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Marilyn B. Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: Payment Policies Under the Physician Fee Schedule for CY 2013; Proposed Rule; 77 *Fed. Reg.* 44,722 (July 30, 2012); CMS-1590-P

Dear Acting Administrator Tavenner:

The American Medical Association (AMA) appreciates the opportunity to provide our comments regarding the Centers for Medicare & Medicaid Services' (CMS) proposed physician fee schedule rule for calendar year (CY) 2013. Our detailed comments are set forth below and our principal recommendations are as follows:

PHYSICIAN QUALITY REPORTING SYSTEM

- **Regarding criteria for satisfactory reporting using the electronic health record-based reporting mechanism for the 2014 incentive payment, we urge CMS to consider a third option: eligible professionals (EPs) would report six clinically relevant clinical quality measures (CQMs), covering at least two domains. If an EP does not have clinically relevant measures, the EP's system must demonstrate zeros in the denominator for six measures covering at least two domains.**

- **The AMA urges in the future that CMS: (i) require the Measure Applications Partnership (MAP) to provide CMS with more explanation for each of its recommendations; (ii) include more information about measure recommendations in proposed rules so there is better opportunity for the public to comment on these recommendations; and (iii) develop an informal process that allows the MAP more time to assess measures and make its recommendations.**
- **The AMA urges CMS to allow individual reporting even if the individual practices in a group that participates in the Physician Quality Reporting System (PQRS) under the Group Practice Reporting Option (GPRO).**

VALUE-BASED PAYMENT MODIFIER

- **The AMA continues to believe that Congress did not provide adequate time for the development and implementation of a value-based modifier (VBM) and that CMS has exacerbated this problem by basing the 2015 modifier on physician performance in 2013, effectively advancing the congressionally-mandated implementation date by two years.**

- **We are pleased that the proposed rule would limit potential payment reductions stemming from the VBM to 1 percent, but at a time when physicians already face PQRS, e-prescribing, and a 2 percent sequester-related reduction, even a 1 percent VBM cut poses some risk.**

- **Although Congress stipulated that the VBM should be applied to all physicians by 2017, experience in the private sector suggests that targeting physicians in every specialty, every community, and every type of practice is neither practical nor cost-effective. CMS' proposed rule goes well beyond private payers' initiatives and should be scaled back considerably.**

- **The proposal to initially apply the VBM to all groups with 25 or more practitioners could affect hundreds of thousands of physicians and should be replaced with one that would apply the VBM only to multi-specialty groups with 100 or more physicians (MDs/DOs) and to those single specialty or smaller groups that request to be included.**

- **Physicians within a group should have the option of avoiding a VBM penalty by participating in PQRS as individuals rather than as a group.**

- **We support CMS' decision to add a PQRS administrative claims option because it gives physicians a low-burden method of avoiding PQRS and VBM penalties. We also support automatic application of the administrative claims measures to unsuccessful PQRS participants so that they could avoid the penalties too.**

- **The AMA is opposed to lowering the minimum number of cases required for inclusion of measures in the VBM calculation from 30 to 20. We believe that additional analysis is needed to determine the most appropriate attribution method and that CMS' risk adjustment tool must be improved before the modifier is applied to small and mid-sized practices.**

PHYSICIAN FEEDBACK PROGRAM

- **We appreciate CMS' outreach to the physician community and have provided a number of recommendations for improving the distribution, content, and utility of these reports. A key take-away from our involvement in the distribution of reports**

to physicians in Iowa, Kansas, Nebraska, and Missouri is that an unprecedented education campaign will be needed to make physicians aware of the reports and the VBM.

PHYSICIAN COMPARE

- **The AMA strongly urges CMS to not adopt the 20-patient minimum threshold for reporting performance information on Physician Compare.**

- **We object to CMS listing the names of the groups for which CMS is not issuing a performance report on Physician Compare. In addition, CMS should clearly and prominently state on Physician Compare that certain groups are not included in the performance reports for various reasons, including that: (i) the requirement to develop a performance report does not apply to all groups, and therefore if a report is not available for a particular group, this in no way reflects the performance level of that group; or (ii) some groups are not covered due to lack of available measures that would apply to the groups' patients or due to lack of data on a particular measure.**

- **The AMA urges CMS to adopt the alternative proposal to provide group practices with confidential data and the opportunity to review their data and make any necessary changes before moving to public reporting on Physician Compare. Practices should also have the opportunity to re-survey patients before any data is publicly reported.**

ELECTRONIC PRESCRIBING

- **We support upgrading electronic prescribing (e-prescribing) standards under the Medicare Part D prescription drug benefit program in order to improve existing standards and enable new e-prescribing functionalities.**

- **We recommend that CMS work to finalize the remaining e-prescribing standards, including the one for prior authorization, and consider the Health Insurance Portability and Accountability Act (HIPAA) mandated ASC X12 278 5010 standard transaction to provide an automated solution for all types of prior authorization, including pharmacy.**

- **We support reducing the minimum GPRO threshold from a minimum size of 24 to two.**

- **We recommend that CMS either establish a reporting threshold of 75 for those practices between 2-24 EPs or simply revert to the reporting parameters established in 2011.**

- **We support the proposal to add additional exemption categories to protect physicians who have registered or attested for the meaningful use EHR program from e-prescribing penalties. The categories should be broad enough to cover any physician who has registered or attested for meaningful use in years 2011, 2012, or 2013.**

- **CMS should add an e-prescribing exemption category for physicians at or near retirement age.**

- **We strongly recommend that the deadline for filing for hardship exemptions to avoid the 2013 e-prescribing penalty be extended to October 31, 2012 (or the effective date of the final 2013 physician fee schedule rule, whichever is later), and that the October 31 deadline apply to <u>all</u> of the hardship exemption categories available to physicians.**

- **The deadline for filing for an exemption from the 2014 e-prescribing penalty should be extended to October 31, 2013.**

- **We strongly support the establishment of an informal review/appeal process for the e-prescribing program, and recommend that CMS allow physicians up through March 31, 2014, to request a review/an appeal regarding the 2012, 2013, and 2014 e-prescribing incentive and penalty programs.**

- **We recommend that physicians who make a good faith effort to e-prescribe and report on their e-prescribing activity or attempt to file for an exemption, but due to an administrative, operational, or technological impediment end up with a penalty, be able to present their case to CMS and be protected from e-prescribing penalties.**

<u>MULTIPLE PROCEDURE PAYMENT REDUCTION</u>

- **The AMA opposes extension of the multiple procedure payment reduction (MPPR) policy to the technical component of certain diagnostic cardiovascular and ophthalmology services because CMS' assumptions about potential efficiencies are overstated due to an inaccurate methodology and the codes at issue are not commonly billed together.**

<u>CARE COORDINATION</u>

- **The AMA applauds CMS' proposal to implement Medicare payment in 2013 for care management services when a physician coordinates a beneficiary's care in the 30 days following discharge to the community from an inpatient hospital stay, skilled nursing facility (SNF) stay, and specified outpatient services.**

- **Current Procedural Terminology (CPT) codes and AMA/Specialty Society RVS Update Committee (RUC) recommendations related to the resources required to provide these care management services will be available for the 2013 Medicare physician fee schedule, and the AMA urges CMS to adopt these CPT codes for the newly-covered care management services rather than the G-codes CMS has proposed.**

POTENTIALLY MISVALUED CODES

- **If CMS has concerns that a code or group of codes with higher volume have overstated evaluation and management (E/M) work within the payment, the agency should work with the RUC to review these services.**

ELIMINATION OF REQUIREMENT FOR TERMINATION OF NON-RANDOM PREPAYMENT COMPLEX MEDICAL REVIEW

- **The AMA recommends that CMS retain its requirement that a contractor must terminate prepayment review once physicians have lowered their error rate or one year has passed to avoid the placement of physicians on perpetual prepayment review.**

DURABLE MEDICAL EQUIPMENT (DME) FACE-TO-FACE ENCOUNTERS

- **We strongly urge CMS to revise its proposal and finalize the six-month period preceding the order as an allowable time frame for the face-to-face encounter, as authorized by Congress.**

CERTIFIED REGISTERED NURSE ANESTHETISTS AND CHRONIC PAIN MANAGEMENT SERVICES

Because chronic pain management poses potentially serious patient health and safety risks, and because Certified Registered Nurse Anesthetists (CRNAs) do not possess the requisite education and training to manage those risks, the AMA strongly urges CMS to rescind its proposal to reimburse CRNAs for chronic pain management services. We are also highly concerned that the proposed regulatory text is far broader than stated in the preamble.

PHYSICIAN QUALITY REPORTING SYSTEM

PQRS Penalties

CMS is continuing to propose 2013 and 2014 as the performance years on which the agency will base penalty payments in 2015 and 2016, respectively, for unsuccessful PQRS participation. To avoid PQRS penalties in 2015 and 2016, CMS proposes two additional reporting options. These options include: (i) reporting one PQRS measure or measures group

using the claims, registry, or EHR-based reporting mechanisms during the 12-month reporting period (2013 and 2014, respectively); or (ii) elect an administrative claims-based reporting option for a proposed set of administrative claims-based measures. This proposed mechanism would not require an EP to submit quality data codes (QDCs) on Medicare Part B claims. Instead, CMS would extract data from claims EPs already submitted for purposes of Medicare billing. Although these proposed reporting options would exempt an EP from PQRS penalties, they do not allow an EP to qualify for an incentive payment during the 2013 and 2014 reporting periods.

The AMA appreciates these new proposed reporting options for purposes of avoiding PQRS penalties, and we agree these options are necessary to broaden participation in the PQRS and allow physicians an opportunity to gain experience with this reporting program, especially since 2013 is the performance year for penalties that are statutorily set to apply two years down the road. We recognize the second option, i.e., the administrative claims-based reporting option, may not produce meaningful data, but we support this option since CMS must balance the goals of allowing physicians to successfully participate in the PQRS (and for a majority of physicians, 2013 would be the first year they participate in the program) and improving quality of care through the use of meaningful data.

Additional PQRS Reporting Option

CMS should use its authority, as provided under the Medicare Improvements for Patients and Providers Act of 2008, to establish a process that allows physicians and other eligible professionals to be deemed successful PQRS participants if they successfully participate in other meaningful quality improvement activities. The process should also be sufficient for assessing quality measure performance under the VBM program. Some physician practices are reporting on specific quality measures to facilitate improved patient outcomes at the local level, through a regional health improvement collaborative or state-initiated health care improvement programs. Many of these efforts have been successful, allowing these practices to appropriately measure and improve upon those health care services and treatments most relevant to their communities, e.g., diabetes, maternity care, HIV. CMS should have the authority to identify a deeming entity, such as Quality Improvement Organizations (QIO), that would determine if a physician practice successfully participated in a regional or local quality improvement program. CMS then could deem approved practices as having met the quality measure requirements for the PQRS, VBM, and meaningful use programs. A deeming process would allow meaningful quality improvement efforts at the regional and local level to move forward unencumbered by conflicting federal requirements.

