technical advisory panel should revisit this issue, and consider whether other sources of data are available to split office rent from other types of office expenses, and to validate the office rent share as a percent of total expense.**

Office Rent and Expenses

The CMS proposal to switch from the HUD apartment rental data to the ASC apartment rental data is a substitution of one office rent proxy for another. **A far better solution would be for the government to develop actual data on the cost of renting medical office space.** The current Medicare physician payment schedule has been in place for 20 years, yet CMS is still

relying on apartment data as a proxy for medical office rent. A plan for replacing this proxy with actual data is long overdue.

CONSOLIDATING REVIEWS OF POTENTIALLY MISVALUED CODES

CMS is statutorily required to review the relative value units (RVUs) of services paid under the physician fee schedule no less often than every three years. In addition, CMS and the AMA/Specialty Society RVS Update Committee (RUC) identify and review a number of potentially misvalued codes on an annual basis. Since these two processes overlap, CMS is proposing to consolidate the formal five-year review of work and practice expense RVUs with the annual review of potentially misvalued codes. To allow for public input and ability to identify and nominate potentially misvalued codes for review, CMS is proposing a process by which the public could submit codes for potential review, along with supporting documentation, on an annual basis (instead of every five years).

The AMA agrees that the five-year review has become redundant due to the extensive nature of the CMS and RUC review of potentially misvalued codes, and therefore we support the consolidation that CMS is proposing. We do have concerns with the proposal, however.

First, we strongly object to the CMS proposal to "consider only nominations of active codes that are covered by Medicare at the time of the nomination." This is contrary to every review that has been conducted to date and is unfair to pediatrics and others who rely on a fair RBRVS for all services. CMS has an established policy of publishing the relative values for preventive services and other non-covered services. These codes should remain open to comment and review.

In addition, we urge CMS to ensure rigorous agency review of public comments and supporting documentation when determining whether a publicly nominated code should be reviewed as a potentially misvalued code, especially when a code is nominated by only a few commenters or even a single commenter. This kind of rigor and discretion is critical so that the RUC review process does not get overly clogged and potentially backlogged. In this vein, we appreciate CMS' comments in the proposed rule that if the agency receives an overwhelming number of nominated codes that qualify as potentially misvalued codes, CMS would prioritize the codes for review and could decide to hold its review for a future year.

MULTIPLE PROCEDURE PAYMENT REDUCTION

Expanding the Multiple Procedure Payment Reduction (MPPR) Policy

General: Currently, when multiple surgical, nuclear medicine, or specified imaging procedures are performed together, Medicare pays the full price for the most expensive procedure and 50 percent for the others. In surgery, both the work and practice expense portions of the payment are cut by 50 percent but for imaging services, it applies only to the technical component. In a

variation of this policy, a 20 percent multiple procedure payment reduction (MPPR) is applied to the practice expense portion of certain therapy services.

In this section of the rule, CMS proposes to extend its current MPPR policy to the physician interpretation (professional component) of 119 imaging codes that are already subject to an MPPR for the procedure (technical component) itself. In addition, the agency serves notice that it is considering additional policies that would make up to 700 diagnostic services subject to MPPR cuts and that would include common, low-cost tests such as x-rays. As justification for the proposal, the rule cites work by the Government Accountability Office (GAO), the Medicare Payment Advisory Commission (MedPAC), and the AMA/Specialty Society RVS Update Committee (RUC). **This analysis oversimplifies related GAO and MedPAC recommendations, misconstrues the findings of the RUC, overlooks relevant CMS data and results in a proposal that is likely to increase costs to Medicare and its beneficiaries while also further fragmenting medical care.**

Flawed Rationale: In support of its proposal, CMS makes a number of arguments which do not hold up to closer scrutiny:

- *Cuts are needed to stop rapid growth and potential overuse of imaging services*. This argument, picked up from MedPAC, ignores the fact that growth in imaging services began to slow in 2007 and by 2010, an AMA analysis of CMS' own data indicates that the volume of imaging services provided in ambulatory care settings actually fell slightly.
- *Arbitrary, across-the-board multiple procedure payment cuts are necessary because despite the work of the RUC, there **may be** (emphasis added) additional imaging and other diagnostic services for which there are efficiencies in work when furnished together*. The RUC has addressed or is working on 75 percent of the code sets that the GAO identified as potential MPPR candidates. If there are additional opportunities for eliminating duplication, CMS should ask the RUC to review the codes and make code-specific recommendations rather than whacking everything by 50 percent based on the assumption that there **may be** additional situations where some recognition of potential efficiencies is appropriate.
- *The recommendation for an across-the-board cut of 50 percent in the professional component of the affected imaging services is consistent with the RUC's work on over-valued procedures*. We strenuously object to this false and misleading characterization. While it is true that in the pelvic and abdominal CT examples cited by CMS, the RUC did recommend reductions similar to what CMS is proposing, this pattern was not repeated across all the other code sets the RUC examined. In fact, as CMS well knows, the RUC's effort to bundle and re-value codes for services that are frequently performed together has identified duplication between the codes ranging from zero percent to 100 percent. There is no standard number and in general, duplication in work on the code sets examined by the RUC has not come close to 50 percent.
- *A 50 percent across-the-board cut is warranted because that is what the reduction is in surgery and the technical component of affected imaging services*. Surgery is billed using 90 day global codes that include several visits as well as the surgical procedure.

> The multiple procedure payment reduction is intended to deal with duplication of visits in the follow-up period as well as in the procedure itself. The opportunity for this degree of duplication is far more limited in services that do not include follow-up after the procedure. Both MedPAC and GAO said that multiple procedure payment reductions should be determined by an analysis of potential efficiencies that may vary by type of service. CMS itself has set a lower reduction for therapy services and had originally limited the cut in the technical component of imaging services to 25 percent.

Unintended Consequences: Although CMS projects savings of $100 million a year from its proposal, it offers no explanation for this estimate. We are not certain that the projection has excluded savings tied to the RUC's previous or future recommendations regarding multiple procedures. We also do not see any evidence that this estimate has been adjusted to reflect movement of services out of physician offices and into hospital outpatient departments.

Imaging services performed in physician offices have been subjected to substantial cuts over the last several years and between 2006 and 2013, some will experience payment cuts of more than 60 percent. AMA's analysis of 2010 Medicare claims data suggests that advanced imaging services are already shifting from physician offices to hospital outpatient settings, and a new round of payment cuts seems likely to intensify the trend. **Medicare will thus make payment to the facility as well as the physician and for a substantial number of services, the total payment is significantly higher in the hospital outpatient setting than in a physician's office**

Medicare beneficiaries, as well as the program, thus will face higher costs if physicians respond to the proposed cuts by selling their practices to a hospital and/or sending more of their patients to a facility for diagnostic imaging. In addition, patients may face additional hassles and further fragmentation of care as a result.

Additional Proposals: CMS also is contemplating proposals to apply MPPR cuts to the technical and/or professional component of up to 530 imaging services. An even broader application that would subject about 700 diagnostic tests to MPPR cuts is also under consideration. In our view, these potential requirements would only exacerbate the problems associated with the current plan by extending cuts to additional services and specialties with arbitrary cuts that do not reflect any analysis of associated costs and potential efficiencies.

CODES WITH "23-HOUR+" STAYS

CMS reiterates 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. As we commented on the physician fee schedule proposed rule for CY 2011, we disagree with CMS' conclusions 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. 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 AMA urges CMS to accept the RUC-recommended values and physician time for all site-of-service anomaly codes, including codes relating to stays of 23+ hours (observation care services) which should be valued the same as an inpatient visit. We also urge CMS to accept the RUC recommendation and restore the time data for all services for which claims data indicate that the service is performed in the inpatient setting. At least three years of consecutive data should be available indicating a site-of-service anomaly before a review and adjustment is considered.**

Further, CMS' adjustments to the RUC recommendations have created rank order anomalies or misvaluation. Since refinement panels will be convened in late August to consider comments received on the proposed changes for 2012, t**he AMA urges that the refinement panels consider the original RUC recommendations and additional information in the RUC comment letter on the proposed five-year review rule, along with comments from the national medical specialty societies.**

