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Mr. Kerry N. Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1403-P
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; and Revisions to the Amendment of the E-Prescribing Exemption for Computer Generated Facsimile Transmissions; Proposed Rule; 73 Fed. Reg. 38,502 (July 7, 2008).

Dear Acting Administrator Weems:

The American Medical Association (AMA) appreciates the opportunity to provide our comments regarding *Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; and Revisions to the Amendment of the E-Prescribing Exemption for Computer Generated Facsimile Transmissions; Proposed Rule*; 73 *Fed. Reg.* 38,502 (July 7, 2008).

The AMA appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed physician payment rule for calendar year 2009. Subsequent to issuance of this proposed rule, Congress enacted the *Medicare Improvements for Patients and Providers Act of 2008* (MIPPA), which contained a number of provisions that would modify or repeal those contained in the proposed rule. We understand that CMS will issue an interim final rule containing revised provisions to implement MIPPA, and there will be an opportunity at that time to comment on any new or revised provisions. In particular, MIPPA averted the 10.6 percent cut in Medicare physician payment rate that took effect on July 1, 2008, by extending the current 0.5 percent payment rate. MIPPA also

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provided a 1.1 percent payment rate update for 2009. **We strongly urge CMS to ensure that the 1.1 percent is established using the current 2008 conversion factor as the base rate.** The statute would not support use of any other base year in establishing the update for 2009 since this would inherently build in a payment rate cut that Congress intended to avoid. Further, Congress has clearly stated that the 1.1 percent is intended to be consistent with the recommendation of the Medicare Payment Advisory Commission (MedPAC), and MedPAC recommended the 1.1 percent physician update as an update to the 2008 conversion factor.

In addition to the above comments, we discuss below various critical concerns with the proposals contained in the rule, along with a number of recommendations to help resolve these concerns. Key recommendations included in this comment letter are:

- CMS should ensure that the 1.1 percent Medicare physician payment update in 2009 is established using the current 2008 conversion factor as the base rate.

- CMS should undertake an aggressive education and outreach program for physicians and eligible professionals on how to successfully participate in the Physician Quality Reporting Initiative (PQRI). This educational program must include detailed confidential interim feedback and compliance reports that clearly inform physicians of any reporting errors and how to correct these errors. Confidential final feedback reports must be issued as well.

- CMS should provide the appropriate 2008 PQRI data set file so that the AMA may immediately undertake a review of this file to help improve physician quality measure design and better understand possible barriers and stimuli to physician reporting.

- CMS should reconsider the proposed exclusion of a number of measures developed by the Physician Consortium for Performance Improvement (PCPI) from the 2009 PQRI. To increase transparency, CMS should provide in the final rule a thorough explanation of why any PCPI-recommended measures are not included in the list of measures proposed for the 2009 PQRI.

- In the absence of strong empirical data to support a statistically valid reporting cohort size, CMS should maintain the option of allowing physicians to report data on 15 patients for a 6-month reporting period.

- CMS should specify in the final rule the procedures and requirements that registries must meet to correct any errors in the registry reporting process to CMS on behalf of eligible professionals, as well as procedures that can be implemented by the registry to minimize errors throughout the reporting period, including interim and final confidential feedback reports.

- CMS should specify the procedures and requirements in the final rule that electronic health record (EHR) product vendors must meet to minimize errors in the EHR reporting process during the reporting period, including confidential interim and final feedback

reports, as well as procedures to be followed to correct for errors that may occur when the vendor submits the data to CMS.

- CMS should provide an appeal process for physicians who submit reports to the PQRI but who are not deemed by CMS to have met the criteria for successful reporting and do not receive incentive payments. CMS should inform physicians and eligible professionals who participate in the PQRI well in advance whether they will be listed on the Internet as an eligible professional that satisfactorily submitted data under the PQRI. CMS should also inform those who participate, but who will not be listed as a successful participant, of the reasons why they will not be listed and allow such physicians an opportunity to correct any errors and/or provide a written explanation for such lack of success. Physicians should be able to elect whether this explanation may be available to the public through the CMS web site.

- CMS must work with Congress before establishing a program to make available to the public PQRI performance information since it currently does not have the authority to do so.

- CMS must ensure that physicians and other providers involved in the treatment of a patient have the opportunity for prior review and comment and the right to appeal with regard to any data that is part of the PQRI (or other) public review process. Any such comments should also be included with any publicly reported data.

- CMS should not extend the inpatient Hospital Acquired Conditions (HAC) policy to the Outpatient Prospective Payment System (OPPS) nor to other settings, such as physician office practices, as it does not have the statutory authority to do so.

- CMS should conduct an analysis of the current inpatient HAC policy, in consultation with technical experts, physician organizations, hospitals and other impacted providers, and such analysis must occur before considering extension of this approach to other settings.

- Rather than extending the inpatient HAC non-payment policy to physician offices or other setting, CMS should focus its efforts on encouraging compliance with evidence-based guidelines by health care professionals.

- CMS should work with the Relative Value System Update Committee(RUC) and its Professional Liability Insurance (PLI) Workgroup in reviewing the pending report of the CMS contractor concerning PLI relative value units and should soliciting comments and recommendations from the RUC and its workgroup to ensure that the 2010 PLI relative values are accurate.

- CMS should not eliminate the current computer-generated facsimile transmissions exemption from the requirement to use the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard in transmitting prescriptions or prescription-

related information on January 1, 2009, and this broad exemption should remain in effect.

- The Secretary should use discretionary authority as provided under the MIPPA to exempt the e-prescribing of controlled substances from any assessment of penalties; and to enhance e-prescribing adoption and use rates, physicians should be entitled to receive incentive payments, regardless of whether they choose to e-prescribe controlled substances in accordance with the DEA's final rule and requirements. CMS should undertake an aggressive education and outreach program for physicians on the reporting requirements for eligible prescribers to receive incentive payments for e-prescribing well in advance of the January 1, 2009, effective date.

- CMS should work with the CPT Editorial Panel and the RUC to develop codes for inpatient consultations approved for telehealth services and substitute these codes for its proposed G codes as soon as possible.

- Since the RUC is in the process of analyzing the increase in home health codes and determining whether such increases are warranted, CMS should delay any policy changes with regard to these home health codes until the RUC has completed its review.

- CMS should adopt the RUC recommendation that CMS include additional clinical labor activity in the practice expense for immunization administration.

- CMS should abandon its proposal to treat physician offices as independent diagnostic testing facilities (IDTFs) and focus instead on ensuring a smooth implementation of the new accreditation standards for advanced imaging services included in MIPPA.

- CMS should withdraw all of its proposed changes to the requirements for physician enrollment in Medicare, including the changes to the effective date of billing privileges, eligibility to participate in the program, enrollment processing, reporting requirements, and revocation of billing privileges.

- CMS should withdraw its proposed changes to the appeals process. To add another major hassle for physicians who have continued to treat Medicare patients even in the face of stagnant payments and the annual threat of draconian cuts would only add insult to injury with little, if any, benefit to taxpayers or Medicare patients.

PHYSICIAN QUALITY REPORTING INITIATIVE (PQRI)

In the proposed rule, CMS sets forth a number of proposals relating to implementation of the PQRI for 2007 through 2009. The AMA strongly supports the quality improvement goals envisioned by such programs as the PQRI, along with many specific aspects of this program. We have several serious concerns, however, with various aspects of the PQRI, as discussed further below, and we look forward to working with CMS to resolve these concerns in an effort to improve the PQRI.

Barriers to Participation in the PQRI

Moving forward with the 2009 PQRI, the AMA urges CMS to evaluate and work with the physician community to address continued barriers to participation in the program. Key barriers to participation that remain include such factors as the lack of applicable measures to certain physician specialties and confusion concerning the requirements for participation in the PQRI. **The AMA and the PCPI are committed to working with CMS to develop appropriate measures so that all physicians have an opportunity to participate. We also look forward to working with CMS to ensure that physicians have the proper education and training concerning how to participate in the PQRI.** There are many opportunities for broadening the potential to participate in the PQRI as well as for educating physicians who wish to participate, and such opportunities are discussed more specifically below.