Criteria for Satisfactory Reporting Using EHR-Based Reporting

Under the proposed rule for the Medicare EHR Meaningful Use Incentive Program (EHR Incentive Program), CMS proposed options for meeting the CQM component of achieving meaningful use beginning with CY 2014. To align the PQRS EHR-based reporting

requirements with those proposed under the Medicare EHR Incentive Program, CMS is proposing the following criteria for satisfactory reporting using the EHR-based reporting mechanism for the 12-month reporting period for the 2014 incentive payment:

> *Option 1a:* EPs would select and submit 12 CQMs available for EHR-based reporting (from Tables 32 and 33 in the proposed rule), including at least 1 measure from each of the following 6 domains: (1) patient and family engagement; (2) patient safety; (3) care coordination; (4) population and public health; (5) efficient use of healthcare resources; and (6) clinical process/effectiveness.
>
> *Option 1b:* EPs would submit 12 CQMs composed of all 11 of the proposed Medicare EHR Incentive Program core CQMs (specified in Tables 32 and 33 of the proposed rule), plus 1 menu CQM (from Tables 32 and 33).

CMS intends to finalize reporting criteria that aligns PQRS program requirements with the CQM component of the Medicare EHR Incentive Program for CY 2014, including making adjustments that may be needed in accordance with the final criteria for meeting the CQM component of the EHR Incentive Program. Therefore, EPs who participate in both PQRS and the EHR Incentive Program, will be able to use one reporting criterion, during overlapping reporting periods, to meet the satisfactory reporting criteria under PQRS and the CQM component of the Medicare EHR Incentive Program.

As the AMA commented concerning CQM reporting under Stage 2 of the EHR Incentive Program, requiring EPs to report on 12 measures is too many and undermines the quality improvement intent of the program. Many of the measures are heavily weighted towards primary care and preventive medicine, which would make it difficult for some sub-specialties to find 12 CQMs to track. Many physicians will be forced to report zero values for many of the measures, which significantly undermines the utility of this process.

Further, we are concerned about both options 1a and 1b. Under option 1a, it would be difficult to identify CQMs that apply broadly across various medical specialties, and therefore some medical specialties would have trouble identifying 12 relevant measures on which to report. This is especially true with the requirement of identifying a measure from each of the six domains since some of these domains have a very limited number of measures.

We are also concerned that Option 1b would pose a significant challenge in identifying 11 "core CQM" measures relevant to all EPs. This option would also undermine meaningful reporting since many EPs would be forced to report on measures that are not fully relevant, with a very small or nonexistent denominator value.

Because of these difficulties with the proposed options, we urge CMS to consider a third option: EPs would report six clinically relevant CQMs, covering at least two domains. If an EP does not have clinically relevant measures, the EP's system must demonstrate

zeros in the denominator for six measures covering at least two domains. This would be a much more feasible option that would help ensure EPs can identify measures relevant to their specialty.

Selection of Proposed PQRS Quality Measures for 2013 and Beyond

In discussing the selection of PQRS measures, CMS states that no special restrictions on the type or make-up of the organizations carrying out the basic process of development of physicians' measures are needed, such as restricting the initial development of measures to physician organizations. The AMA is very concerned about CMS' view, and we urge CMS to reconsider. **It is critical that PQRS measures have the benefit of multi-stakeholder input at all stages—from development to endorsement—especially from the physicians who ultimately are the end-users of a measure.** This is necessary to ensure measures are relevant to a particular specialty along with development of a quality reporting program that physicians are confident will improve the quality of care.

Quality Measures Not Being Retained for 2013 and Beyond

CMS proposes to add new quality measures, and, in Table 31, lists measures it proposes not to retain for 2013 and beyond, based on recommendations by the MAP. The MAP is a public-private partnership convened by the National Quality Forum (NQF) to provide input to the Department of Health and Human Services (HHS) on the selection of performance measures for public reporting and performance-based payment programs.

The AMA acknowledges that this is the first cycle of MAP recommendations for PQRS measures, and that this process occurs under a very short statutory timeframe that does not facilitate in-depth explanations for its recommendations. In the proposed rule, CMS simply states that it agrees with the MAP's assessment to not retain measures in Table 31, but does not offer any other explanation. **The AMA urges in the future that CMS: (i) require the MAP to provide CMS with more explanation for each of its recommendations; (ii) include more information about measure recommendations in proposed rules so there is better opportunity for the public to comment on these recommendations; and (iii) develop an informal process that allows the MAP more time to assess measures and make its recommendations. In addition, the AMA urges CMS to provide the MAP with additional information regarding the agency's rationale for proposing certain measures for the MAP's review.**

PQRS Group Practice Participation

CMS proposes that if a group practice participates in the PQRS as a GPRO, the EPs in the group practice cannot participate in the PQRS individually. **The AMA has strong concerns about this proposal, and for the following reasons we urge CMS to allow individual reporting even if the group is participating in the PQRS under the GPRO:**

- Currently, such individual reporting is permitted, and it is important to preserve this option so that EPs can individually report on measures most clinically relevant to their particular practice.

- Such individual reporting is critical for promoting alignment among the PQRS, VBM, and the EHR Incentive program. If EPs in a group practice (that participates as a GPRO) cannot participate individually, the PQRS would be out of sync with Stage 1 of the Medicare EHR Incentive Program. Stage 1 does not have a GPRO, and therefore EPs have to report individually. Further, even though Stage 2 has a group practice option (beginning in 2014), it only applies to Medicare, not Medicaid.

- Removing the individual reporting option for EPs whose group participates as a GPRO will have a chilling effect on registry reporting. Currently, when large groups participate as a GPRO, individual EPs in the group may continue to report to separate registries that are relevant to their practice. This data is important to collect, and therefore CMS should support registry reporting by permitting this practice to continue.

CMS also proposes that when a group practice changes its Tax Identification Number (TIN) within a PQRS program year (e.g., a group practice may undergo a mid-year reorganization that leads to the group practice changing its TIN mid-year), the group practice cannot continue to participate in PQRS as a GPRO. **The AMA urges CMS to continue to allow groups that change their TIN to continue participating in the PQRS. In this case, CMS could continue measurement across more than one TIN for the group.** Otherwise, these groups could be hit with huge PQRS and VBM penalties. CMS suggests that EPs in a group practice that has changed its TIN within a year may still participate as individuals. Yet, this may not be feasible or could be a huge burden depending on when the group changes its TIN during the year. This proposal would create a significant incentive for groups not to reorganize or merge with other groups at a time when such reorganizations may be necessary for groups to meet their quality improvement goals.

Measures for Cardiovascular Disease Prevention

To support the Million Hearts initiative and maintain a focus on cardiovascular disease prevention, CMS is proposing "individual PQRS Core Measures" (specified in Table 29 of the proposed rule) for 2013 and beyond. These measures are the same measures that were finalized under the 2012 PQRS in the CY 2012 Medicare Physician Fee Schedule final rule. CMS notes in the proposed rule that although these measures serve as core PQRS quality measures, CMS is not proposing to require that EPs report on these proposed PQRS core measures. The AMA supports the Million Hearts initiative and cardiovascular disease prevention. **We recommend, however, that CMS avoid labeling these measures as "core" measures since this term is very specific to the EHR incentive program and is synonymous with "mandatory" measures.** Use of this term in the PQRS program for measures, especially those that are not "mandatory," could cause significant confusion.

Requirements for an EHR Vendor's Products

For 2014 and beyond, CMS is proposing to no longer: (i) require qualification of EHR products in order to be used for reporting under the PQRS; and (ii) qualify EHR data submission vendor products in order to use such products under the PQRS.

These proposals will cause an undue burden on EPs. It is not reasonable to ask EPs to determine whether an EHR product can produce the required file in appropriate format and submit to CMS. Many EPs, particularly small physician practices, will not have the technical resources to determine if a particular vendor's products meet CMS requirements. Additionally, if there is a disagreement between the vendor and CMS as to whether the vendor meets CMS requirements, it will be difficult for each EP to verify the vendor's capability to meet CMS requirements. (This could also be a burden on vendors, which could potentially trickle down to the physicians as increased costs).

The AMA urges CMS to continue to require the qualification process at least until such time as the Office of the National Coordinator for Health Information Technology (ONC) certification process can be used for both the Medicare EHR Incentive Program and PQRS. Further, the ONC certification process should only be used for both the PQRS and the EHR Incentive Program if the reporting parameters, i.e., the measures, specifications and reporting format, are identical.

Use of Quality Reporting Data Architecture as a Reporting Standard

CMS proposes that, although EHR data submission vendor products would no longer be required to undergo the testing and qualification process, as referenced above, CMS would only accept data if the data are: (i) transmitted in a CMS-approved XML format utilizing a Clinical Document Architecture (CDA) standard such as Quality Reporting Data Architecture (QRDA) level 1 and for EHR data submission vendors who intend to report for purposes of the proposed PQRS Medicare EHR Incentive Program pilot, if the aggregate data are transmitted in a CMS-approved XML format; and (ii) in compliance with a CMS-specified secure method for data submission.

The AMA supports use of a standard reporting structure in XML. The QRDA Level 1 should be able to capture quality measure information for patients and types of measures where the analysis is something other than the patient (e.g., final radiology reports or procedures requiring prophylactic antibiotics). We support testing of these named standards for all measures within various products.

Nationwide Health Information Network

As CMS recognizes in the proposed rule, the agency has not traditionally collected data received via a direct EHR product through the Nationwide Health Information Network (NwHIN), but CMS encourages this method with EHR-based reporting. **The AMA does not**

support use of the NwHIN as a means to collect PQRS data until such time as it is a fully supported network with a dedicated funding stream to maintain the network. Until this happens, it should not be considered as a means to receive PQRS quality measure data via a direct EHR product.

Definition of Direct EHR

CMS proposes to define an EHR data submission vendor as "an electronic health record vendor's product and version that acts as an intermediary to submit data on Physician Quality Reporting System measures on behalf of an eligible professional or group practice." Under the Medicare EHR Incentive Program, modules can be certified for quality reporting. **The AMA recommends that a certified quality reporting module also be considered as a direct EHR product for purposes of submitting PQRS measures to CMS.**

Registry Measures Groups

CMS has proposed to set the threshold for measures groups reporting via registry at the same level for six and 12-month reporting, i.e., report at least one measure for at least 20 patients (for each measures group). We urge CMS to clarify that it will not limit the bonus payment to a six-month amount if the 20 cases fall in the last six months of the year. Physicians who meet the 20 patient target should receive a full 12-month reporting period incentive payment, regardless of when their 20 cases were seen. Registries often are not prepared to initiate contracts with physicians and begin accepting data until fairly late in the reporting year, anywhere between April and July. This is due in part to CMS' testing requirements for registries. **Therefore, CMS should base bonus payments on a 12-month reporting period.**

Registry Based Reporting for 2013 and Beyond

CMS proposes that registry self-nomination statements must be submitted by January 31, 2013. **The AMA urges CMS to extend this deadline, especially if a registry is submitting its self-nomination via regular U.S. mail.** CMS has developed and is proposing new criteria that a registry must meet, and therefore a registry will need time to make any needed changes and submit its statement to CMS.