BUNDLING/THREE-DAY PAYMENT WINDOW

Legislation enacted in 2010 requires that services provided within three days of a hospital stay generally must be bundled into the hospital stay. CMS has previously applied this requirement to services provided in hospital outpatient departments and provider-based clinics. This proposed rule "clarifies" that the requirement also applies to physician offices and clinics that are not provider-based but are wholly owned or wholly operated by the hospital receiving the admission. Physicians' payments in these cases would be limited to the lower facility based rate. CMS says it doesn't know how many physician offices meet the definition but that physician offices should know who they are because this information is required as part of the Medicare enrollment process. Given the problems and inaccuracies that have plagued the enrollment process, **the AMA requests that CMS notify all physician offices that it believes would be subject to this requirement and provide time for them to review and verify the designation. To allow time for this verification to take place and for hospitals and physicians to set up systems to identify cases subject to the requirement, we also believe that the start date for this provision should be delayed by one year**.

ANNUAL WELLNESS VISIT

The AMA is concerned about the lack of clarity for physicians and patients on what elements of traditional preventive services are actually covered under the new Annual Wellness Visit

(AWV). While increased emphasis on preventive care is essential to improving health outcomes, the services that are currently defined as included in the AWV are medically insufficient to establish a personalized prevention plan for Medicare patients.

Physical Exam

Physicians firmly believe that a physical exam is medically necessary to establish individualized preventive health plans for patients and to ensure high standards of integrated care. The CMS "Guide to Medicare Preventive Services" for physicians makes it clear that the AWV does not include a physical exam:

The AWV is a preventive wellness visit and is **not** a "routine physical checkup" that some seniors may receive every year or two from their physician or other qualified non-physician practitioner. **Medicare Part B does not provide coverage for routine physical examinations.**

The Medicare Claims Manual indicates that if a physician provides a preventive physical examination, this is a non-covered service and should be coded using the CPT codes for preventive visits. Guidance is also provided to physicians that separate E/M services provided to patients at the same encounter as the AWV should be reported using modifier -25. Because physicians believe in the medical necessity of physical exams, the AMA is particularly concerned that administering and coding for a separate physical exam may confuse physicians and deter provision of these services.

Adding to the confusion, Medicare beneficiaries are not informed that the AWV does not include a physical examination. In fact, the opposite is true. The beneficiary handbook, *Medicare and You*, lists Physical Exams as one category of services covered by Part B and states on page 39: "Medicare covers two types of physical exams—one when you're new to Medicare and one each year after that." Aside from this conflicting information provided to patients and physicians, most patients simply do not feel that they have had a full visit if they are not examined, and thus expect that a physical exam is included in the annual wellness visit.

Continuing concerns about professional liability and the ever-increasing costs of liability insurance coverage add to this problem. It is critical that a practicing physician conduct the physical exam as a basis for developing an accurate and appropriate "list of risk factors and conditions for which primary, secondary or tertiary interventions are recommended or are underway." The issue of tertiary prevention is particularly important for the Medicare population due to the high prevalence of chronic conditions among people over 65.

In addition, if physicians examine, diagnose, counsel, and treat both formerly known conditions and new ones at an AWV, it is not clear whether this work should be billed separately, with the patient responsible for cost-sharing for some portion of the service. In addition to a physical examination, laboratory tests and blood work are standards in physician practice to screen and identify potential illnesses, but these are not included in the AWV. Some specialty societies have tried to remedy the conflicting information by developing their own communications for

patients. For example, the American College of Physicians recommends sending a letter to patients stating: "The visit does *not* include a hands-on exam or any testing that your doctor may recommend, nor does it include any discussion about any new or current medical problems, conditions, or medications." **We urge CMS to help clear up this confusion by ensuring Medicare coverage for a physical exam as part of the AWV.**

Patient Cost-Sharing

Another major source of confusion related to the AWV is patient cost-sharing. Beneficiaries have been led by Medicare to believe that the AWV is free. The *Medicare and You* handbook states, for example, "You pay nothing for this exam if the doctor accepts assignment."