PQRI Transparency

The AMA strongly encourages CMS to ensure greater transparency in all aspects of developing the PQRI program, and especially with respect to the process of measure selection. Many of our physician members have expressed concern that a rigorous, systemic process is not in place to determine which measures will be included in the program. For example, in March of this year, CMS solicited measure topics from the physician community for inclusion in the 2009 PQRI. This was a very broad solicitation, and it remains unclear how and why certain measures are (or are not) included in the list of proposed measures for the 2009 PQRI. In fact, the PCPI submitted to CMS numerous performance measures for consideration for 2009, but many of these measures, as listed below, were not included in the proposed rule and thus will not be part of the 2009 PQRI. Various measures on this list would have provided the only opportunity to participate in the PQRI with respect to certain physicians for whom no other PQRI measures are applicable to their practice. **Inclusion of such measures in the PQRI would be an excellent opportunity to increase opportunities for participation in the PQRI. Further, in an effort to increase transparency, we urge CMS to provide in the final rule a thorough explanation of why these measures were not included in the list of measures proposed for the 2009 PQRI.**

The measures that were submitted to CMS by the PCPI but were not included in the proposed list of measures for 2009 are as follows:

Topic	**Measure Title**
Anesthesiology/Critical Care	Anesthesiology and Critical Care: Perioperative Temperature Management
Endoscopy	Endoscopy & Polyp Surveillance: Comprehensive Colonoscopy Documentation & Communication
Endoscopy	Endoscopy & Polyp Surveillance: Screening Colonoscopy Interval in Average-risk Patients

Topic	Measure Title
Eye Care	Cataracts: 20/40 or Better Visual Acuity Within 90 days Following Cataract Surgery
Eye Care	Primary Open-Angle Glaucoma: Counseling on Glaucoma
HIV/AIDS	HIV/AIDS: Screening for High Risk Sexual Behaviors
HIV/AIDS	HIV/AIDS: Screening for Injection Drug Use
HIV/AIDS	HIV/AIDS: Hepatitis B Vaccination
HIV/AIDS	HIV/AIDS: Other Infectious Diseases-Hepatitis B Screening
HIV/AIDS	HIV/AIDS: Other Infectious Diseases-Hepatitis C Screening
HIV/AIDS	HIV/AIDS: Sexually Transmitted diseases-Chlamydia and Gonorrhea Screenings
HIV/AIDS	HIV/AIDS: Sexually Transmitted Diseases-Syphilis Screening
HIV/AIDS	HIV/AIDS: Tuberculosis (TB) Screening
HIV/AIDS	HIV/AIDS: Influenza Immunization
HIV/AIDS	HIV/AIDS: Pneumococcal Immunization
Melanoma	Melanoma: Overutilization of Imaging Studies in Stage 0-1A Melanoma
Nuclear Medicine	Nuclear Medicine: Communication to Referring Physician of Patient's Potential Risk for Fracture for all Patients Undergoing Bone Scintigraphy
Obstructive Sleep Apnea	Adult Obstructive Sleep Apnea: Adherence to Positive Airway Pressure Therapy
Obstructive Sleep Apnea	Adult Obstructive Sleep Apnea: Assessment of Symptoms
Obstructive Sleep Apnea	Adult Obstructive Sleep Apnea: Positive Airway Pressure Therapy Prescribed
Obstructive Sleep Apnea	Adult Obstructive Sleep Apnea: Severity Assessment
Oncology	Oncology: Cancer Stage Documented
Oncology	Oncology: Treatment Summary Communicated-radiation Oncology
Radiology	Radiology: Communication of Suspicious Findings From the Diagnostic Mammogram to the Patient
Radiology	Radiology: Communication of Suspicious Findings From the Diagnostic Mammogram to the Practice Managing Ongoing Care

Topic	Measure Title
Radiology	Radiology: Mammography Assessment Category Data Collection
Radiology	Radiology: Reminder System for Mammograms
Radiology	Radiology: Stenosis Measurement in Carotid Imaging Reports
Substance Use Disorders	Substance Use Disorders: Counseling Regarding Psychosocial and Opioid Agonist Maintenance Treatment Options
Substance Use Disorders	Substance Use Disorders: Counseling Regarding Psychosocial and Pharmacologic Treatment Options for Alcohol Dependence
Substance Use Disorders	Substance Use Disorders: Screening for Depression Among Patients with Substance Abuse or Dependence
Wound Care	Chronic Wound Care: Assessment of Wound Characteristics in Patients Undergoing Debridement
Wound Care	Chronic Wound Care: Patient Education Regarding Diabetic Foot Care
Wound Care	Chronic Wound Care: Patient Education Regarding Long Term Compression Therapy
Wound Care	Chronic Wound Care: Use of Superficial Swab Culture in Patients with Skin Ulcers (overuse measure)
Wound Care	Chronic Wound Care: Use of Wet to Dry Dressings in Patients with Skin Ulcers (overuse measure)

PQRI 2007

Under the *Tax Relief and Health Care Act of 2006* (TRHCA), CMS initially implemented the PQRI for the reporting period of July 1, 2007 through December 31, 2007, with a bonus payment for participation in the PQRI. CMS recently provided the first data on interim participation and reporting statistics related to the 2007 PQRI. According to this initial report, approximately 16 percent of physicians and eligible professionals participated in the 2007 program, but nearly 50 percent of participants did not receive any bonus payment. It is clear from this alarming statistic that there is significant confusion among physicians about how to successfully meet the requirements of the PQRI. **This strongly points out the need for CMS to undertake an aggressive education and outreach program for physicians and eligible professionals on how to successfully participate in the PQRI. This educational program must include detailed confidential interim feedback and compliance reports that clearly inform physicians of any reporting errors and how to**

correct these errors. Confidential final feedback reports must be issued as well. This will assist in increasing the number of eligible professionals that successfully report in the PQRI. **Accordingly, we urge CMS, as it moves forward with the 2008 and 2009 PQRI (and beyond), to develop a more effective educational and outreach program that clearly informs physicians and eligible professionals who wish to participate in the PQRI of the requirements that must be met to successfully participate in the program.**

In addition, physicians who report PQRI measures but are not deemed by CMS to have successfully reported and therefore do not receive their incentive payments should have the ability to appeal. CMS should put a process in place that allows physicians to contest the judgment that they did not successfully report.

Further, the AMA looks forward to working with CMS in an effort to glean additional information from the 2007 PQRI data set file to help improve physician quality measure design. The AMA would also like to conduct a more detailed review of the 2007 data to better understand possible barriers and stimuli to physician reporting. Moving forward, this will help to: improve development of new, and modification of existing, physician measures; clarify any confusion about certain measures; and advance education efforts so that physicians can better understand how to report on measures, especially those for which there is a high error rate. In conducting this review, the AMA is particularly interested in exploring participation and measure selection for reporting by specialty; the frequency of CPT-II modifiers (exclusions), reporting by measure and by specialty. We would also like to determine whether reporting and error rates vary with respect to characteristics of measures, such as coding complexity, logical complexity, allowance for exclusions, and/or type of measure (i.e., whether a measure addresses management of chronic conditions, acute care episodes, procedures or care coordination). **We urge CMS to provide the appropriate data so that the AMA may immediately undertake review of the 2007 PQRI data set file.**

PQRI 2009

The *Medicare, Medicaid, and SCHIP Extension Act of 2007* (MMSEA) extended the PQRI through 2009. In the proposed rule, CMS sets forth proposed measures, requirements, and other aspects of the 2009 PQRI.

Additional Reporting Periods and Options

For the 2009 PQRI, CMS proposes additional reporting options and periods to promote physician participation in quality measures reporting. **The AMA supports additional reporting options and periods as this provides more flexibility and opportunities for physicians to participate in the PQRI. We caution, however, that more options and reporting periods can result in more confusion, and thus it is critical that CMS initiate a strong educational program aimed at helping participating physicians successfully report data under the 2009 PQRI. We urge CMS to work with the AMA and other physician organizations to educate physicians about the requirements that must be met to successfully report under the numerous reporting options and periods in 2009.**

Further, CMS must provide more detailed education resources on its PQRI web site well in advance of the 2009 PQRI's January 1, 2009, effective date.

CMS is also proposing basic criteria for satisfactory reporting of measures groups. The AMA also supports the development of measures groups as this will help capture a more comprehensive view of the care provided to patients and reduce the reporting burden. In the near future, the PCPI will begin to bundle its measures, which will be complementary to the PQRI measure grouping process. The AMA also wants to work with CMS to develop one CPT II composite code to capture all actions for a measure group. CPT II composite codes currently exist for other sets of PCPI measures and use of such codes in the PQRI would reduce the reporting burden on physician practices.

The AMA cautions CMS, however, with respect to the proposed criteria for satisfactory reporting of a measures group. One of these criteria is that eligible physicians (and other professionals) must report quality data for 30 consecutive patients for one measures group for which the measures group is applicable during the full-year reporting period. (This criteria is applicable to both claims-based and registry-based submissions.) CMS has requested comments on the proposed use of consecutive patient reporting criteria and on the use of 30 consecutive patients as the required sample under these criteria during the full-year 2009 reporting period. Unlike 2008, CMS does not propose an option for 15 consecutive patients for the 6-month reporting period. CMS states that "[w]hile we do not have the results of the 2008 reporting, we are concerned that samples of fewer than 30 consecutive patients may be insufficient to calculate comparable performance rates across eligible professionals furnishing comparable services." CMS further adds that it expects "additional experience with PQRI reporting to clarify optimal sample sizes and reporting criteria for use in future reporting periods."

Without the results of the 2008 reporting, the impact of eliminating the 15 consecutive patients option is unclear, as CMS acknowledges. The AMA is very concerned that the 30 consecutive patients criteria may be too large, and many physicians who may wish to participate in the PQRI will not be able to do so because they may not treat 30 patients for whom they can report data on a particular measure. **In the absence of strong empirical data to support a statistically valid reporting cohort size, the AMA urges CMS to maintain the option of allowing physicians to report data on 15 patients for a 6-month reporting period.**

Registry-Based Reporting

In accordance with TRHCA and MMSEA, CMS is proposing for the 2009 PQRI that eligible professionals would be able to report quality measures data through a qualified clinical registry by authorizing or instructing the registry to submit quality measures results and numerator and denominator data on quality measures to CMS on their behalf. **The AMA supports CMS' use of registries (as well as EHRs) as a reporting mechanism, and we look forward to collaborating with CMS to identify innovative and creative means to measure performance using these rich medical data sources.** The use of registries allows greater flexibility in reporting, and, in particular, allows physicians to report data

after submission of claims. The AMA also supports allowing reporting of some non-Medicare patients via registry-based reporting.