CMS also proposes that a registry must be able to separate out and report on Medicare Part B fee-for-service patients. **We urge CMS to clarify how a registry should achieve this criterion since registry reporting involves reporting on all patients, not just Medicare.**

Finally, CMS proposes that a registry must perform the validation outlines in a "validation strategy" and send the results to CMS by June 30 of the year following the reporting period. **The AMA urges CMS to clarify the specific "results" CMS is proposing that a registry must submit.** Without more specificity, a registry runs the risk that it will not send the exact "results" CMS expects, and in that case would not be qualified as a registry.

PQRS Measure Classification

The AMA recommends that CMS re-classify PQRS Measure 19: Communication with the Physician Managing Ongoing Diabetes Care. CMS has classified this as a Clinical Process/Effectiveness measure, set forth in Table 30, yet it is more appropriate to classify it as a Care Coordination measure. The measure requires that the ophthalmologist who performs an annual retinal exam on a patient with diabetic retinopathy communicate the results of the exam to the primary care physician overseeing care for the patient's underlying condition: diabetes. This is the specific type of activity (communication and coordination between primary care and specialists) that CMS seeks to address through the care coordination domain. As the measure domains begin to play a bigger role in Medicare quality programs, it will be particularly important that this measure is appropriately classified.

Measure Tables for 2013 and 2014

The AMA has numerous comments about the measures included in Table 29 through Table 34. Our comments on these measures are included in **Attachment 1** at the end of this comment letter.

VALUE-BASED PAYMENT MODIFIER

General

Although the law does not require implementation of the VBM until 2015, CMS is proceeding with last year's decision to base 2015 VBM-generated payment adjustments on physician performance in 2013. As permitted in the law, the proposed rule would implement the VBM in steps starting with inclusion of all groups of 25 or more. Non-MD/DO practitioners eligible to participate in PQRS would not be subject to payment adjustments, but would be counted in determining group size, potentially lowering the MD/DO threshold to well below 25.

To avoid a penalty in 2015, affected physicians would need to ensure that their group registered by January 31, 2013, to participate in one of the PQRS group reporting modalities and then successfully completed the requirements associated with that modality. Those who wished to reduce the burden or eliminate the possibility of being found to be an unsuccessful PQRS participant could elect an option that simply authorizes CMS to compile a performance report based on data from the claims filed for billing purposes. Physicians in groups that were not successful PQRS participants would face a 1 percent cut in 2015 Medicare payments. Those that were successful could choose to be held harmless with neither a positive nor a negative VBM payment adjustment in 2015. Or they could choose to be evaluated through a three-tiered system that would incorporate both costs and quality. Those in the low tier would face 1 percent pay cuts; those in the middle would see no change;

and those in the high tier would receive an as-yet-undetermined increase. Some groups participating in the tiering system would also be eligible for an additional 1 percent increase for treating "high risk" beneficiaries.

Costs would be calculated based on the group's risk-adjusted costs per beneficiary for all services and for four chronic conditions (COPD, CHF, CAD and diabetes). In addition to PQRS participation, quality would be judged according to the group's performance on several community-based outcome measures related to increasing the frequency of post-discharge visits and reducing potentially preventable hospital admissions and readmissions.

Initial Performance Period

As the AMA has repeatedly pointed out, CMS is not required to base the 2015 VBM payment adjustments on what physicians did or did not do in 2013, and there are alternatives that would make a later performance period feasible. We do not see how it will be possible to make all of the affected physicians and groups aware that they must sign-up as group PQRS participants in the three-month span between the publication of the final rule and the deadline for registering for group PQRS participation. In addition, although we appreciate CMS' interest in obtaining stakeholder comments on both the current and future options it is considering, the rule raises questions that cannot be answered without additional testing and analysis. More time is also needed to refine the methodology and ensure that the modifiers are fair and reliable. **VBMs are not ready for primetime, and we continue to believe that CMS could and should use the time between now and 2015 to do further testing and refinement of the modifier's components, including risk adjusters, a Medicare-specific episode grouper, cost and quality measures, attribution and benchmarks.**

Application of the VBM

CMS estimates that its proposal to apply the VBM to all physicians in groups of 25 or more practitioners would make 4,000 to 6,000 medical groups subject to the VBM. While CMS has not yet made estimates of the number of physicians involved public, we believe that it would be hundreds of thousands. **Experience in the four states (Iowa, Kansas, Missouri and Nebraska) where about 24,000 confidential feedback reports based on 2010 data were released earlier this year has confirmed our concern about the prospect of notifying and signing up 4,000 to 6,000 groups for PQRS group participation by the deadline that CMS is proposing.** Even groups that know about the requirement may assume that they are protected from VBM cuts because their individual members are participating in PQRS. Others may not understand that the 25-member threshold includes non-MDs. Still others may have had staffing changes that bring them below the 25-practitioner threshold but have not yet been incorporated into CMS' data.

While the AMA supports CMS' plan to use its confidential quality and resource use reports (QRURs) to advise the affected groups that they will be subject to the VBM and how it will likely affect them, these reports will only have been distributed in nine states prior to the

2013 group participation notification deadline. It should also be noted that, even after extensive encouragement by CMS, the AMA and state and specialty medical societies, only one in three physicians opened their feedback reports in the four states mentioned above. Some practices had availability to data for physicians who were not in the group, while others had missing reports. Some could never locate anyone who received a notice that the reports were available. Our point here is not to criticize the work of either the contractor or CMS, but simply to emphasize the herculean size of the task ahead and advocate for a slower VBM ramp-up than CMS has proposed. If the contractor CMS considered to have the best physician communication system in the country could only reach one in three physicians, what are the chances of making many times that number aware of a VBM deadline just three months away?

As a more feasible option, **the AMA recommends that if CMS is determined to make 2013 the initial performance year, only multi-specialty groups with 100 or more MDs and DOs should automatically be subject to the VBM. Smaller groups and single specialty groups could participate on a voluntary basis.** We believe this would reduce the number of physicians and groups that would need to be notified and would focus on practices that are most likely to follow the federal regulatory process and have staff devoted to value-based performance initiatives. Tying the threshold to the number of MDs and DOs rather than all PQRS-eligible practitioners would eliminate potential misunderstanding about which groups are covered. Removing single specialty groups would mitigate a number of problems with the lack of relevant quality measures available for many specialties under the group reporting modalities.

On a related subject, despite our previously mentioned reservations regarding the use of administrative claims measures, we would like to thank CMS for providing groups with a low-burden PQRS option where they could choose to have the agency produce performance reports using data abstracted from claims billing data. **The AMA supports CMS' suggested alternative of defaulting any groups that are unsuccessful in PQRS reporting into the administrative claims option rather than applying a 1 percent VBM penalty to their 2015 payment rates.** We also concur with the decision to exempt Medicare Shared Savings Program and Pioneer ACO participants from the VBM and would urge CMS to extend this exception to other Center of Medicare and Medicaid Innovation (CMMI) pilots that are targeted at practicing physicians, especially those in small or independent groups.

In response to questions raised in the rule regarding the application of the VBM to individual physicians, **the AMA is not convinced that it will ever be possible to construct a modifier that is valid for all specialties at the individual physician level.** As indicated in **Attachment 2** of specialties currently covered by major payers in the private sector, no payer is currently applying value-based payments to <u>all</u> specialties because, at least at this point in time, the tools for calculating a value modifier cannot adequately distinguish between physicians who have high costs due to their patient mix from those who have high costs due to their practice and/or referral patterns.

Quality Measurement

As was pointed out by physicians who examined the confidential feedback reports distributed earlier this year, the administrative claims measures that CMS is using are most applicable to primary care physicians and have little relevance for many specialties. Rather than refining administrative claims measures, we believe CMS should focus on expanding the availability and use of measures developed by physician organizations. **This would include our previously mentioned call for a modification in the rule to allow physicians within the VBM-subject groups to avoid a penalty by continuing to report on individual measures rather than forcing them to use group reporting measures which may not be relevant to their specialty.**

CMS is also proposing to calculate four outcome measures (with 11 elements) for all groups covered by the VBM regardless of which reporting mechanisms the group chooses. It is critical that measures adopted for use in any payment program be "fit for purpose" in that they are relevant to the setting and provider being measured. CMS' proposed outcomes measures were developed to be applied at the community or "metropolitan" level—captured on populations of 100,000 or more, or a minimum of 1,000 or more discharges—and are therefore not appropriate for use as a tool to measure physician practices. **We therefore urge CMS to withdraw these outcome measures and consider, in conjunction with relevant stakeholders, the substitution of several physician level care transition measures recently endorsed by the National Quality Forum (NQF). (See Attachment 3)** These NQF-endorsed measures cover areas such as medication reconciliation, use of advance-care plans and other metrics related to healthcare services provided by physicians across different settings.

Cost Measurement

As we commented last year, the AMA has significant concerns with a process that would increase or decrease physician payments based only on comparisons of per patient costs in the aggregate and for four chronic conditions as risk adjusted by CMS' Hierarchical Condition Category (HCC). Our immediate concerns regarding this approach are mitigated somewhat by CMS' decision to let groups choose whether or not to participate in an option with payments tied to cost and quality comparisons. However, we still believe that **cost comparisons based on such crude measures are not a viable long term solution and that groups should continue to have the option of avoiding such cost comparisons until such time as CMS has adopted and tested a Medicare–specific episode grouper and made improvements to the HCC**.

Quality-Tiering Model

The AMA has some qualms about this proposal but so long as it remains an option rather than a requirement, we are willing to take a wait and see approach. We are inclined to think it might be more appropriate to define high and low value groups as those that are two or

three standard deviations away from the mean rather than one. It also appears to us that despite CMS' laudable goal of creating a score card that physicians can "easily understand," the mechanics of deriving a score will not be easily understood and accepted. For example, we wonder what happens when results for measures common to several reporting modalities, including individuals, are rolled up into a national average and then used to compare groups with varying degrees of flexibility in selecting the patients for whom the measure will be reported.