If a physician identifies an issue during the AWV that requires a physical examination to be provided for diagnosis and treatment purposes, this separately identifiable visit is to be reported with a CPT visit code and modifier -25. For these services, patients would be responsible for regular Part B cost-sharing. If the patient had not yet paid their deductible, they could be responsible for the entire cost of the visit. Similar concerns arise for laboratory and other diagnostic tests that may be ordered during the AWV. As these tests are not included in the AWV, patients could be responsible for cost-sharing. These confusing messages from CMS have led to distress among patients, who do not understand how the "free" preventive service visit that has been promised has become something for which they have to pay a considerable amount (deductible and co-pays).

Physicians are also concerned because the line that CMS has attempted to draw between the portion of the history and exam that may be covered by the AWV and a separately payable E/M service is unclear. **We urge CMS to revisit the decision to divide a normal medical preventive service into two services with two different coverage and payment policies.**

To summarize, current regulations and service descriptions for the AWV are confusing and misleading for both the physicians and patients. Greater clarity on AWV provisions and requirements is urgently needed. The AMA recommends that CMS issue clear guidance to beneficiaries and their physicians on what is and is not covered in the "free" visit.

Survey of Physicians

To assist in preparing these comments, the AMA conducted a brief online survey of physicians about their knowledge of, and experience, with providing the AWV. Although the short turnaround time of the survey led to a limited number of responses (99), the survey responses and written comments provided by the respondents underscored the concerns outlined above for each of the requested areas of interest:

- *Impact on practices of using a health risk assessment (HRA):* More than half the respondents are familiar with and have utilized the AWV codes, either alone or in

combination with the CPT visit codes and modifier –25. About one third of the respondents currently use a pre-visit health questionnaire or HRA form with their Medicare patients, and of those 42 percent said that incorporating the AWV HRA into their practice is somewhat or very difficult.

- *Impact of elements included in first and subsequent AWV definitions:* More than three quarters of respondents at least annually compile patient information on weight or body mass index, medical and family history, recommendations for preventive services and interventions, immunization records, and results of other age appropriate preventive services. In light of these ongoing annual assessments, it is striking that the Medicare HRA is considered burdensome by a number of them. Many survey respondents took the time to write comments indicating that the rigidity of the CMS AWV requirements discourages them from providing this service, and that CMS requirements are in sharp contrast to other program policies on preventive services, including Medicare Advantage plans, which leave it to the patient's physician to determine which elements are appropriate for each patient.
- *AWV and HRA burdens on practices*: In addition to comments about the requirements and guidelines for the AWV, the respondents identified other burdens to practices including time, resources and coding changes. A few described the requirements for the AWV as "onerous." A number of respondents concurred that "wellness and disease care should be integrated, not singled out as separate visits." They emphasized that their concerns are not confined to physicians, but that their patients also do not like to "separate out wellness from disease care in a visit," and " want to discuss other issues as well." One physician stated, "if I'm seeing a diabetic person 4 times a year, it is a waste of my time and their time to bring them in for an extra visit." Some respondents highlighted billing concerns, with one stating "billing is a nightmare." A number emphasized that Medicare patients misunderstand what is covered by the AWV and what is not covered. A few were unclear how they would know if another physician had already completed and/or billed the AWV. On the other hand, several respondents noted the benefits of the AWV and said that they are providing the service to their patients without difficulty. One respondent highlighted that it is a "nice addition and allows us to address [preventive service] issues in a more organized manner.

REQUEST FOR RE-REVIEW OF EVALUATION AND MANAGEMENT AND OTHER HIGH VOLUME SERVICES

The AMA is committed to health care delivery and payment reform. Improved care coordination is a critical element of providing high quality care to patients with chronic disease and in ensuring that valuable resources are used in the most efficient manner in caring for these patients. The CMS call for an examination of whether Medicare is adequately reimbursing physicians for care coordination activities is therefore very timely and important. However, the specific CMS request to re-survey 91 E/M CPT codes does not allow for the consideration of alternatives that are more directly related to care coordination services, and is therefore too limiting to allow for appropriate assessment.