CMS announced in August that 32 registries "qualified" to submit data on 2008 PQRI quality measures or measures groups on behalf of eligible professionals. We are concerned, however, about the lack of procedural provisions in the event that a qualified registry fails to report or incorrectly reports the quality data on behalf of a physician. **We urge CMS to specify in the final rule procedures and requirements that registries must meet to correct any errors in the registry reporting process to CMS on behalf of eligible professionals, as well as procedures that can be implemented by the registry to minimize errors throughout the reporting period.** For example, the registry could be required to provide feedback reports, including interim reports, to physicians detailing any reporting errors that can be corrected by the physician. (This same recommendation applies to EHRs as well.)

CMS also sets forth under Table 9 in the proposed rule, options for registry-based reporting. These options allow flexibility in reporting periods for registry-based reporting, yet the AMA is concerned that only physicians who are able to report on at least 3 measures are eligible for registry-based reporting, as indicated in Table 9. If this is erroneous, we urge CMS to clarify in the final rule that physicians are eligible for registry-based reporting using 1 or 2 measures if fewer than 3 measures apply to that physician. Not allowing registry-based reporting by specialties that only have 1 or 2 applicable measures does not serve to advance the use of registries, which we all agree is preferable to reporting through administrative claims. **We also urge CMS to ensure that the reporting requirements (i.e., the number of measures) applied to registry-based reporting are consistent with the "traditional" PQRI claims reporting requirement.**

EHR-Based Submission for Reporting Individual Measures

CMS is preparing to test the submission of clinical quality data extracted from electronic health records (EHRs) for five 2008 PQRI measures. This testing period will occur from July 1, 2008 through December 31, 2008. CMS proposes for 2009 to accept PQRI data from EHRs for a limited subset of the proposed 2009 PQRI quality measures, contingent upon successful completion of the 2008 EHR data submission testing process and a determination that accepting data from EHRs on quality measures for the 2009 PQRI is practical and feasible.

The AMA supports EHR-based reporting. We also support expansion of the EHR reporting program, when feasible to do so, to include group reporting and additional PQRI measures, and we are committed to working with CMS in this effort. In fact, the Collaborative for Performance Measure Integration with EHR Systems (Collaborative), initiated in 2006, is co-sponsored by the AMA, along with the HIMSS Electronic Health Record Vendors Association (ERHVA) and the National Committee for Quality Assurance (NCQA). The Collaborative is comprised of a broad group of stakeholders—performance measure developers, EHR vendors, expert EHR users, national quality improvement organizations and technical experts in physician performance measurement and quality

improvement—who have a shared goal of facilitating the integration of performance measures with EHR systems. As measure development organizations develop performance measures designed to assist physicians in improving the quality of patient care delivered in the ambulatory environment, EHR vendors are working to incorporate performance measure functionality into EHR products.

We are concerned, however, that as CMS undertakes the EHR reporting testing process, similar to registry-based reporting, the agency should ensure through the regulatory process that there are mechanisms in place to increase the accountability of the EHR vendor for successful submission of data from physicians and eligible professionals. **Similar to our recommendation for registry-based reporting, we urge CMS to specify procedures and requirements in the final rule that EHR product vendors must meet to minimize errors in the EHR reporting process during the reporting period, including interim and final feedback reports, as well as procedures to be followed to correct errors that may occur when the vendor submits the data to CMS. Since EHR reporting is in the testing process, it is particularly important to incorporate appropriate mechanisms to minimize errors and confusion throughout the reporting period and to ensure that there is a continued process in place to correct any errors that may occur when the EHR vendor submits the data to CMS on behalf of physicians and other eligible professionals.**

Proposed 2009 PQRI Measures

Tables 11 through 14 of the proposed rule set forth 175 measures that CMS is proposing for the 2009 PQRI, provided that a measure retains or receives NQF endorsement or AQA adoption by August 31, 2008. The AMA has the following comments with regard to specific measures.

In setting forth the proposed measures for 2009, CMS notes that "in some instances, those 2008 PQRI measures intended or requested by the measure developer to be retired from PQRI and replaced by new AQA-adopted or NQF-endorsed measures are not included in the list of proposed measures for 2009. The two 2008 PQRI measures not proposed for this reason are: Measure #4, Screening for Future Fall Risk; and Measure #88, Hepatitis A and B Vaccination in Patients with HCV." The PCPI is the measure developer for Measure #4, yet the PCPI did not recommend retirement or replacement of this measure. **We urge CMS to correct this error and strongly advocate that Measure #4 remain in use for the 2009 PQRI.** For Measure #88, this measure has been revised into two separate measures, which are listed correctly in Table 13.

Measures #5, 6, and 7, as included in the 2008 PQRI, also apply to the inpatient settings. During the request for measures for 2009, the list submitted by the AMA-PCPI requested that an additional three measures, that mirror Measures #5, 6 and 7 respectively, be added to the 2009 PQRI to be used when reporting data at the time of discharge. (Existing measures # 5, 6 and 7 would continue to be available for use in the office setting for ongoing patient care.) This separation of measures addresses ongoing concerns related to physician

attribution and accountability. **We urge CMS to add these three new measures for use at the time of discharge for the 2009 PQRI.**

Table 11 contains Measure #86, "Hepatitis C: Consideration for Antiviral Therapy in HCV Patients," developed by the PCPI. During the NQF endorsement process, the specifications and title for this measure were modified. The new title is: "Hepatitis C: Antiviral Therapy Prescribed." In addition, the measure title and specifications for Measure #11: "Stroke and Stroke Rehabilitation: Carotid Imaging Reports," were expanded to include all carotid imaging studies performed and not only those limited to patients with a diagnosis of stroke. The title of this measure should read: "Carotid Imaging Reports." These measures and core specifications remain in place, and since both measures are in the proposed rule, there is adequate opportunity for public comment on them. **We, therefore, urge CMS to exercise flexibility and retain these measures in their revised formats for use in the 2009 PQRI.**

In Table 14, three measures have had title changes. The title of the Endoscopy measure has changed to: "Surveillance Colonoscopy Interval for Patients with a History of Colonic Polyps - Avoidance of Inappropriate Use." In addition, the title of the measure currently called "Chronic Wound Care: Offloading of Diabetic Foot ulcers" has been revised slightly to: "Chronic Wound Care: Offloading (Pressure Relief of Diabetic Foot Ulcers." The "Unhealthy Alcohol Use: Screening & Brief counseling" measure title has been revised to "Unhealthy Alcohol Use: Screening." These titles do not represent material changes in the measures and the titles were modified slightly only for purposes of clarity and to better communicate the measures' intent. **We urge CMS to retain these measures for use in the 2009 PQRI with revised titles.**

Also, in Table 14, the "Lipid Screening" measure will not be available for use in the 2009 PQRI since the underlying guideline used to create the measure (the United States Preventive Services Task Force) changed in June 2008, thereby not allowing time to revise the measure based on the revised recommendations. In addition, we wish to clarify which lipid-focused measure was intended to be included in the 2009 coronary artery disease (CAD) measures group. CMS included "Lipid Screening" in the CAD measures group (Table 19). It is unclear whether this title refers to the Preventive Care & Screening measure on lipid screening or the lipid profile measure that is a part of the PCPI-developed CAD measurement set. As stated above, the "Lipid Screening" measure is not available for use in the 2009 PQRI; in addition, we do not believe that this measure is appropriate for the CAD measures group since it is aimed at screening the general population of patients as a primary prevention measure for CAD. The PCPI-developed "CAD: Lipid Profile" measure, which is AQA-selected, is specifically designed as a secondary prevention measure for patients with a diagnosis of CAD. **The AMA urges CMS to consider including the "CAD: Lipid Profile" measure as part of the CAD measures group in the 2009 PQRI.**

Finally, with respect to Table 14, we note that the "measure source" for measures relating to rheumatoid arthritis, endoscopy, and wound care is listed as AMA-PCPI. All of these measures were developed jointly with the NCQA and thus the NCQA should be added as an additional "measure source." The NCQA should also be added as a "measure source" for the rheumatoid arthritis group of measures in Table 14. Similarly, the AMA-PCPI should be

added as a "measure source" for the "Palliative Care: Dyspnea Screening and Management" measure.

In Table 18, the coronary artery bypass graft (CABG) measures group is very large. **We recommend limiting measures groups to a smaller number of measures unless a composite code is created for all of the aspects of care in the measures. This will ease the administrative burden of reporting data for a measures group.**

Finally, CMS has not proposed certain measures, such as the eye care outcomes measures, for use in the PQRI because some of these measures are too complex for the "traditional" PQRI. Nevertheless, they would be ideal for use in registry-based reporting and eventually in EHR-based reporting. We understand that CMS prefers to keep the same list of measures available for use in the PQRI as well as for registry-based reporting. We recommend, however, that CMS consider measures for use in registry-based (and eventually EHR-based) reporting beyond those that are available in the "traditional" PQRI. Some data sources, such as registries and EHRs, allow more robust data collection, and every opportunity should be taken to allow these measures (particularly outcomes measures) to be implemented.