Other Methodological Questions

In the proposed rule, CMS asks for comments on a number of other issues including the minimum case threshold, attribution method, risk adjustment, and comparison benchmarks. **Our general response is that more time is needed to test various options and that CMS should not compromise the methodology unduly in order to come up with a VBM for every single physician who ever treats a Medicare patient**. **The AMA does not support lowering from 30 to 20 the number of cases that would be required before a measure could be included in a group or individual's VBM.** We are not enamored with the "level of involvement" attribution method and think that CMS should use data from the physician feedback reports to examine the impact of different attribution methods on groups' cost and quality scores. Our concerns with the HCC risk adjuster are long-standing and should be addressed before the VBM is applied to small and mid-sized practices. **In particular, we urge CMS to evaluate and consider new approaches that have been suggested by the Medicare Payment Advisory Commission and the contractor that is developing a Medicare specific episode grouper**.

PHYSICIAN FEEDBACK PROGRAM

Following the March release of confidential feedback reports to nearly 24,000 physicians in four midwestern states, the AMA formed a work group with representatives from state and specialty medical societies. This effort was encouraged by CMS officials, who provided de-identified versions of the Quality and Resource Use Reports (QRURs) for physicians in a number of different specialties. Members of the AMA/Specialty Society RVS Update Committee (RUC) also reviewed some of the reports. Ultimately, this group presented CMS with recommendations (see **Attachment 4**) covering the reports' distribution, format and methodology as well as suggestions for additional analysis that could better inform efforts to refine the reports.

Our initial efforts focused on helping CMS and the Medicare Administrative Contractor (MAC) for the area get the word out to physicians that they should review and respond to the reports. As noted above, even with these efforts, only one in three physicians actually opened the reports, and this was considerably better than in earlier phases of the feedback report initiative. While our group has provided a number of suggestions for ways that CMS and the MACs can improve communications with physicians and their professional societies,

the AMA believes that fair implementation of the VBM will require an unprecedented education and outreach campaign from CMS and its contractors.

Another key recommendation of the work group is that the reports should employ a drill-down format with a top-line condensed summary with the opportunity to pull up additional information for further analysis. **The work group members strongly agreed that patient-specific information should be included in the drill down since this level of detail is needed to verify and take action on the report.** Work group members also highly preferred PQRS quality measures over the administrative claims measures used in the report and urged CMS to analyze the impact of different methods of aggregating and attributing costs, the effect of site of service on costs, and the use of sub-specialty or procedure oriented comparison groups.

PHYSICIAN COMPARE

Minimum Patient Threshold for Publicly Reporting Performance Information

No earlier than 2013, CMS expects to post on Physician Compare performance information collected through the GPRO web interface for group practices participating in the 2012 PQRS GPRO. Specifically, CMS will make public performance information for measures included in the 2012 PQRS that meet the minimum sample size, and that prove to be statistically valid and reliable. CMS previously established a minimum threshold of 25 patients for reporting performance information on the Physician Compare Web site.

CMS now proposes to lower the minimum patient sample size, from 25 patients to 20 patients, beginning with data collected for services furnished in 2013. CMS discusses that this lower threshold is intended to align with the proposed minimum patient reporting thresholds for PQRS measures group reporting for the 2013 and 2014 incentives, and the proposed reliability threshold for the physician value-based payment modifier. CMS invites comments on the proposed new minimum patient sample size for Physician Compare, including whether or not CMS should retain the existing threshold of 25 patients.

The AMA strongly urges CMS not to adopt the 20 patient minimum threshold for reporting performance information on Physician Compare. The AMA has concerns about a 25 patient minimum threshold, much less a 20 patient threshold. This is much too low and will seriously compromise the validity of the performance information, and will result in public reporting that is inaccurate and therefore useless or even harmful to patients. It could also unnecessarily harm the reputation of a group practice and its individual physicians who practice as part of the group.

In proposing to publicly report performance information on Physician Compare, CMS states that if the minimum threshold is not met for a particular measure, or the measure is otherwise deemed not to be suitable for public reporting, the group's performance rate for that measure will be suppressed and not publicly reported. **The AMA urges CMS to specify in the final**

rule what "not publicly reported" means. We are concerned that if a group practice is not listed on Physician Compare, there will be confusion about the groups' performance and some may assume the group had poor performance or that the group did not attempt to report quality data, was not successful in its reporting efforts, or does not have enough patients. **Therefore, we object to CMS listing the names of the groups for which CMS is not issuing a performance report. In addition, CMS should clearly and prominently state on Physician Compare that certain groups are not included in the performance reports for various reasons, including that: (i) the requirement to develop a performance report does not apply to all groups, and therefore if a report is not available for a particular group, this in no way reflects the performance level of that group; or (ii) some groups are not covered due to lack of available measures that would apply to the groups patients or due to lack of data on a particular measure.**

Further, with regard to posting on Physician Compare the names of EPs who successfully participate in the electronic prescribing and PQRS programs, CMS should prominently display a notification on Physician Compare that a physician's participation in the PQRS and e-Prescribing Programs is in no way linked to, or representative of, the legal standard of care to which physicians are bound.

Standard of Care for Measures

CMS proposes in the rule that for all measures publicly reported on Physician Compare, CMS would post a standard of care, such as those endorsed by the NQF. Such information will serve as a standard for consumers to measure individual provider and group level data. **We therefore urge CMS to clarify these "standards of care" in the final rule and provide notice and opportunity for public comment on each standard. We also urge CMS to ensure that the standard of care is based on evidence-based guidelines.**

Posting Measures Collected and Developed by Specialty Societies

CMS proposes to allow measures that have been developed and collected by specialty societies to be reported on Physician Compare, as deemed appropriate by CMS. **The AMA has concerns about this provision, and we urge CMS to ensure that these additional measures are statistically reliable and properly risk-adjusted.**

Developing Composite Measures at the Disease Module Level

When technically feasible, but no earlier than 2014, CMS proposes to publicly report composite measures that reflect group performance across several related measures. As an initial step, CMS plans to develop "disease module level" composite scores for PQRS GPRO measures. **The AMA is unclear as to what the methodology would be for developing these disease module level composite scores, and we urge CMS to clarify this methodology in the final rule.**

Patient Satisfaction Survey Data

CMS proposes to make publicly available on Physician Compare information on certain patient experience of care measures. For patient experience data reported under either the PQRS GPRO or the Medicare Shared Savings Program (MSSP), CMS considered an alternative option of providing confidential feedback to group practices and accountable care organizations (ACOs) using 2013 patient experience data before publicly reporting the patient experience data on Physician Compare. In lieu of publicly reporting the patient experience data relating to 2013 PQRS GPROs and ACOs participating in the MSSP, CMS would use the 2013 results as a baseline to be shared confidentially with the group practices and ACOs, during which time the group practices and ACOs would have the opportunity to review their data and implement changes to improve patient experience scores. Under this alternative option, program year 2014 patient experience data would be the first to be publicly reported on Physician Compare, and CMS would publicly report 2014 patient experience data for ACOs and group practices participating in the 2014 PQRS GPRO on Physician Compare no earlier than 2015.

The AMA appreciates that CMS, at least initially, intends to administer and collect the patient experience survey data on a sample of the group practices' beneficiaries. Further, the AMA urges CMS to adopt the alternative proposal to provide group practices with confidential data and the opportunity to review their data and make any necessary changes before moving to a public reporting system. Practices should also have the opportunity to re-survey patients before any data is publicly reported. Physicians' ability to review, correct, and comment on patient experience survey results, as well as re-survey, prior to final evaluation and public release is particularly critical because these types of surveys are based on people's perceptions, are inherently subject to people's prejudices, memories, and even visit outcomes not related to the physician or practice. A patient who received a poor diagnosis may remember a physician visit quite differently than a patient who received a clean bill of health. Therefore, temperance is required in the use of such results that could impact a physician's reputation and compensation.

ELECTRONIC PRESCRIBING

Updating existing e-prescribing technological standards under Medicare Part D and lifting the long term care settings (LTC) exemption

CMS proposes to retire the current National Council for Prescription Drug Programs (NCPDP) SCRIPT Version 8.1 on October 31, 2013, and replace it with the NCPDP SCRIPT Version 10.6 as the Medicare Part D e-prescribing standard for certain e-prescribing functions on November 1, 2013. The NCPDP SCRIPT Version 10.6 has a number of new functionalities which would allow users to obtain national drug code (NDC) source information, pharmacy prescription fill numbers, and date of sale information that could then be used in a medication history response.

CMS also proposes to recognize the use of either Version 1.0 or 3.0 of the NCPDP Formulary and Benefit standard as a Medicare Part D e-prescribing standard. Finally, CMS proposes to eliminate the long-term care exemption from the NCPDP SCRIPT Version 10.6 standard as of November 1, 2013, for entities transmitting prescriptions or prescription-related information where the prescriber is required by law to issue a prescription for a patient to a non-prescribing provider (e.g., nursing facility) that in turn forwards the prescription to a dispenser.

The AMA supports the upgrading of e-prescribing standards under the Medicare Part D program in order to improve existing standards and enable new e-prescribing functionalities. The formulary and benefits standard continues to remain a challenge for physicians given that formulary and benefits information is complex and always changing, which makes it difficult to rely on them for drug selection. Faced with this unreliability, many physicians continue to rely on patients or pharmacists to notify them regarding medication costs or other health plan considerations in order to select an alternative medication. **We recommend that CMS work with physicians, health plans, and other relevant industry stakeholders to resolve the data quality problems associated with accessing real-time, accurate formulary and benefits information.**

We also recommend that CMS work toward finalizing the remaining e-prescribing standards for prior authorization, structured and codified SIG, and clinical terminology. The Medicare Modernization Act of 2003 (MMA) specifically mandates the development and promulgation of uniform standards, including prior authorization. The need for real-time prior authorization for Medicare patients is critically important given that most Part D plans require prior authorization for selected drugs. Physicians should be able to obtain real-time information about their patients' benefits and medications authorization status. Moreover, there is significant time and cost savings that could be realized by implementing a prior authorization standard.

While CMS' proposal simply updates the standards used in the Medicare Part D program to communicate information between health plans/pharmacy benefit managers and prescribers including what drugs are on a formulary and the prior authorization requirements, it does not address the actual process physicians need to obtain prior authorization. Historically, it was assumed there needed to be a separate transaction for pharmacy prior authorization; however, the enhancements in the ASC X12 270/1 5010 version of the eligibility request and response coupled with the enhancements in the ASC X12 278 5010 version of the authorization standard now allows for a single, standard electronic prior authorization process for all authorizations including medical, pharmacy, laboratory, radiology, and DME services.