The CPT Editorial Panel and the RUC are initiating a significant effort to address the broader question of how to best describe and value care coordination services. A joint workgroup will be convened in the coming weeks to begin a strategic review of the issue. CPT and the RUC have a long history of developing recommendations related to non-face-to-face services and care coordination. CPT codes and relative values exist for telephone calls, team conferences, anticoagulation management, and case management. At CMS' request, the RUC studied the resource costs associated with the provision of medical home monthly management services. To date, none of these solutions have been accepted by CMS. It will be critical that CMS participate in the current initiative so that medicine understands the limitations that have precluded payment for these services to date. The committees, however, are prepared to address this issue and develop a model that may be acceptable not only to our physicians, but also to the Medicare program.

We note that CMS has also requested RUC review of other high volume services under the premise that the services may be misvalued. Simply because a service is frequently performed, does not indicate that the service may be overvalued. However, the RUC will discuss CMS' specific request and articulate recommendations regarding a plan to review or provide additional comment following its September 22-25 meeting. We understand that the RUC will also articulate to CMS that some of the services on the proposed list have been recently addressed or are already under review. **The AMA requests that CMS consider the specific RUC comments regarding these codes as the agency prepares the final rule.**

AVERAGE SALES PRICE

The AMA continues to have significant concerns that the current average sale price (ASP) methodology for calculating payment for Part B drugs is artificially low for community-based practices. Adjustments to Part B drug payment methodology which further reduce payment, even for a limited period of time, will exacerbate shrinking access to community-based practices for Medicare beneficiaries. This problem is driven by manufacturer-to-distributor prompt pay discounts that are included in the calculation of ASP as well as other discounts that smaller clinical practices are not able to secure. Over the past three years nearly 200 cancer clinics have closed and 369 practices, with multiple clinic locations, are struggling financially according to one study.

We strongly support CMS' efforts to avoid payment reductions that result from incomplete and inaccurate volume-weighted price comparisons of Average Manufacturer Price (AMP) and ASP because this will only deepen the crisis among community-based practices and patient access to treatment for some of the most vulnerable Medicare beneficiaries such as those with cancer. However, we believe that this proposal is not sufficient to protect access. We strongly urge CMS to work with impacted specialties and community-based clinics to exercise greater latitude and agency discretion in the area of payment particularly for community-based clinical practices. Furthermore, we have significant concerns with CMS' proposal to substitute 103 percent of AMP for 106 percent of ASP where an applicable threshold has been satisfied under several scenarios. We urge CMS to consider the current crisis faced by community-based practices and

re-visit the threshold targets, or, alternatively assess the extent of the agency's discretion to specifically target payment adjustments that preserve beneficiary access to treatment at community-based practices.

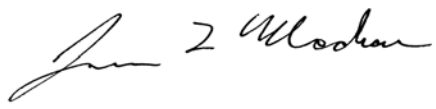
MEDICARE TELEMEDICINE SERVICES

Under proper conditions and circumstances, telemedicine provides access to health care for Medicare beneficiaries in remote geographic locations. We are in general agreement with CMS' proposed disposition of requests for additions to the list of approved telehealth services vis-à-vis smoking cessation and genetic counseling. However, in the case of genetic counseling, we do have beneficiary access concerns as well as concerns about the adverse impact this limited access to genetic counseling could have on health disparities, but acknowledge the statutory constraints faced by the agency. We look forward to working on the access issues as they pertain to personalized medicine services through the regulatory and legislative process.

Furthermore, we do support CMS' re-evaluation of the telehealth comparability category utilized by the agency to evaluate requests to add services to the approved telemedicine list that are not similar to services currently on the approved telehealth list of services. The current comparability standard requires that the requestor must demonstrate similar diagnostic findings or therapeutic interventions with respect to a candidate delivered through telehealth compared to an in-person delivery of the service. We urge CMS, nonetheless, to proceed with caution. While no service has been approved in the last decade utilizing the comparability standard, we recommend that CMS carefully evaluate the impact of the proposed new standard identified as the "clinical benefit" standard. The clinical benefit standard would entail the agency assessing whether the service is accurately described by the corresponding code when delivered via telehealth and whether the use of a telecommunications system to deliver the service produces demonstrated clinical benefit to the patient. This change could drive delivery changes where Medicare beneficiaries in remote areas receive consistently a lower level of care if clinical benefit has no relationship to the equivalent of an in-person visit.

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,



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