Uses of PQRI Information

The *Medicare Improvements for Patients and Providers Act of 2008* (MIPPA), which became Public Law No. 110-275 on July 15, 2008, authorizes CMS to post on the Internet, in an easily understandable format, a list of the names of the eligible professionals or group practices that satisfactorily submit data on quality measures (as well as with respect to those that are successful electronic prescribers). As discussed further below, we urge CMS to comply with its statutory authority, as directed under MIPPA, and make available to the public only the names of the eligible professionals or group practices that satisfactorily submit data on quality measures (as well as with respect to those that are successful electronic prescribers). **In implementing this provision, we urge CMS to inform physicians and eligible professionals who participate in the PQRI well in advance whether they will be listed on the Internet as an eligible professional that satisfactorily submitted data under the PQRI. CMS should also inform those who participate, but who will not be listed as a successful participant, of the reasons why they will not be listed and allow such physicians an opportunity to correct any errors and/or provide a written explanation for such lack of success. Physicians should be able to elect whether this explanation may be available to the public through the CMS web site.**

Further, CMS discusses in the proposed rule its intent to make information on the quality of care for services provided by physicians to Medicare beneficiaries publicly available in future years through a "Physician Compare" web site. As part of this initiative, CMS proposes to explore using information collected from the PQRI, including performance results, for this purpose. CMS is requesting public comment on a number of issues related to public reporting of PQRI performance information.

The AMA is committed to the development of quality improvement initiatives that increase the quality of care provided to patients. The AMA-convened PCPI has adopted a

transparent, consensus-based process for developing physician-level measures and has worked aggressively in developing to date more than 200 physician performance measures and specifications for over 34 clinical topics and conditions. These measures are available for implementation and are designed to help achieve the important goal of quality improvement. In fact, many of these measures have been adopted by CMS for use in the PQRI as well as in other CMS quality improvement demonstration projects.

As the AMA continues in our ongoing efforts to enhance quality improvement, we strongly urge CMS to ensure the development of a quality reporting program that physicians are confident will improve quality of care. In doing so, we urge CMS to work with Congress before establishing a program to make available to the public PQRI performance information. CMS currently does not have the statutory authority to publicly report performance data gathered under the PQRI. MIPPA, as recently enacted, only authorizes CMS to post on the Internet, in an easily understandable format, a list of the names of the eligible professionals or group practices that satisfactorily submit data on quality measures (as well as with respect to those that are successful electronic prescribers). This provision shows Congress' intent that only limited information can be made public under the PQRI. If Congress intended broad scale performance data under the PQRI to be made publicly available, it would have provided the Secretary of the Department of Health and Human Services (HHS) with the authority to do so. Moreover, if Congress thought that CMS already had the authority to act on this goal, Congress would not have needed to provide authority to CMS to post on its web site the names of those who satisfactorily submit data.

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

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

If done correctly, public reporting has the potential to help provide such appropriate information to patients. There remain, however, several critical issues that must be resolved

before public reporting provisions can be implemented. There must be a method for ensuring that any publicly reported information is: (i) correctly attributed to those involved in the care; (ii) appropriately risk-adjusted; and (iii) accurate, user-friendly, relevant and helpful to the consumer/patient. Moreover, as CMS acknowledges in the proposed rule, an important aspect of a quality reporting program is that physicians (and other eligible professionals) have the opportunity to review their data on reporting rates on PQRI quality measures. We strongly agree. **Physicians and other providers involved in the treatment of a patient must have the opportunity for prior review and comment and the right to appeal with regard to any data that is part of the public review process. Any such comments should also be included with any publicly reported data.** This is necessary to give an accurate and complete picture of what is otherwise only a snapshot, and possibly skewed, view of the patient care provided by physicians and other professionals or providers involved in the patient's care. In fact, when establishing the quality reporting program for hospitals and ASCs under TRHCA, Congress signaled its agreement with this concept by requiring that CMS procedures to make quality data available to the public "shall ensure that a hospital [or ASC] has the opportunity to review the data that are to be made public with respect to the hospital [or ASC] prior to such data being made public."

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

- To date, there has been no formal, rigorous evaluation of the PQRI to determine such factors as: its impact on quality of care, whether it allows for fair and meaningful comparison of performance among physicians and other eligible professionals, and whether the data on physician participation is valid and can be verified. Further, the appropriateness of using PQRI data at this point is extremely uncertain due to the relatively limited successful participation by physicians in the program. According to CMS' initial reports, approximately 16 percent of physicians and eligible professionals participated in the 2007 program, and nearly 50 percent did not receive any bonus payments because they did not meet the 80 percent threshold or include their National Provider Identifier (NPI) number on their claims. Some have also raised questions concerning the validity of the participation data. **Since, as discussed above, successful public reporting depends on valid, reliable, comprehensible and meaningful information reported to consumers, it is critical that CMS assess whether the PQRI results in the compilation of quality data that meets these criteria.**

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

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

Development (CED) mandates, health plans and various other quality initiatives. Physicians should have an opportunity to highlight these quality improvement efforts.

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

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

ESRD PROVISIONS: APPLICATION OF HEALTHCARE ASSOCIATED CONDITIONS TO OTHER SETTINGS

In the proposed rule, under Section H relating to end-stage renal disease services, CMS suggests that the Medicare non-payment policy for healthcare associated conditions (HACs) in the hospital inpatient setting could be applied more broadly to other Medicare providers, including hospital outpatient departments, ambulatory surgical centers, skilled nursing facilities, home health care, end-stage renal disease facilities and physicians. CMS requests comments about the application of this policy to other Medicare payment systems.

Under the Deficit Reduction Act of 2005, Congress specifically provided CMS with the authority to begin applying the HAC policy to the hospital inpatient setting. If CMS were to extend this policy to other settings, it would need similar statutory authority. **Without this statutory authority, CMS cannot extend the inpatient HAC policy to the OPPS nor to other settings, such as physician office practices.**

Further, the AMA strongly opposes non-payment for HACs in the inpatient or in any payment setting that are not reasonably preventable through the application of evidence-based guidelines, developed by appropriate medical specialty organizations based on non-biased, well-designed, prospective, randomized studies. Because the current inpatient HACs do not meet that criteria, we have grave concerns about extending this policy to other payment settings, including physician practices.

It is unacceptable that CMS is expanding the inpatient HAC policy beyond the original eight conditions identified last year when the first phase of the program has not even begun. CMS has not yet conducted any analysis of: (i.) the impact of the current HAC inpatient policy on quality of care relative to the additional Medicare costs required to comply with the HAC requirements; (ii.) the need for better risk adjustment techniques; (iii.) attribution issues with respect to when, where and why a condition has occurred; and (iv.) the reasonable expected incidence of these conditions in individual hospitals especially with regard to high-risk patients—when evidence-based guidelines are followed.

We, therefore, urge CMS to conduct an analysis of the current HAC policy, in consultation with technical experts, physician organizations, hospitals and other impacted providers. Such analysis must also occur before considering extension of this approach to other settings. It would defy logic to extend an approach to other settings without a cost-benefit analysis to determine whether any quality improvements it achieves outweigh its potential to increase Medicare spending and create incentives for delay or denial of needed care for challenging patients.

As we observed in our June 13, 2008 comments on the hospital inpatient prospective payment system proposed rule for fiscal year 2009, many provisions proposed for the inpatient HAC policy will present confusion and unintended consequences for both the individual beneficiary and Medicare. Although the HAC conditions that CMS proposed at that time were supposed to be "reasonably preventable," there is strong and unequivocal disagreement with that premise throughout the medical community. Subsequent to our June 13 comments, CMS finalized a list of conditions subject to the inpatient HAC non-payment policy, and we continue to stand by our comments in our June 13 letter.

The AMA continues to work aggressively to improve quality and efficiency for patients, but simply not paying for complications or conditions that are not entirely preventable is not good for patients or the Medicare program. In the race to improve health care quality, HHS is confusing events that should never happen in a hospital, like wrong-patient surgery, with often unavoidable conditions, like surgical site infections. To be reasonably preventable, there should be solid evidence that by following guidelines, the occurrence of an event can be reduced to zero or near zero. This is not the case for many of the now-banned conditions. Focusing on determining whether or not medical conditions exist when the patient enters the hospital will increase Medicare spending on tests and screenings with questionable benefit to patients.

Finally, we emphasize that expanding the inpatient HAC nonpayment to other settings would be extremely problematic, especially in physician offices because the payment approach is completely different from the hospital setting. For example, in the inpatient setting, Medicare denies the portion of payment associated with care complications when the complications are associated with a condition on the HAC list. However, there is no clear way to determine some portion of a physician's payment that would be denied due to presumed mismanagement of a reasonably preventable condition. The appropriate level of an evaluation and management service is based on the conditions managed at a given encounter and the time and intensity of the work associated with those conditions. Because the presence and severity of additional conditions present during the visit will vary greatly among patients, identifying and valuing the work attributable to a preventable condition managed by the physician at a visit would be very difficult.

In addition, the lack of adequate risk adjusters is an even greater problem in physician practices than in hospitals because some physicians specialize in treating the riskiest patients and do not have the ability to make up for losses on these patients through care of patients with below-average risks. Further, patient compliance outside of the physician office setting would be extremely difficult to assess and monitor, which also could seriously hamper any

risk adjustment techniques. Many factors outside of a physicians' control could cause a patient to acquire various conditions while under a physician's care.

We are pleased that CMS recognizes in the proposed rule that the implications of applying the inpatient HAC payment policy approach "would be different for each setting, as each payment system is different and the reasonable preventability through the application of evidence-based guidelines would vary for candidate conditions over the different settings." **Rather than considering any similar approach for physician practices, we urge CMS to instead focus its efforts on encouraging compliance with evidence-based guidelines by health care professionals.**

PHYSICIAN SELF-REFERRAL AND ANTI-MARKUP ISSUES

Gainsharing arrangements are meant to provide incentives to improve a hospital's clinical performance and quality outcomes and to reduce its costs by paying the program participants a percentage of hospital cost savings for their discrete, identifiable contributions toward these goals. The AMA believes that there are both significant risks and significant benefits associated with gainsharing programs. While gainsharing attempts to promote hospital cost reductions by aligning physician incentives with those of the participating hospitals, these arrangements also potentially implicate current fraud and abuse laws. Thus, we strongly encourage CMS to proceed with caution as they evaluate whether to encourage the use of these programs in Medicare.