Under the ePrior Authorization initiative initiated by the AMA, we have outlined a proposal for using the HIPAA mandated ASC X12 278 5010 standard transaction to provide an automated solution for all types of prior authorization, including pharmacy. We believe that the best automated solution for electronic prior authorization allows for a single automated, end-to-end physician workflow for all authorizations that is integrated within the practice

management/electronic medical record (PMS/EMR). This solution will also simplify the process for physicians using stand-alone e-prescribing systems. More information on the AMA's ePrior Authorization initiative can be found here and we would welcome the opportunity to discuss this more with CMS.

Lastly, CMS should also ensure that vendors of e-prescribing and EHR systems adopt the new Medicare Part D e-prescribing standards by the set compliance deadlines. Physicians do not have the expertise or capability to upgrade their health IT systems on their own; they completely rely upon IT experts including health IT vendors to upgrade systems to meet new technological requirements. **Therefore, a physician should be protected from e-prescribing penalties and his/her participation in the e-prescribing or other health IT programs should not be adversely affected due to a vendor's lack of compliance with CMS' technological upgrade requirements.**

Changes to Group Reporting on E-prescribing

Under the Medicare 2013 e-prescribing incentive program, CMS proposes an alternative submission mechanism for reporting e-prescribing activity for groups in the MSSP, Pioneer ACO, and Physician Group Practice (PGP) Demonstration that wish to participate in the e-prescribing incentive program via the GPRO. These groups would be able to submit their self-nomination statement along with additional information via mail to CMS. In addition, CMS proposes to revise the group practice definition to cover a single TIN with two or more EPs, as identified by their individual National Provider Identifier (NPI), who have reassigned their Medicare billing rights to the TIN. CMS also proposes that for e-prescribing groups eligible under the GPRO comprised of 2–24 EPs, the number of e-scripts required for reporting purposes would be 225 for the 2013 e-prescribing incentive program. In addition, CMS proposes that GPROs comprised of 2–24 EPs would only be required to report 225 e-scripts from January 1, 2013 – June 30, 2103, in order to avoid the 2014 e-prescribing penalty. The AMA appreciates that CMS has proposed to reduce the minimum GPRO threshold from a minimum size of 24 to 2; however, we are concerned that the proposed 225 reporting threshold could be burdensome for some smaller practices. **Therefore, we recommend that CMS either: (a) establish a reporting threshold of 75 for those practices between 2-24 EPs; or (b) simply revert to the reporting parameters established in 2011 (2-10 EPs report 75 times; 11-25 EPs report 225 times; 26-50 EPs report 475 times; 51-100 EPs report 925 times; 101-199 EPs report 1,875 times).**

Additional Hardship Exemption Categories to Avoid E-prescribing Penalties

In order to avoid the 2013 and 2014 e-prescribing penalties, CMS already established exemption categories that physicians would have to apply for as follows:

- Eligible professional or group practice in a rural area with limited high speed internet access.

- Eligible professional or group practice in an area with limited available pharmacies for electronic prescribing.
- Eligible professional or group practice is unable to electronically prescribe due to local, state, or federal law or regulation.
- Eligible professional or group practice has limited prescribing activity, as defined by an eligible professional generating fewer than 100 prescriptions during a six-month reporting period.

CMS has responded positively to the AMA's concerns and has agreed to add additional exemption categories to protect physicians from e-prescribing penalties. CMS proposes to add the following additional exemption categories for 2013 and 2014:

- Eligible professional or group practice who achieves meaningful use during certain e-prescribing penalty reporting periods.
- Eligible professional or group practice who demonstrates intent to participate in the meaningful use EHR incentive program and adoption of certified EHR technology.

In order to be eligible for the first new exemption category, an individual eligible professional would need to achieve meaningful use of certified EHR technology for a continuous 90-day EHR reporting period (as defined by the meaningful use EHR incentive program) that falls within the 6-month reporting period (January 1 – June 30, 2012) for the 2013 e-prescribing penalty program or the 12- or 6-month reporting periods (January 1 – December 31, 2012 or January 1 – June 30, 2013, respectively) for the 2014 e-prescribing penalty program. In addition, CMS proposes that this hardship exemption category would also apply to individual EPs and group practices (that is, every member of the group) who achieve meaningful use of a certified EHR for an EHR reporting period within calendar year 2012. We believe that the exemption category as written is confusing and too prescriptive. It is unclear why an eligible physician who has successfully participated in the meaningful use EHR program, a health IT program which includes an e-prescribing requirement, would be required to adhere to time period limitations in order to avoid a penalty under the Medicare e-prescribing program. **While the AMA appreciates that CMS is proposing this exemption category, we believe that in order to better align the meaningful use and e-prescribing programs and reduce unnecessary burdens on eligible physicians, CMS should modify and broaden this exemption category to allow any physician who attests to meaningful use in years 2011, 2012, or 2013, to apply for an exemption from the e-prescribing penalty program.**

In order to be eligible for the second new exemption category, an individual eligible professional or group practice would have to register to participate in the Medicare/Medicaid meaningful use EHR incentive program and adopt certified EHR technology by a deadline specified by CMS. **We again, urge CMS to modify and broaden this exemption category to allow physicians who have registered for the meaningful use program in years 2011, 2012, or 2013, to apply for an exemption from the e-prescribing penalty program.**

CMS is proposing that the deadline for eligible physicians to apply for one of these two additional hardship exemption categories in order to avoid the 2013 e-prescribing penalty would be October 15, 2012, or the effective date of the final 2013 physician fee schedule rule, whichever is later. The proposed deadline for applying for a hardship exemption request to avoid the 2014 e-prescribing penalty is June 30, 2013. **We recommend that CMS extend the deadline to the end of the month (October 31, 2012) and allow physicians to file for any of the available exemptions (not just those limited to the Meaningful Use EHR program) by October 31, 2012, or the effective date of the final rule, whichever is later. As for avoiding the 2014 e-prescribing penalty, physicians should be allowed to file for an exemption through October 31, 2013, or the effective date of the final 2014 rule, whichever is later.** CMS should also review its meaningful use EHR registration and attestation systems as a protective measure to ensure that all physicians who have registered or attested for the meaningful use program in 2012 or in 2013, regardless of whether they applied for an e-prescribing exemption on-line, be protected from e-prescribing penalties.

In addition, while we believe that the CMS proposal to add the two Meaningful Use hardships could help reduce the number of physicians who experience a penalty, we are very concerned that unless CMS conducts outreach well in advance of October 2012, that these two additional hardship options will be rendered meaningless. **Therefore, we strongly urge CMS to begin educating the Quality Help Desk immediately about the two Meaningful Use new hardship exemption categories and allow physicians to begin filing for these new exemptions starting Tuesday, September 4, 2012. We look forward to working with CMS on educational outreach as soon as possible.**

CMS' rationale for adding the additional two hardship exemption categories is that there are significant hardships relating to the selection, purchase, adoption, and/or meaningful use of health IT. For this reason, physicians who are in the process of implementing health IT into their practices should not be burdened with meeting e-prescribing reporting requirements. We agree with CMS that the proposed additional hardship exemption categories are warranted. We also believe that the same level of burden exists for physicians who intend to retire in the next several years and are winding down their practices but are facing hardships because they are being forced to install and use an e-prescribing or EHR system for a limited period of time to avoid financial penalties. It would also be wasteful to our health care system overall for these physicians to make a long-term investment in purchasing and maintaining costly health IT systems for extremely short-term use. **While we support CMS' existing hardship exemption categories and the proposal to add additional exemption categories to protect physicians who have registered or attested for the meaningful use EHR program from e-prescribing penalties, we continue to strongly urge CMS to add an exemption category for physicians who are currently eligible for Social Security benefits or will be eligible for Social Security benefits by 2014.**

E-prescribing Informal Review/Appeals Process

We appreciate that CMS has agreed to implement an AMA recommendation and establish an informal review/appeals process for physicians who encounter problems with the e-prescribing incentive and penalty programs. We urge CMS to expand the review process, however, to also cover problems that physicians encountered under the 2012 e-prescribing incentive and penalty programs. The AMA continues to receive complaints from physicians who faced difficulties with the 2012 e-prescribing incentive and penalty program requirements through no fault of their own. For example, CMS informed the AMA late in the afternoon on June 28, 2012, that physicians would not be able to apply on-line for an exemption request on June 30, 2012, the deadline for filing for an exemption, due to CMS' web maintenance efforts, and so the deadline for physicians to file their exemption requests would be extended to July 2, 2012. The AMA did not have a reasonable opportunity to notify physicians about CMS' technological challenges and the extension period. Moreover, a number of state and specialty organizations contacted CMS staff directly to inform them that physicians were having difficulty filing exemption requests on-line. We also learned that physicians who attempted to apply for an exemption on-line using a MAC computer were unable to do so because CMS' system did not support these users. These physicians were, therefore, unable to file for an exemption on-time to avoid a penalty. **These physicians' concerns need to be fully resolved, and so we strongly recommend that CMS' review process cover all of the e-prescribing incentive and penalty program periods from 2012 through 2014. In addition, we strongly recommend that physicians who make a good faith effort to e-prescribe and report on their e-prescribing activities or attempted to file for an exemption but due to an administrative, operational, or technological impediment ended up with a penalty, should be able to present their case to CMS and be protected from e-prescribing penalties.**

We further urge CMS to extend the deadline to allow physicians to file a review/request an appeal through March 31, 2014, regardless of the program year at issue (e.g., 2012, 2013, and/or 2014). It is very confusing for physicians to keep up with review deadlines that vary for each program year, which is what CMS is proposing. Physicians also need ample time to review their claims to determine whether a penalty was applied to them inappropriately or whether they should have received incentives in a particular year(s), but did not. This additional time is also needed to enable the AMA as well as other physician organizations to pursue effective physician communication and outreach efforts on the informal review/appeals process. **Therefore, we urge CMS to extend the deadline to allow physicians to apply for an informal review/appeal through March 31, 2014, for any problems that they encountered under the e-prescribing incentive and penalty programs for program years 2012, 2013, and 2014.**

MULTIPLE PROCEDURE PAYMENT REDUCTION

CMS proposes to apply a 25 percent MPPR to the technical component of certain diagnostic cardiovascular and ophthalmology services when these services are furnished by the same

physician (or a physician in the same group practice) to the same patient on the same day. **The AMA opposes this extension of the MPPR policy because CMS' assumptions about potential efficiencies are overstated due to an inaccurate methodology and the codes at issue are not commonly billed together.**

Potential Efficiencies Overstated

CMS discusses in the proposed rule that the agency found support for payment reductions ranging from 8 to 57 percent for second and subsequent cardiovascular procedures and payment reductions ranging from 9 to 62 percent for second and subsequent ophthalmology procedures. Yet, we believe CMS implemented a flawed methodology in achieving these findings. CMS compared the line items of 16 clinical labor activities listed in the proposed rule for both codes. For each line item, CMS compared the clinical labor minutes and completely removed the lower of the two. Then the associated equipment minutes were readjusted and the practice expense relative value unit (RVU) was recalculated.

This methodology is inaccurate and produces skewed results. It incorrectly assumes there is clear duplication in clinical labor activities, such as greeting the patient, retrieving medical records, educating the patient and even preparing and cleaning more than one room. Yet, in actuality, there is not major duplication in clinical labor activities when two studies are done in the same session, and there is even less duplication in clinical labor activities when these services are done in separate sessions on the same day. Even when there is the potential for overlap in clinical labor activities, the efficiencies would result in overlap of only a minute or two. Therefore, the proposal to completely remove these minutes from the subsequent test is completely unfounded and inappropriate.

Codes Not Commonly Billed Together

CMS states in the proposed rule that the code pairs in Table 14 are frequently billed together. The RUC conducted a review of the 2010 Medicare five percent claims file for these codes and determined that only four of the cardiology pairs are typically reported together on the same date of service (93320-93325, 93320-93351, 93965-93970 and 78452TC-93017). (The ophthalmology codes are also infrequently billed together, with only 92235 and 92250 typically billed together. The computerized ophthalmic diagnostic imaging codes (92133-4) were created in 2011 and were not included in this analysis.) Every other code pair is reported together at or below 40 percent of the time, with over half below 20 percent. In addition, a broader analysis of the claims data for all the available codes listed in table 12 and 13 suggest that only roughly four percent of the code combinations are typically performed together on the same date of service. Given that these services are rarely performed on the same day together, it is unreasonable to assume there would be efficiencies gained when these services are performed together. Efficiencies in practice expense are potentially created only when the two services are analogous and commonly performed together. However, for these code pairs, the practice will not have the same level of familiarity, including the office equipment set up to conduct these services with absolutely zero

physician work overlap in key elements of the practice expense. Furthermore, the dissimilarities between these services are such that even if all these services were commonly billed together, physician staff could not provide noticeable efficiencies.

Finally, we disagree with CMS' assumption that a MPPR is a valid and accurate mechanism to value services when performed on the same date of service. We recognize that efficiencies can be gained when services are commonly performed by the same physician on the same date of service, but only when explicit criteria are met, and CMS' proposal does not meet these criteria. These services are not commonly billed together, the services are not analogous services performed on contiguous body parts, and the policy is expanded to services not performed by the same physician, but to a physician in the same group practice.

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

The AMA believes that evaluating the duplication of work in services performed on the same date of service should be conducted at the individual code level, not through arbitrary, across-the-board payment policy modifications proposed by CMS. In a good faith effort, organized medicine has worked to resolve any duplication in the Resource-Based Relative Value Scale (RBRVS) over the past few years and continues to comply with efforts in the coming years. **Therefore, we urge CMS not to adopt its proposal to expand the MPPR on either the professional or technical component of any additional services.**

PRIMARY CARE AND CARE COORDINATION

The AMA applauds CMS' proposal to implement Medicare payment in 2013 for care management services when a physician coordinates a beneficiary's care in the 30 days following discharge to the community from an inpatient hospital stay, a SNF stay, and specified outpatient services. The AMA's Chronic Care Coordination Workgroup (C3W), which is comprised of members of the CPT Editorial Panel and the RUC, recommended that CPT codes and valuation be developed for transitional care management from a facility to the community. **The CPT codes and RUC recommendations related to the resources required to provide these care management services will be available for the 2013 Medicare physician fee schedule, and the AMA urges CMS to adopt these CPT codes for the newly-covered care management services rather than the G-codes CMS has proposed. CMS discusses in the proposed rule that it is committed to considering new payment options for primary care services, including care management. The AMA encourages CMS to continue on this path.**

The budget impact of this proposal assumes that every transitional care management service will be reported for every hospital discharge. A one billion dollar offset to the Medicare conversion factor is proposed to redistribute this cost from other physician services, including those performed by primary care physicians. The impact is overstated. Not every discharge will require this level of care coordination and the desired increase in transitional care may not be immediate. **CMS should review data from the primary care community and the RUC regarding expected utilization when it is submitted in early October. In addition, CMS should first determine savings from readmissions prior to applying redistributions within the RBRVS or physician payment. CMS should propose a methodology to track success of the new transitional care management services and to then apply a readmission savings offset to the Medicare physician fee schedule.**

Further, in a comment letter of June 3, 2011, on the MSSP proposed rule, the AMA recommended that CMS allow flexibility for ACOs by covering non-face-to-face care coordination services. **We anticipate that ACOs will utilize the new transitional care management services to help improve quality and lower costs for patients attributed to the ACO. It is important, therefore, that the final impact estimates for this service be incorporated into the benchmark spending targets for Medicare ACOs.**

POTENTIALLY MISVALUED CODES

RUC Progress in Identifying and Reviewing Potentially Misvalued Services

CMS acknowledges and the AMA strongly agrees that "CMS and the AMA RUC have taken increasingly significant steps to address potentially misvalued codes." The RUC has identified more than 1,300 physician services for review and has offered recommendations for over 1,000 services. Much of this analysis led to clarification on bundling within CPT. The RUC's efforts have resulted in more than $1.5 billion redistributed to the physician fee schedule, and the RUC is continuing to analyze possible bundling solutions and identify services using objective criteria and data analysis.

Measuring Post-Operative Physician Work

As part of CMS' statutory obligations to identify and review potentially misvalued codes and respond to stakeholder concern that global surgical package payments may be misvalued, CMS is seeking comments on methods of obtaining accurate and current data on E/M services furnished as part of a global surgical package.

As its impetus for seeking comments on a new methodology for acquiring data on the E/M services furnished as part of a global surgical package, CMS mentions two reports on global surgery fees, one for ophthalmology services and one for orthopaedic surgery services, published by the HHS Office of Inspector General (OIG). In these reports, the OIG often relies on a review of records for only a handful of claims for an individual service. However, the RUC requires that survey data from a median of 30 physicians be collected to estimate

the number of post-operative visits. The RUC collects data on the level of E/M visit, while the OIG report did not. The OIG review cannot be considered to be more reliable than the information obtained from the national medical specialty societies and peer reviewed by the RUC.

CMS states that "some global surgical packages have been valued by adding the RVU of the surgical procedure and all pre- and post-operative E/M services included in the global period. Others have been valued using magnitude estimation, in which case, the overall RVU for the surgical package was determined without factoring in the specific RVUs associated with the E/M services in the global period." CMS asserts that varying methodologies used to review services with global periods have caused variation in the allocation of E/M services for similar procedures across the RBRVS. There are a total of 4,258 services on the Medicare physician fee schedule with a global period. Of these, only six percent, or 271 services, are performed more than 10,000 times annually across the entire nation. Most of these few CPT codes that truly impact the RBRVS relativity have been reviewed since 2005. CMS acknowledges that more recently reviewed codes have fewer E/M services in the global service period. This is indicative of the greater attention that has been paid to these data as the resource-based practice expense methodology impacted the importance of the visit data. In addition, it is extremely rare for a code with a surgical global to have an office visit level above a 99213, while 42 percent of all stand alone E/M visits are reported as a 99214 or 99215. **If CMS has concerns that a code or group of codes with higher volume have overstated E/M work within the payment, the agency should work with the RUC to review these services.**

Review of Services with Stand Alone Practice Expense Procedure Time

CMS states that improving the accuracy of procedure time assumptions is a high priority of the potentially misvalued codes initiative. As part of the potentially misvalued code screen a series of radiation treatment services were reviewed for the 2012 Physicians Payment Schedule. CPT codes 77418, *intensity modulated radiation therapy (IMRT) delivery services,* and 77373, *stereotactic body radiation therapy (SBRT) delivery services,* were approved without refinement by CMS in the 2012 physician fee schedule final rule. Shortly after publication, the RUC informed CMS that seven equipment items for IMRT treatment delivery (77418) were inadvertently omitted from the direct practice expense recommendation. CMS was not able to include these items in CY 2012, and we appreciate that they are included in CY 2013.

CMS noted inconsistencies between the procedure time assumption used in establishing non-facility direct practice expense inputs and the procedure time noted for the patient in "publicly available resources." Although the AMA would generally welcome new data sources and information, we are concerned that the data being cited in the proposed rule on this issue does not meet the same standards the RUC applies to extant data. For example, the resources cited in the proposed rule are patient marketing materials that describe all forms of external beam radiation therapy, not just IMRT. There is more that goes into the direct

practice expense inputs than just the time that the beam is on the patient for a radiation oncology procedure. For example, 77418 requires the radiation therapists to attach immobilization devices, verify vertical/horizontal patient position around the site to be treated, use orthogonal 3-point laser light system to align patient with external tattoos, verify isocenter, and verify proper performance of two audio/video monitoring systems, all before the therapy begins. In total, the intra-service time for each of the two radiation therapists is 35 minutes and the patient is present, but not actively being treated with the beam, for 14 of those 35 minutes. **We understand that radiation oncology has requested that the RUC re-review these clinical staff times at the October 4-6, 2012, meeting, and we urge CMS to postpone any modifications until the specialty is able to offer more data and information for consideration.**

GEOGRAPHIC PRACTICE COST INDICES

As required by law, CMS updates the geographic practice cost indices (GPCIs) every three years, and the next GPCI update will be in 2014. Therefore, CMS is not proposing GPCI changes in the proposed rule. As CMS considers potential future GPCI policy proposals, the agency is analyzing recommendations from a panel convened by the Institute of Medicine (IOM). CMS plans to address the IOM Phase I and II recommendations more fully in future rulemaking.

The AMA looks forward to CMS' further discussion of GPCI proposals based on the IOM recommendations, and we will provide our views on these proposals at that time. **In the meantime, however, we urge CMS to consider the potential for significant disruption to physician practice revenues as it evaluates the IOM recommendations.** For example, the proposed rule discusses an IOM recommendation that could increase the number of employee wage index payment areas from the current 89 to over 3,000. This would also mean that current state-wide payment localities, including states that wish to remain as one locality, would be broken up into many different localities. This could cause serious disruption for physician practices, and we urge CMS to keep these dynamics in mind as it considers the IOM recommendations.

ADVANCED PRIMARY CARE MEDICAL HOME MODEL

CMS seeks comments in the proposed rule on the idea of paying for services furnished in an advanced primary care practice that has implemented a medical home model. While the AMA would strongly support Medicare payment for services furnished by medical homes, we share CMS' concerns that the process of securing accreditation as a medical home through one of the four existing credentialing programs can be costly and lengthy, and that some aspects of the accreditation processes would be considered proprietary. Through its new Comprehensive Primary Care Initiative, the CMMI will be evaluating practices' readiness to serve as medical homes for their patients. **The CMMI experience may provide guidance on how CMS could develop its own medical home recognition process so that physicians would not need to rely exclusively on private accreditation bodies for this**

purpose. Another alternative is that CMS could issue a Request for Applications for organizations that could deem practices as having met medical home criteria to be developed by the agency.