To date, the Office of the Inspector General (OIG) has issued seven favorable advisory opinions on gainsharing arrangements. When evaluating the risks posed by a gainsharing program, the OIG has focused on measures that promote accountability, adequate quality controls, and controls on payments that may change referral patterns. The OIG's primary concerns have been that gainsharing could result in (i) stinting on patient care; (ii) "cherry picking" healthy patients and steering sicker, costlier patients to hospitals that do not offer such arrangements; (iii) payments in exchange for patient referrals; and (iv) unfair competition (a "race to the bottom") among hospitals offering cost savings programs to foster physician loyalty and attract more referrals. Despite these concerns, however, the OIG has noted that properly structured gainsharing arrangements may offer opportunities for hospitals to reduce costs without causing inappropriate reductions in medical services or rewarding referrals of federal health care program patients.

The AMA believes that gainsharing has the potential to make such improvements in the health care system as: facilitating collaboration between physicians and hospitals; increasing efficiency and access to needed services by implementing quicker turn around time on procedure scheduling, and test results; providing a new source of funds to support quality initiatives; adding payment to augment physician fee schedules, improving the financial health of hospitals; and reducing the rate of growth in Medicare spending. However, the AMA remains concerned that gainsharing arrangements could harm the patient-physician relationship, produce illusory short-term cost savings at the expense of long-term health, limit access to the most appropriate care, increase hospital control over physicians, create

access problems for certain patients regarded as noncompliant or resource-intensive, and punish the physicians who treat them.

Physician input and partnership is vital to any gainsharing proposal, as physicians can best determine how to maintain quality while decreasing costs. Physicians have ultimate responsibility and legal liability for their patients' care and treatment. Thus, they have the most fundamental and essential role in determining and delivering the highest quality care that will also eliminate waste in the system. For this reason, the AMA believes that any gainsharing proposal must ensure that hospitals cannot make choices and implement strategies with which physicians must simply comply. Rather, hospitals must engage physicians as partners so that the most appropriate choices for patients, which will result in decreased health care costs, are implemented.

While the AMA strongly supports the need to eliminate wasteful health care costs, we remain concerned about gainsharing arrangements. The absence of actual regulatory language and the number of questions that are posed in the rule suggest that CMS does not have a clear idea of how it wants to proceed in this area. Many of these questions might be answered once CMS receives complete feedback on the six ongoing gainsharing pilot programs and it is therefore premature to write new regulations at this time.

Should CMS decide to create an exception for gainsharing arrangements; however, we encourage CMS to ensure that such an exception be very carefully targeted and limited. We hope that any proposal would guarantee that physicians retain control over their payments, rather than allowing hospitals or other entities to determine payment allocations. We would also encourage CMS to make certain that the exception not create incentives to cut back on patient care, limit the therapeutic choices available to doctors and their patients, create disincentives to treat patients with disabilities and chronic health conditions, or slow the development and diffusion of medical innovation.

PROFESSIONAL LIABILITY RVUs

The Balanced Budget Act of 1997 (BBA) required CMS to implement resource-based professional liability insurance (PLI) relative values by 2000, replacing the charge-based PLI relative values that had been in use since the inception of the RBRVS in 1992. To date, over ten years after enactment of the BBA, this has not occurred. CMS acknowledged in 2004 that the agency had not complied with statute and had retained charge-based relative values for all services paid via a professional component/technical component split (i.e., PC/TC services). Responding to a comment from the American College of Radiology (ACR), CMS further conceded that "technical component services do not have physician work relative value units (RVUs), they are still valued using charge-based RVUs instead of the resource-based malpractice RVU methodology. We look forward to working with the ACR and other interested specialty organizations to examine alternative methodologies that would allow technical component services to also reflect resource-based malpractice RVUs."

The RUC, ACR and other organizations have repeatedly requested that CMS address the overpayments in the TCs. CMS stated that resource-based PLI relative values for TCs could not be developed without specific data, and requested data related to PLI premiums for the technicians who perform the technical services. The RUC further encouraged all specialties to explore if such policies were purchased for this level of employee but was not provided with any premium data or other evidence that these policies were in place. The RUC then sent a recommendation (approved unanimously) urging CMS to set the PLI relative values for technical components at zero since no evidence exists that PLI premiums are typical for the employees that perform this service. The PLI relative values would then be appropriately redistributed within the RBRVS via a lower budget neutrality adjustment applied at the end of the methodology.

In the proposed rule, CMS states that as part of the update to the PLI RVUs in CY 2010, CMS will instruct its contractor to research available data sources for the PLI costs associated with the TC portion of these codes. CMS will also ask the contractor to look at what is included in general liability insurance versus PLI for physicians and other professional staff. If data sources are available, CMS will implement revised PLI RVUs for the TC of these codes in conjunction with the update of the PLI RVUs for the PCs in 2010. **We strongly caution CMS that general liability insurance premiums are included in the practice expense component. Any use of this data in the PLI component would be a duplication of payment. Further, we agree with the RUC that PLI RVUs removed from the TC portion of these codes should be redistributed across all physicians' services. Finally, we urge CMS to work with the RUC and its PLI Workgroup in reviewing the pending report of the contractor and to solicit comments and recommendations from the RUC and its workgroup to ensure that the 2010 PLI relative values are accurate.**

COMPUTER-GENERATED FAX TRANSMISSIONS

Proposed Amendment to the Exemption for Computer-Generated Facsimile Transmissions for Transmitting Prescription and Related Information for Part D-Covered Drugs

CMS proposes to extend the computer-generated facsimile transmissions exemption to allow for an exemption from the NCPDP SCRIPT standards for electronic prescription refill request transactions and to retain the current exemption in cases of temporary network transmission failures.

We urge CMS not to eliminate the current computer-generated facsimile transmissions exemption from the requirement to use the NCPDP SCRIPT standard in transmitting prescriptions or prescription-related information on January 1, 2009 and strongly recommend that this broad exemption remain in effect. We do not agree with limiting the exemption to just refill requests and network transmission failures. Prohibiting computer-generated facsimile transmissions would adversely impact the workflow and process of filling new prescriptions as well as refill requests. We believe that prescribing physicians and the industry as a whole will continue to move as quickly as possible to the

use of the NCPDP SCRIPT standard. Allowing prescribers and dispensers to continue to transmit prescriptions or prescription-related information by means of computer-generated facsimiles would enable the ongoing adoption of e-prescribing without significantly impeding existing prescription workflows at both the prescriber and dispenser ends.

The AMA also recommends the establishment of an Advisory Panel, comprised of both public and private stakeholders, to closely monitor e-prescribing adoption rates and the capabilities of the NCPDP SCRIPT standard with respect to all prescribers and dispensers, to provide solutions for further facilitating and encouraging the rapid adoption of e-prescribing, and to provide recommendations for the timing of lifting the computer-generated facsimile transmissions exemption

Section 132 of the *Medicare Improvements For Patients And Providers Act of 2008*: Incentives For Electronic Prescribing

Although the DEA recently published the long anticipated proposed rule on allowing e-prescribing of controlled substances, the proposed rule would impose multiple, stringent security, authentication and risk management requirements for e-prescribing controlled substances. The AMA is concerned that these additional requirements will require physicians to create two separate electronic workflows for e-prescribing: one for controlled substances and one for noncontrolled substances. Given the complexity, costs, and liability concerns associated with the DEA's proposed rule, physicians may be reluctant to adopt e-prescribing for controlled substances. **Moreover, the DEA has projected that it will take over 15 years for the adoption of e-prescribing of controlled substances. The AMA, therefore, strongly recommends that the Secretary use his discretionary authority as provided under MIPPA to exempt the e-prescribing of controlled substances from any assessment of penalties.** In order to enhance e-prescribing adoption and use rates, physicians should be entitled to receive incentive payments, regardless of whether they choose to e-prescribe controlled substances in accordance with the DEA's final rule and requirements. In addition, we strongly urge CMS to undertake an aggressive education and outreach program for physicians on the reporting requirements for eligible prescribers to receive incentive payments for e-prescribing well in advance of January 1, 2009, the effective date of the incentive payment program.

MEDICARE TELEHEALTH SERVICES

CMS is proposing new HCPCS G Codes to allow billing for follow-up inpatient consultations approved for telehealth services. Prior to 2006, follow-up inpatient consultations (CPT codes 99261 through 99263) were approved for telehealth. CPT 2006 deleted the follow-up inpatient consultation codes. Physicians and practitioners instead billed for these services using the codes for subsequent hospital care (CPT codes 99231 through 99233). For CY 2006, CMS removed the deleted codes for follow-up inpatient consultations from the list of approved telehealth services. Because there is currently no method for practitioners to bill for follow-up inpatient consultations delivered via telehealth, CMS is now proposing to create a new series of HCPCS codes for follow-up inpatient telehealth consultations.