MEDICARE ECONOMIC INDEX TECHNICAL ADVISORY PANEL

Previous physician fee schedule rules have discussed the Medicare Economic Index (MEI) and the recently convened MEI Technical Advisory Panel (TAP). The MEI is a significant factor affecting Medicare physician payment policy, the sustainable growth rate (SGR), and required reductions in physician payment rates due to the SGR that are discussed in the current proposed rule. **The AMA wishes to take this opportunity to express its appreciation to CMS and the Office of the Actuary for organizing a comprehensive review of the MEI, and to urge that CMS adopt the recommended refinements to the MEI developed by the TAP. From our attendance at the TAP meetings, we anticipate the following refinements will be recommended:**

- Changing the price proxy for physician compensation to the wages of professional and technical workers instead of all private non-farm workers;
- Increasing the benefits share of physician compensation;
- Within non-physician compensation, creating a new category for clinical labor (health care workers);
- Within office expenses, creating an "other professional services" category to account for billing, legal and similar services;
- Moving the wages of non-physician health professionals who can independently bill to physician compensation ("work") instead of "practice expense;"
- Refining the office expense category by collapsing some categories that have very small weights;
- Refining certain office expenses to reflect information technology costs and better capture the types of capital expenses physicians face;
- Using nonresidential rents for professional office buildings instead of residential rents as the price index for fixed capital;
- Exploring potential methods for gathering data that will allow regular updates to the MEI weights, including a potential future joint CMS-AMA survey; and
- Continued monitoring of how economy-wide productivity growth compares to physician productivity.

The AMA urges CMS to give serious consideration to adopting the MEI refinements recommended by the TAP in future rulemaking. In the AMA's view, these refinements will help to make the MEI better reflect the types of input costs and prices medical practices actually face than does the current MEI. We recognize that the TAP recommendations may be too late to be included in the final rule for 2013, but we encourage CMS to consider including refinements to the MEI in the 2013 final rule on an interim basis for the coming year.

ELIMINATION OF REQUIREMENT FOR TERMINATION OF NON-RANDOM PREPAYMENT COMPLEX MEDICAL REVIEW

CMS proposes to rescind its requirement that contractors terminate non-random prepayment complex medical review of a provider or supplier no later than one year following the initiation of the complex medical review or when calculation of the error rate indicates the provider or supplier has reduced its initial error rate by 70 percent or more. Instead, CMS proposes that contractors would not be required to terminate non-random prepayment medical review by a prescribed time, but would instead terminate each medical review when the provider or supplier has met all Medicare billing requirements as evidenced by an acceptable error rate as determined by the contractor.

We understand the statutory basis for CMS' proposal. However, we urge CMS, in its discretion, to impose a limit on non-random prepayment medical review. Prepayment medical review can impose additional paperwork burden and interruption to the office workflow. Physicians may need to hire an additional staff member to collect and submit the additional documentation, or to follow up on outstanding claims. And, while physicians wait for a contractor to review the claim and remit payment, they lose the interest on those payments, which may be substantial if a high volume of the claims are subject to prepayment review. CMS' proposal would literally allow prepayment review to extend without end; in light of the burden of prepayment review, this is unreasonable and without merit. It also is inconsistent with President Obama's January 18, 2011, Executive Order calling on federal agencies to reassess and streamline regulations in order to reduce regulatory burden.

While these additional burdens might make sense for providers who have been identified as serious threats to program integrity, many physicians now find themselves subject to prepayment review simply because of their location. CMS and its contractors routinely impose prepayment review on entire regions that they have identified as "hot spots," without differentiating between those providers that are outliers and those that are not. This methodology catches many physicians in a "net" of ongoing prepayment review that has no meaningful link to the physician's billing or practice. It is inequitable to impose such onerous review on physicians who are correctly coding and only implicated in the review because of their geographic location.

Physicians may also find themselves under prepayment review because they have been billing incorrectly. In light of the numerous and constantly-evolving Medicare policies and procedures, these mistakes are not surprising. CMS should employ greater physician education and outreach to solve this type of improper billing *before* placing the physician under prepayment review. Once a physician has been placed under prepayment review, the review should be terminated when the physician has demonstrated an understanding of the correct policy and is billing properly. This is consistent with CMS' current policy in which prepayment review is terminated when the physician has reduced the initial error rate by 70 percent or more.

Therefore, we suggest that CMS retain its requirement that a contractor must terminate prepayment review once a physician has lowered their error rate by 70 percent. In addition, we ask that CMS retain its time limit of one year to avoid the placement of physicians on perpetual prepayment review.

DURABLE MEDICAL EQUIPMENT (DME) FACE-TO-FACE ENCOUNTERS

Encounter Timeframe

Section 6407(b) of the *Patient Protection and Affordable Care Act* (ACA) generally requires that a DME order be written pursuant to the physician documenting that a physician, a physician assistant (PA), a nurse practitioner (NP), or a clinical nurse specialist (CNS) has had a face-to-face encounter with the individual involved during the 6-month period preceding such written order, or other reasonable timeframe as determined by the Secretary. CMS proposes to require that the face-to-face encounter take place no more than 90 days prior or 30 days following the date of the order. **While we support CMS' proposal to allow the face-to-face encounter to take place 30 days following the date of the order, we strongly urge CMS to revise its proposal and finalize the 6-month period preceding the order as an allowable time frame for the face-to-face encounter, as authorized by Congress.**

CMS invokes its experience with the home health face-to-face encounter requirement when proposing the 90-day window prior to the encounter as requisite. In the context of home health, the requirement is meant to ensure that the patient is homebound and that the home health services are medically necessary at that time. However, this same clinical timeframe does not apply in the case of DME ordering.

For example, a physician could be trying various therapeutic alternatives to manage a patient's condition. At a face-to-face encounter, the physician may prescribe a set of exercises or a drug regimen and wait to see their effectiveness before deciding to order a DME supply. The DME could be ordered some months after the face-to-face encounter had occurred. Or a patient's chronic condition that has been managed over a long period of time may worsen and require a DME supply. If the physician has been seeing the patient every six months for the condition, a phone call with the patient may well suffice to make it clear that the DME is needed.

While both the home health and the DME face-to-face encounter requirements were established under the umbrella of program integrity, the DME requirement is meant to address vulnerabilities specific to DME, including concerns about inappropriate marketing of DME and fraudulent and abusive practices by some DME suppliers. Physicians and practitioners tasked with addressing these DME program integrity concerns through a face-to-face encounter should be allowed the maximum flexibility to do so, as should patients. We strongly suggest that CMS allow the full six months preceding the order for such DME face-to-face encounters to take place.

Physician Documentation

We support CMS' proposal that when the face-to-face encounter is performed by a physician, the submission of the pertinent portion(s) of beneficiary's medical record, containing the requisite information, would be considered sufficient and valid documentation of the face-to-face encounter. This proposal minimizes duplication and interruption to the physician office workflow. CMS also solicits comment on whether a face-to-face encounter performed by a physician should be subject to further requirements, based on the requirements for physician documentation of face-to-face encounters performed by a PA, NP, or CNS, which we discuss below. We do not believe that such additional requirements are necessary when the physician is personally performing the face-to-face encounter, as they would require the physician to certify his or her own impressions as already memorialized in the medical record.

We urge CMS to give physicians and other practitioners maximum flexibility by allowing any and each of the options proposed in regard to the physician documentation of a face-to-face encounter performed by a PA, NP, or CNS. In considering each of these options, we ask that CMS consider the potential interruption to workflow that each option could cause, and suggest that while one physician office may find one option desirable and of minimal interruption to their workflow, that same option could be immensely problematic to another physician office, and vice versa. **Therefore, CMS should allow each of the outlined options so that practices may choose which option will best meet their needs and those of the patient.**

For example, while some of the physician documentation options that CMS proposes could be burdensome for practices that have paper medical records, the same option might be preferable for physician practices that utilize an EMR system. A paper-based practice may not find the attestation option desirable because it presents an additional sheet of paper that must be produced, signed, and included in the record. A paper-based office may instead find that a single physicians' signature on the record, or initials on the pertinent portion of the record, is most easily accommodated in the office workflow. On the other hand, an EMR system may not be able to accommodate the initials of a physician at the pertinent section of the medical record, or on the record itself. In an office that uses EMRs, the attestation may be more easily accommodated in the record as a checkbox or digital signature.

Supplier Notification

CMS outlines several proposals regarding how documentation of the face-to-face encounter must be delivered to the supplier. **Again, we urge CMS to give physicians and other practitioners maximum flexibility by allowing them to choose among the options CMS proposes.** Either the physician who completes the documentation of the face-to-face encounter, or the physician or non-physician practitioner who has the face-to-face encounter, should be able to send the documentation directly to the supplier. Or, as CMS proposes, the

physician should be able to give the beneficiary a copy of face-to-face documentation for the beneficiary to deliver to the DME supplier of their choice.

CMS proposes an option that would require that the documentation, no matter who completes it, "travel together" to the DME supplier on the same pathway with the written order for the DME. We caution CMS that in many cases this will be impractical. If, for example, the patient sees the physician two weeks after the order has been submitted, per the proposed post-order window of 30 days, then the requirement that the order and the documentation travel together would not work.

Other Issues

Covered Items: CMS should exclude nebulizers, home blood glucose monitors, and other DME that is typically distributed in an in-office physician setting from CMS' proposed list of covered items. The need for these items will already have been documented in the patient's medical record, and the extra step of documenting the need via an attestation, additional signature, or initials is not needed.

Physician Payment: **We strongly support CMS' proposed G-code, estimated at $15, to compensate a physician who has documented that a PA, NP, or CNS practitioner has performed a face-to-face encounter.** CMS is correct that there is a burden associated with the requirement placed on the physician as a result of the requirements discussed herein, and the proposed G-code will aid in relieving this burden.

Requirement Implementation: **CMS should suspend implementation of the DME face-to-face requirement for at least 6 months following the publication of the final rule to allow physicians, suppliers, and other providers to be educated on the new requirement.** In the home health face-to-face requirement, many physicians were unfamiliar with the requirement when it was newly issued, and CMS at that time had to implement a series of stays to allow time for greater education and outreach. We suggest that for DME face-to-face requirement, CMS preemptively set aside time to allow for education and outreach on the parameters of the requirement to ensure maximum compliance and minimize confusion.