The AMA has long been concerned about CMS' development of G codes instead of requesting the development and valuation of appropriate codes through the CPT Editorial Panel and the RUC. Development and valuation of codes through this regular process avoids massive billing confusion and ensures credibility of the coding process. There is an enormous amount of effort and expertise that is required by each specialty in developing coding proposals, conducting surveys to determine physician time and work, convening consensus panels, and determining appropriate direct practice expense inputs for each new CPT code that is created. The results of these efforts are then validated through multi-specialty groups of physicians, including CPT Advisors, the CPT Editorial Panel and the RUC. This process provides stability and credibility to the development of a code.

The AMA urges CMS to implement these proposed telehealth G codes as an interim measure while working expeditiously with the CPT Panel and the RUC to develop codes and relative values for inpatient consultations approved for telehealth services.

OTHER ISSUES—PHYSICIAN CERTIFICATION/RECERTIFICATION CODES FOR MEDICARE-COVERED HOME HEALTH SERVICES

CMS has requested in the proposed rule comments on policy options concerning payment and coverage requirements to ensure active physician involvement in the delivery of home health services. Specifically, CMS is considering: (i) a review of the RVUs associated with the certification (G0180) and recertification (G0179) of the home health plan of care (POC); and, (ii) proposing new requirements to ensure more active physician involvement in the certification and recertification of the home health patient's POC.

CMS initially created these codes in response to an Office of Inspector General (OIG) report, entitled *The Physician's Role in Medicare Home Health 2001* (Dec. 2001; OEI-02-00-00620), addressing physicians' practices in prescribing, certifying and monitoring Medicare home health services. This report found that physicians play a key role in Medicare's home health benefit. CMS states in the proposed rule that physician involvement is key to maintaining the quality of home health care, and thus is proposing a review of the above codes to ensure proper physician involvement in patients' home health care. We agree that physician involvement is critical; yet, it is not clear to us that physicians are not adequately involved in the home health care of their patients. In fact, the OIG report referenced above states that "[e]ighty percent of physicians report that they see their patients at least once a month while they are receiving home health services." Further, we do not believe that increased usage of the home health codes automatically implies that physicians are over-using the codes or are not adequately involved patient's POC. We also do not believe that an unwarranted reduction in the RVUs for these codes would improve physician involvement or the quality of patient care. In fact, to this end, CMS has separately requested that the RUC analyze the increase in home health codes and determine whether such increases are warranted. **Since this process is underway, we urge CMS to delay any policy changes with regard to these home health codes until the RUC has completed its review.**

POTENTIALLY MISVALUED SERVICES UNDER THE PHYSICIAN FEE SCHEDULE

CMS has requested that the RUC review potentially misvalued CPT codes, including a review of: (i) the fastest growing procedure codes; (ii) Harvard-valued codes; and, (iii) practice expense RVUs. **We appreciate that CMS has asked the RUC to undertake this review of potentially misvalued codes and we look forward to working with the RUC and CMS to assist in such review.**

IMMUNIZATION ADMINISTRATION

CMS has proposed to reject the RUC-recommended clinical staff time related to quality activities for immunization services. CMS stated that the "Mammography Quality Standards Act (MQSA) is not a regulatory requirement for immunization services." We agree that the MQSA is not applicable to immunization services. The RUC, however, referenced the MQSA as a similar clinical labor task and as a benchmark during its decision making process. Nevertheless, the RUC agreed that there is additional clinical labor time now associated with immunization services to reflect the work of maintaining a vaccine registry, and in monitoring and documenting refrigerator and freezer temperature logs/alarm systems. **Thus, we urge CMS to adopt the RUC recommendation that CMS include this additional clinical labor activity in the practice expense for immunization administration.**

INDEPENDENT DIAGNOSTIC TESTING FACILITY (IDTF) ISSUES

CMS is proposing in this section to require physician offices that provide diagnostic testing to enroll as IDTFs and comply with most of the standards now required of these stand-alone testing facilities. Under the most onerous version of this plan, use of even basic tests such as ultrasound and electocardiograms would subject the physician to completion of a lengthy application, on-site inspections, and proof of competency for each type of test that is performed. Both primary care and specialist physicians would be caught in the net.

In the AMA's view, this proposal is unnecessary and unwise. CMS has provided no data to support the need for yet another regulatory burden. The agency also acknowledges that it is "unable to determine" how many physicians and groups currently providing diagnostic testing "will be unable to meet these requirements and therefore have their billing privileges revoked." It then suggests that the requirement might be extended only to advanced imaging or to "more costly testing and equipment."

Even this narrower application is unwarranted, however, because subsequent to the rule's publication, Congress enacted legislation that will require all physicians providing the technical component of advanced imaging services to meet rigid new accreditation standards. Neither CMS nor physicians offices have the resources to deal with the largely overlapping goals and requirements of a more rigorous enrollment process and the new accreditation program. As a result, **CMS should abandon this proposal to treat**

physicians' offices as IDTFs and focus on ensuring a smooth implementation of the new accreditation standards mandated by Congress.

PHYSICIAN AND NON-PHYSICIAN PRACTITIONER ENROLLMENT ISSUES

Based upon ongoing conversations between the AMA and CMS over the past several years in which we have continuously expressed our concerns over the complexity and time associated with physician enrollment in Medicare, the changes to Medicare enrollment proposed by CMS are both disturbing and disappointing. **We strongly urge CMS to withdraw these proposals in its final rule.**

As we have communicated to CMS, we continue to receive reports from physicians that the current enrollment process is unduly confusing, time intensive, and bureaucratic. Changes to the effective date of billing privileges, eligibility to participate in the program, enrollment processing, and revocation of billing privileges will only exacerbate a bad situation. Our major concerns with the proposals are as follows:

- Changes are Unjustified: CMS has neither explained the rationale nor provided examples—whether program integrity-related or merely administrative in nature—that have prompted such sweeping changes to an already over-taxed enrollment process. These changes will provide marginal additional benefit to the agency while subjecting physicians to substantial administrative burden and creating yet another disincentive to participate in the program. We have already heard from physicians who have decided to stop taking any new Medicare patients following the implementation of the national provider identifier (NPI), which resulted in widespread requirements to re-enroll. In brief, these changes constitute "a lot aimed at the few," requiring all physicians to assume significant financial risk and shoulder the cost of slow processing by contractors at a time when many of the newly enrolling physicians are just beginning their practices and cannot afford such outlays.

- Changes are Unnecessary: Many of the proposed changes in this section are designed to conform enrollment policies for all physicians, especially those who provide imaging services, to changes that the agency previously adopted for IDTFs. However, the concerns that CMS has expressed could be addressed through other existing laws and the advanced imaging accreditation standards included in MIPPA.

- MAC Transition: CMS is proposing yet more changes to an already burdened enrollment process at a time when carriers are still in the midst of transitioning to Medicare Administrative Contractors (MACs). New MACs are subsuming leftover problems from old carriers and inheriting old contractor workloads. Adopting additional enrollment changes at this time leaves no room to accommodate the inevitable hiccups that occur with operational changes of this magnitude.

- Volume of Changes: Given the frequency with which CMS has changed its enrollment policies over the past several years, physicians and their staff struggle to keep on top of existing and changing requirements. The process is considered so convoluted that many physicians have to hire separate staff to help them become credentialed.

- PECOS Web Not Fully Operational: The CMS Internet-based enrollment system, Provider Enrollment, Chain, and Ownership System (PECOS) Web, has not yet been rolled out and no further policy changes should be implemented until this system is up and running successfully. CMS is placing an ever-expanding documentation and paperwork burden on physicians even though the program and its contractors are incapable of handling the current flow of required data. To place additional demands on a group of providers whose payment rates have been stagnant since 2001 without streamlining the process is counterproductive for CMS and the contractors as well as physicians.

For these reasons and the ones detailed below, the AMA firmly believes that any further changes to the enrollment process will only serve to make it more cumbersome. The proposals are ill-advised and likely to create widespread confusion and yet another barrier to physician participation in the Medicare program at a time when the agency should be implementing strategies to increase participation by physicians. Our specific concerns are described below.

Effective Date of Medicare Billing Privileges

While physicians are currently prohibited from billing Medicare prior to their enrollment date, the program has long permitted physicians to retroactively bill for services delivered to Medicare patients up to 27 months prior to enrollment. CMS has proposed removing physicians' ability to retroactively bill stating that "it is possible that physicians…who meet our program requirements on the date of enrollment may not have met those same requirements prior to the date of enrollment." For example, the rule suggests, some physicians may not have complied with beneficiary protections such as providing an advance beneficiary notice (ABNs) when the physician suspects that Medicare will not pay for a given service.

In its place, CMS has proposed two alternative approaches to establishing the effective date for physician Medicare billing privileges. The first option would prohibit physicians from billing before they are approved and enrolled by a Medicare contractor. The date of approval would be the date that the Medicare contractor determines the physician meets all federal and state requirements. Under the second option, which is only marginally better than the first, billing would be permitted following the later of two dates: (1) the date of filing of a Medicare enrollment application that was subsequently approved by the contractor; or, (2) the date an enrolled physician first started rendering services at a new practice location. The filing date would be the date the contractor receives a signed enrollment application that it is able to process to approval. Under both proposals physicians would remain financial prisoners of the Byzantine enrollment process and penalized given the time and resource intensive enrollment process.

The AMA is strongly opposed to removing a physician's ability to retroactively bill Medicare. CMS provides no evidence or data to demonstrate that a large percentage of physicians applying to participate in the Medicare program do not meet Medicare enrollment or other program requirements which would warrant the imposition of this hardship on all physicians. State licensing and other requirements already protect beneficiaries from the most important kinds of issues that could arise in medical care. Even after enrollment, physicians may inadvertently fail to provide an ABN or violate one of the other hundreds of Medicare regulations they are expected to obey. Simply adding another "gotcha" regulation to the mix will only make matters worse. If CMS really wants to help physicians comply with the program's requirements, it should consolidate and clarify its existing regulations and improve education and outreach to the physician community.

Removing a physician's ability to bill retroactively will create a barrier to entry into the Medicare program as well as medical practice since physicians would not be able to see Medicare patients while they await processing of the enrollment application. Moreover, as we have shared with CMS over the past several years, many physicians today continue to face serious financial hardship when enrollment applications or modifications are held up for a variety of reasons, many through no fault of their own. As CMS is also aware, the transition to the NPI was rife with unanticipated problems and hold-ups. For many physicians the NPI transition, a process closely linked to the Medicare enrollment process, continues to be a rocky transition for this reason. Furthermore, despite increased attention to the enrollment process and as acknowledged by CMS staff, backlogs still remain at some contractors and now are being absorbed by the new MACs. If the current retroactive billing policy is changed, more physicians will be forced to close their practices to Medicare patients—we have been told as much by several physicians who experienced severe processing delays related to Medicare requiring re-enrollment to establish a "good link" between their Medicare legacy numbers and their new NPI numbers.

The AMA remains concerned about the spotty contractor customer service records. We are constantly contacted by physicians who complain about their inability to get through to the contractor's customer service lines. And, when they are able to finally get through after hours, days, and sometimes weeks of trying, they are frequently given incorrect information about the status of their enrollment application. The customer service staff often do not have accurate information on physician enrollment, further undermining a physician's chances of having their application processed in a timely manner.

The AMA appreciates the need for physicians to submit complete applications. However, CMS must appreciate how convoluted this process is for physicians. It is neither straightforward nor easy to navigate. Although CMS guidelines require contractors to notify physicians within 15 days as to whether their application is missing information, this process is often overlooked or delayed well beyond the deadline. Based upon significant feedback from our members, enrollment staff commonly lose paperwork, further prolonging the process and resulting in physicians having to resubmit items multiple times. We have most recently received several inquiries from physicians who finally were able to get their applications approved just to find that the contractor sent them an acknowledgement letter

with incorrect information (i.e., listed incorrect specialty or address) resulting in additional steps the physician had to take to get this corrected.

Incidentally, CMS asserts that the new Internet-based PECOS enrollment system will be available to most states in early 2009. As CMS is aware, this is a long-anticipated application that we are hopeful will streamline some of the problems that exist in the current paper system. The AMA feels it would be naïve to assume that systems issues will not ensue with a system of this size and that it would be imprudent to impose significant policy changes leading up to and during this transition. Implementing a new electronic system will bring its own operational issues.

CMS has said it expects the Internet-based PECOS will reduce enrollment and changes in enrollment processing by the contractor from the 60-to-90 day range to a 30-to-45 day range. We are very supportive of reducing the processing timeframes and have long looked forward to a time when it will become operational. Aside from reducing the application-processing timeframes, we can see no reason for requiring massive policy changes at a time when this program is about to lift off. When contractors are able to establish a track record of quality customer service, and timely processing, and when CMS ensures the operational capability of Internet-based enrollment process, then the proposed changes may impose fewer burdens on physicians and their staff, but given the shortcomings of the existing enrollment process, removing retroactive billing is an ill-advised, draconian change.

The aforementioned proposed changes presented by CMS would financially penalize physicians for an enrollment process that remains unduly fragmented, provides uneven customer service, is marked by slow processing by select poor performing contractors, and is antiquated based on today's technological standards. More importantly, CMS has not identified the scope and significance of the problem presented to the Medicare program of the existing regulation. Unless and until CMS allocates additional resources—both technological and human—in order to significantly upgrade the enrollment infrastructure, this alternative would represent a significant deterrent to participation in the program. Furthermore, it confers contractors with an excessive amount of discretion that could impose significant financial and administrative hardship on individual physicians.

Medicare Billing Privileges and Existing Tax Delinquency and Denial of Enrollment in the Medicare Program

CMS indicates that it may, in the future, offer two separate proposals that would apply to physicians who have an existing federal tax delinquency. (The agency emphasizes that it is not proposing the following changes in this year's PFS, but will consider this issue for future rulemaking.) One proposed change would allow CMS to deny enrollment to a physician with a federal tax delinquency because the agency maintains "that it is essential that a physician...resolve any existing Federal tax delinquency before entering the Medicare program." CMS asserts that "[t]his will ensure that the Medicare program is not making payment to an individual who has not met his or her obligation to pay their tax debts." This proposal is irrational and not reasonably calculated to ensure that the federal government ever recovers the tax debt. It is not in the best interests of either the government or a

physician who may want to participate in the Medicare program but does not have the financial reserves to pay the tax debt all at once.

The proposal is counterproductive for the government because CMS also indicates in this notice of proposed rulemaking that it will utilize the Federal Payment Levy System (FPLS) process starting in fiscal year 2009 for Medicare payments made under Part A and Part B. Thus, if a physician participates in the Medicare program, the government is guaranteed to receive payment for the tax debt (subject to one exception addressed below) via FPLS. On the other hand, if a physician with a tax debt is denied participation in the Medicare program, the government's recovery of the debt could be difficult, indeed, particularly if other companies follow the government's example and the physician cannot secure employment until the whole tax debt is retired. Unless the agency has documented statistics that physicians who have a federal tax debt are, in fact, "detrimental to the best interest of the Medicare program," it should maximize the probability that the government will recover the tax debt by employing physicians with such a debt, thus ensuring collection of the debt under the FPLS while at the same time avoiding the creation of barriers that will reduce Medicare participation of new physicians needed to meet the growing medical needs of an aging population.

In addition, having seen the numerous problems that physicians and Medicare contractors are already having with what should be a relatively simple and easy process of enrolling in the Medicare program, we have no confidence that contractors can now appropriately expand their scope to also include federal tax delinquencies. These are matters for physicians and their accountants to resolve with the IRS and there is sufficient room for errors and misunderstandings already between these parties without adding Medicare contractors as a party to what may be disputatious issues. This proposal would add still more delays and confusion to a system that already leaves much room for improvement.

CMS also indicates that it is considering another change involving revoking the billing privileges of an already enrolled physician or taking some other type of administrative action when the physician has a tax delinquency that cannot be levied through FPLS because the physician has reassigned payment to third parties. We urge CMS to identify and propose progressive administrative action prior to revocation of billing privileges as part of any future rulemaking.

Reporting Requirements for Providers and Suppliers

The AMA is extremely concerned with the agency's proposal to establish what it characterizes as more stringent reporting requirements for physicians. Specifically, CMS proposes establishing its authority to revoke Medicare billing privileges if physicians fail to report a change of ownership, "any" adverse legal action, or change in practice location within 30 days. Our overarching concern rests on the unreasonably short period of time that will be afforded to physicians to report this information for the reasons detailed at length above vis-à-vis the enrollment process.

We are specifically troubled by the requirement that physicians report "any" adverse legal action. This is unreasonable and overbroad, as this would include adverse decisions in divorce proceedings, landlord-tenant disputes, and a host of civil actions that may have no relationship to the physician's participation in the Medicare program.

Furthermore, we strongly oppose conferring the agency with the authority to revoke billing for failure to report a change in practice location within 30 days. There are other administrative steps that the agency could take to ensure compliance with this requirement that would not involve subjecting a potentially large pool of physicians to significant financial risk. Certainly 30 days is an inadequate amount of time to report such information.

Finally, CMS indicates that physicians who do not report a move to a new location within 30 days are subject to overpayment recoupments retroactive to the date of any move from a more expensive to a less expensive payment area. We note, conversely, that CMS is also obligated to repay any monies owed physicians who move from a less expensive locality to a more expensive one retroactive to the date of the move as well.

Revocation of Enrollment and Billing Privileges in the Medicare Program

CMS also proposes to significantly curtail the current amount of time—up to 27 months—physicians whose billing number has been revoked may continue to bill for services furnished prior to the revocation. CMS now proposes that all outstanding claims not previously submitted must be submitted within 30 calendar days of the revocation effective date. This is patently unreasonable. First, it does not take into consideration when the physician receives actual notice of the revocation date. Under a number of proposed changes in this rule, the effective date of the revocation date could be well after 30 calendar days of the physician receiving actual notice. Second, 30 calendar days for submission of claims may be insufficient and inadequate under the best of times, but would be particularly difficult for a physician under duress who may have been burdened with production of documents, relocation, heightened contractor and agency review, and a drain on staff and administrative resources in the lead up to the revocation. Third, patient care services are often not so cut and dried that the billing for the entire episode of care can easily be wrapped up within 30 days.

CMS says they "know that some physician and NPP organizations and individual practitioners are able to create false documentation to support claims payment." The AMA is concerned again that CMS is overreacting with a policy that is aimed at a few but could affect many others—particularly if the agency also proceeds with its plans to revoke physician billing privileges for trivial infractions such as not providing a relocation notice within 30 days. We are also troubled that CMS is proceeding down this path based only on what it thinks physicians **are able to do** as opposed to any evidence that a significant number actually **have done** it. **There is a reasonable period between 27 months and 30 days and we urge the agency to provide physicians with up to 6 months to submit claims for services rendered prior to the revocation.**

OTHER ISSUES—REVISIONS TO APPEALS FINAL RULE

CMS proposes to change the appeals process to challenge the agency's revocation of a physician's billing authority as well as the effective date of the revocation. Under this proposal, the physician would receive no actual notice prior to the effective date of any revocation that is imposed because a physician is operating at a specific location, has a felony conviction, or has been subjected to license suspension or revocation. We do not agree that practice location should be treated as an urgent matter for what would be retroactive revocation of billing authority and urge CMS to withdraw this aspect of its proposal.

We have already detailed in the enrollment section of this comment letter our opposition to the proposed addition of failure to report practice location within 30 days as a basis for revoking billing authority. Our opposition to that proposed change is deepened by the prospect of revocation without prior notice. This proposal weakens physicians' due process rights and is a significant departure from current policy in which all revocations except those for federal exclusions or debarments are effective 30 days after CMS or its contractor mails notice to the physician.

To comprehend the full scope of the problem, it is important to understand that physicians whose billing privileges are revoked cannot reapply to Medicare for at least one year, and the clock for appealing their revocation starts on its effective date. Retroactive revocation therefore creates a situation where Medicare denies payment for services physicians have provided in good faith, reduces the time available for appeal and then locks the physician out of Medicare for at least a year. CMS proposes to create an expedited reconsideration process for revocations based on federal debarment or exclusion, felony conviction, license suspension or revocation, or failure to report a location change within 30 days. While we believe that at a minimum physicians must be provided an expedited reconsideration process, this does not begin to compensate for the diminished lack of notice and due process that would occur if the agency insists on retroactive revocations for such a minor infractions.

This change, if adopted, would represent a crippling hardship for many physicians. CMS has not provided a shred of evidence that failure to report a relocation within 30 days have led to significant overpayments by Medicare. Also, as the rule concedes, Medicare already can remedy any problems associated with billing area changes by simply recalculating the payment rates and collecting any overpayments. To add another major hassle for physicians who have continued to treat Medicare patients even in the face of stagnant payments and the annual threat of draconian cuts would only add insult to injury with little, if any, benefit to either taxpayers or Medicare patients.

ASP ISSUES

Medicare Part B covers a limited number of prescription drugs and biologicals (hereafter both referred to as drugs) that are physician administered. In 2005, Medicare began paying for Part B drugs using the average sale price (ASP) plus 6 percent. The ASP is currently calculated based on data reported quarterly to the agency by manufacturers.

In this proposed rule, CMS modifies the ASP regulations to reflect a new volume weighted formula required by the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) and implemented on April 1, 2008. In addition, CMS proposes to continue to utilize a 5 percent threshold when evaluating whether or not to disregard ASP for a drug that exceeds the widely available market price (WAMP) or the average manufacturer price (AMP) for the drug. CMS notes that it does not have data suggesting a more appropriate threshold or the impact of the MMSEA changes.

The AMA agrees with CMS's decision to maintain the 5 percent threshold and retain the current ASP plus 6 percent payment rate for physician-administered drugs. We are aware that the Office of the Inspector General (OIG) did a comparison simulating the use of the new ASP formula and projected annual savings of $13 million if payments for the 35 drugs that exceeded the 5 percent threshold were reduced to AMP plus 3 percent. However, this analysis did not reflect the actual implementation of the new formula and does not take into account the impact that payment reductions could have on small practices that do not have the purchasing power to demand drug manufacturers' and wholesalers' lowest price.

We have previously cited MedPAC reports indicating that "most physicians" reported that they cannot purchase some drugs at the ASP payment rate." Rather than making further payment reductions, CMS should identify the types of practices or categories of drugs where Medicare is not covering physicians' costs and propose legislation or regulations to create an exceptions process or other means of addressing this problem.

Since the ASP includes discounts such as those for bulk purchases, small physician practices are finding it increasingly difficult to continue providing physician-administered drugs. This is particularly true where these and other discounts are not passed along to the physician, but may be provided by the manufacturer to a wholesaler or some other "middle man." In MedPAC's January 2007 report on the *Impact of Changes in Medicare Payments for Part B Drugs*, the physicians surveyed by the Commission consistently indicated that "large practices were better able to adapt to the payment changes than smaller practices." MedPAC noted that "larger practices were better able to negotiate lower drug prices" and "achieve economies of scale" than small practices. This means that smaller practices over time will be pushed out of the market. This diminishes access since over 50 percent of physician practices have five physicians or less yet account for 80 percent of outpatient visits.

In addition, according to MedPAC, certain specialties have been particularly hard hit, including oncologists, urologists, and infectious disease specialists. MedPAC reported urologists and infectious disease specialists provided fewer physician-administered drugs in their offices in 2005 than in 2004. Physicians, particularly oncologists, report spending considerable time and staff resources seeking to secure patients' drugs at ASP payment rates.

A recent analysis of access to drugs in the *Journal of Clinical Oncology* 26: 2008, entitled "An examination of oncology drug purchasing compared to average sales price," provides further evidence. Reportedly, drug costs make up approximately 70-85 percent of expenses

for community oncology practices. The study examined the buying power of 20 community oncology practices ranging from 1 to 18 physicians relative to ASP in the second and third quarters of 2007. The researchers found that the median pricing data submitted for all 12 of the drugs they studied were higher than ASP. The minimum price for 5 of the 12 was higher than ASP and the maximum price for 8 out of 12 was higher than ASP plus 6 percent.

The average product difference in price between practices was $84.41. The 20 practices reported multiple different prices for individual products ranging from 14 up to 19 unique prices for a given product. The researchers found that few of the practices were able to negotiate prices below ASP and many practices paid prices above ASP plus 6 percent reimbursement for key products. The researchers concluded that this economic strain combined with inadequate reimbursement limits patient access to care when practices are forced to turn away patients or go out of business. The researchers also concluded that there was a wide variance of pricing occurring in community oncology and that this variation is a signal of a highly fragmented market in need of unity to gain buying power and pricing visibility.

In addition to the foregoing, urologists must contend with an additional payment requirement—the "least costly alternative" policy—which applies to payment rates for certain drugs utilized by urologists to treat advanced prostate cancer and further complicates problems with ASP rates for this specialty. We urge CMS to exercise its discretion to ensure that the ASP does not systematically short change small physician practices or particular specialties.

CAP ISSUES

As required by Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), in 2005 CMS developed and implemented the Competitive Acquisition Program (CAP). CAP was designed to be an alternative to payments based on the ASP plus 6 percent. Physicians who elect to participate in CAP obtain Part B drugs from a CAP vendor. The vendor purchases a large volume of drugs, thereby utilizing its bargaining power to negotiate lower prices from manufacturers. In theory this is supposed to help small practices that are unable to purchase drugs at the ASP rate. However, as we have commented previously, the program has proven to be overly restrictive and administratively burdensome. CMS now proposes a number of changes regarding the annual CAP vendor payment amount update and the restriction on physician transportation of CAP drugs.

As a threshold matter, we remain concerned about the viability of CAP as an alternative to ASP. Currently, there is a single CAP vendor, Bioscrip, Inc., and it has reported publicly that it plans to exit the program at the end of 2008. The stated rationale for withdrawal is Bioscrip's belief that the proposed terms of the new CAP contract present an unacceptable short- and long-term profit risk to its business. The fact that there was only one vendor in 2008 and it has elected to exit the program may leave physicians with no alternative to Medicare payments that do not cover their costs and also suggests that vendors did not believe that the CAP payment which is tied to the ASP based payment was adequate. The payment amount for drugs furnished during the first year of an approved CAP vendor's

contract are set through a competitive process using bidders' prices *limited* by the ASP based payment amount which is subsequently updated based on a vendor's reasonable net acquisition cost. This may depress payment in the first year so much that it deters an adequate number of vendors from participating. This underscores the challenges faced by physicians in obtaining the drugs based on the ASP payment amount. As discussed more fully in the ASP ISSUES section, we believe that the current payment levels for many covered Part B drugs remains inadequate and is adversely impacting patient access.

CMS proposes to ease the restrictions on physician transport of CAP drugs to settings other than a participating CAP physician's office. We had previously strongly urged CMS to exercise its discretion to allow physicians to transport CAP drugs including to satellite offices or to administer to patients in their homes or other placements because the prohibition is overly restrictive and has an adverse impact on rural clinics and other physician satellite offices in underserved areas. **It would be reasonable and sufficient for physicians to certify that drugs will "not be subjected to conditions that will jeopardize their integrity, stability or sterility while being transported" and the appropriate steps will be taken "to keep transportation activities consistent with all applicable laws and regulations."** We believe any additional requirement laid out in regulation will only create additional administrative burdens with little attendant benefit

As other commenters noted during the prior rule-making process, physicians and their staff are knowledgeable and capable of ensuring the proper transport and maintenance of the covered drugs. **We urge the agency to require CAP vendors to allow those physicians who elect to transport CAP drugs (and file the necessary certification described above) to do so.** This takes on particular importance where there is only one vendor. If Bioscrip, Inc., or some successor is not willing to voluntarily allow physicians to transport the covered drugs, then physicians cannot shop around to find a vendor who will permit such transport. The end result is the same: physicians in underserved and rural areas are likely to be the most adversely impacted. CMS should take steps to ensure that a physician's ability to provide necessary care is not impaired, because such a restriction is a significant deterrent to greater physician interest in the CAP as an alternative of ASP.

The AMA appreciates the opportunity to provide our views on these critical issues, and we look forward to working with CMS to achieve consensus on the foregoing matters and develop payment and quality improvement policies that maintain Medicare beneficiary access and improve their quality of care.

Sincerely,

Michael D. Maves, MD MBA