Wheelchair Advertisements: Deceptive advertisements that promise "free" wheelchairs "paid for by Medicare," and assure seniors that they will be covered for such supplies, do not promote program integrity. Physicians have reported patient inquiries regarding such advertisements, and some incidences of "physician shopping" by seniors—at the urging of wheelchair suppliers—to solicit a wheelchair order. **CMS should increase its oversight of advertisements of wheelchair suppliers, and consider the impact of such advertisements on beneficiaries and the physician-patient relationship.**

Physician In-Office DME Suppliers: In situations where a physician treats a patient and subsequently supplies an office-based DME to a patient, there is no need for documentation to flow between the physician and the supplier (who is also the physician). These situations

are clearly different than the situation of a physician office and a commercial supplier. **CMS should clarify that for the purposes of this section of the rule, as appropriate, that DME supplier means a commercial DME supplier, not a physician or other practitioner who is office-based.**

Audits: Physicians have reported deceptive practices by DME suppliers who have sent physicians letters—on letterhead co-branded with CMS without CMS authorization—indicating that because the DME supplier is undergoing a CMS audit, that the physician must produce extensive and costly medical record documentation and submit it to the DME supplier. **CMS should make clear in its regulation that after a physician or beneficiary has submitted a medical record and documentation of the face-to-face visit to the DME supplier, the DME supplier must retain a copy of that already-submitted record, and the physician is not required to supply subsequent medical records or documentation to the DME supplier.**

PAYMENT FOR MOLECULAR PATHOLOGY SERVICES

The AMA strongly supports CMS' placement of the molecular pathology service codes (MoPath codes) on the physician payment fee schedule for CY 2013. There are compelling clinical and policy factors that dictate the placement of these codes on the physician fee schedule. Fundamentally, these codes relate to professional interpretations of individual patient test results. Furthermore, in light of the information provided to CMS by the RUC, the College of American Pathologists (CAP), and other stakeholders during the CY 2012 and CY 2013 comment periods, the AMA urges CMS to adopt national pricing instead of delegating this important function to regional carriers. We outline below the basis of the foregoing recommendations.

In brief, the adoption of the MoPath codes will interject increased certainty and clarity into the identification, coding, and payment of molecular pathology services. The decision to forgo placing the MoPath codes on the physician fee schedule for CY 2012 generated widespread confusion that reportedly impacted investors, innovators, providers, and payers, and taxed the administrative capacity of many provider coding and reimbursement staff. Unfortunately, it also contributed to an ongoing inaccurate perception among key policy-makers and other stakeholders that an alternative to the CPT stacking codes had not been developed despite a significant investment of time, resources, and effort to provide new molecular pathology codes for CY 2012. In addition, the late-breaking announcement by Palmetto GBA that providers in its jurisdiction would also have to utilize an additional code along with the CPT stacking codes exacerbated the confusion.

The current MoPath codes represent an important iteration in a process that is evolving to capture rapid innovation and knowledge of clinically valid molecular pathology services. We fully anticipate forthcoming codes as evidenced by the ongoing discussion of

stakeholders concerning next generation sequencing.[1] In addition, there will continue to be CPT molecular pathology process enhancements.

Background

CMS has historically acknowledged that the services reflected in the MoPath codes were physician laboratory procedures rather than clinical laboratory tests due to the level of involvement of physician interpretation. As a direct result of the foregoing, CMS initiated the process for recognition of analyte-specific CPT codes developed and assigned by the CPT Editorial Panel. Essential to the foregoing, CMS requested recommendations from the RUC. The RUC reviewed the physician work, direct practice expense inputs, and professional liability insurance required to generate a relative value unit (RVU) for those procedures. CMS may rely upon this gathered information when establishing a test price for the PFS.

In 2009, the CPT Molecular Pathology Coding Workgroup (MPCW) was formally established to develop a new coding system for molecular pathology services to replace the antiquated stacking codes. To that end, an aggressive schedule of intensive stakeholder engagement and input ensued that involved providers, payers, and CMS representatives. The concerted efforts resulted in the creation of new molecular pathology CPT codes for CY 2012 within a ten month time period.[2] The speed of the most recent CPT effort reflects modifications to accommodate the rapid developments in molecular pathology services and other improvements while retaining transparency and multi-stakeholder engagement.

The MoPath codes were approved by CPT in October 2010 and February 2011. CAP provided additional input regarding the molecular codes that required physician involvement in February 2011. The foregoing information was analyzed by the RUC and submitted for CMS' consideration. In addition, CAP developed physician work RVU recommendations, as well as practice expense (PE) direct inputs for medical supplies, equipment, and clinical staff for the new codes at the request of the RUC and CMS. The RUC reviewed and agreed with these recommendations, and forwarded them to CMS in May and October of 2011. CMS representatives participated throughout all of the CPT and RUC processes.

Although we have summarized above the streamlined development of the MoPath codes since 2009, it is important to highlight the CPT activities related to molecular pathology services that pre-date the successful mapping of the human genome and the application of DNA sequencing breakthroughs since 2003 that have sped new discoveries and clinical applications in the last couple of years.[3] The following chronological chart underscores the

[1] In May 2012, the Association for Molecular Pathology (AMP) announced it was finalizing a framework proposal for CPT coding of Next Generation Sequencing (NGS) assays.

[2] It is important to note that the placement of codes on a fee schedule will typically occur once every twelve months. The placement on the fee schedule is a process that is controlled by CMS, not by CPT.

[3] While mapping the human genome and dramatic breakthroughs in computing capabilities were not a necessary prerequisite to the development of the first generation of molecular pathology services, the

rigorous, transparent, and rapid adaptation of the CPT process to facilitate and encourage engagement and input from physicians, doctoral scientists representing large commercial laboratory/organizations and geneticists, payer community representation (governmental and private), and representatives from industry.

Date	Action
February 1998	Presentation to the CPT Editorial Panel by representatives of the American College of Medical Genetics that outlined the coming revolution in medicine that would require intense coding strategies for molecular pathology.
January 1999	CPT adds new stacking codes for reporting molecular pathology services.
December 2003	Stakeholders (laboratory representatives, medical specialties, software developers, payers (CMS, Blue Cross Blue Shield, and Health Insurance Association of America)) met to discuss strategies for adding molecular pathology codes to existing CPT stacking codes. The meeting consensus was that the stacking codes should be updated and a new appendix (known as Appendix I) would be added to the CPT code set to include disease/condition specific modifiers to allow payer identification of the disease/condition on the claim with which the stacking codes were associated. The stakeholders agreed to delay specific identification of test methodologies to allow maturation of the technology to enable determination of the most clinically significant services.
January 2005	New Appendix of disease/clinical condition modifiers added to CPT as interim solution to the expected growth of molecular genetics in clinical practice over the next decade. Consensus reached that this would allow maturation of molecular pathology services and nomenclature before addition of granular molecular pathology codes. Continued use of the stacking codes to identify molecular pathology services on the claims using the conditions/reasons for testing and to allow distinct identification of 260 potential combinations which were known at that time. In addition, this was intended to allow

intersection of both has begun to fuel the development of the next generation of molecular pathology services within an extremely short period of time. A number of critics of the CPT process have taken an ahistorical view of molecular pathology service developments and fail to acknowledge the ongoing and active engagement of CPT and participating stakeholders to address rapidly changing conditions as they have unfolded.

	complete capture of the human genome.
January 2009	More refinements to stacking codes implemented with feedback that very few payers made use of the Appendix I modifiers. The Appendix I modifier listing was intended to identify for payers on a claim the disease or condition that necessitated the reporting of multiple stacked molecular pathology service codes.
October 2009	Presentation to medical specialty representatives at Annual CPT meeting outlining the need to address molecular pathology services and to launch overhaul.
December 2009	Fly-in meeting hosting stakeholders. Association of Molecular Pathology white paper used as model for workgroup direction.
January 2010	MPCW assembled. The intervening opening of the CPT process tripled the number of participating representatives. The greatest increase in representation came from the consulting and vendor sectors. It included 23 organizations and 28 individuals.
February 2010	Workgroup began biweekly meetings for purposes of identifying solutions to issues for coding molecular assays in cancer, genetics, and histocompatibility. The most commonly-performed tests (Tier 1) were assigned analyte specific CPT codes. Less commonly-performed tests (Tier 2) were assigned to 9 resource level codes determined by level of resources required for their performance and interpretation.
November 2010	100+ Tier 1 (disease/condition specific) and Tier 2 (methodology-specific) codes submitted in application for consideration by CPT Editorial Panel.
February 2011	100+ codes were presented to the CPT Editorial Panel, which accepted them.
March 2011	As part of continuing improvements to CPT process, the MoPath code descriptors were published for the first time on the public AMA/CPT web site with a request for public

	comment. The foregoing enhances transparency and agility while continuing to promote widespread participation in code development across many sectors.
February April 2011-	Codes surveyed and sent to the Relative Value Update Committee (RUC) for valuation recommendations and inclusion in the CMS proposed fee schedule CY 2012.

The MoPath codes were the product of the first major undertaking of the MPCW—and it constituted an aggressive and time/resource intensive effort to establish new codes that represent about 86 percent of pertinent molecular pathology services billed analyses (using a large commercial lab's frequency data). This was an ambitious launch that included significant stakeholder input and modifications, including a public comment period for the initial MoPath codes prior to approval by the Panel to gain wide input on the accuracy of the proposed Tier 1 code descriptors. In a subsequent phase, and in response to requests for increased identification of low frequency, low population sole source analyses, CPT published on the AMA web site for expedited reporting an index of multi-analyte assays with algorithmic analyses (MAAA) to provide the detailed information sought by payers and the industry at large. The AMA plans to continue publishing the CPT Tier 1, Tier 2, and MAAA codes three times annually following each Panel meeting to support the agile process created for review and addition of molecular pathology and MAAA codes to the CPT code set.

These efforts demonstrate that the CPT process continues to add increasing speed and transparency to accommodate rapid technological evolution, a growing number of stakeholders (many new to the process), and substantial growth in the volume of information. The CPT molecular pathology services process has not been, nor will it be in the future, a static process, but seeks continued opportunities for increased transparency and agility to accommodate the need for reporting dynamic and evolving technologies. The benefits of this approach are evident since molecular pathology services are being driven by what is widely believed to be a highly "disruptive innovation." However, the foundation of the CPT process is firmly anchored in fidelity to evidence-based clinical integrity. It is irrefutable that the CPT process continues to provide the important function of convening and providing input from a diverse cross-section of key stakeholders. The CPT process is an indispensable platform for CMS to obtain information from these stakeholders in an increasingly complex, yet transparent, environment. CPT is regarded as the gold standard for stakeholder engagement and transparency and is uniquely situated, independent, and driven by clinical considerations.

In light of the foregoing, it is both appropriate and expedient for CMS to no longer delay the adoption of the MoPath codes.

Clinical and Public Policy Factors Dictate Placement of MoPath Codes on PFS

CMS is currently seeking input on where MoPath codes should be placed—either the physician fee schedule (PFS) or clinical laboratory fee schedule (CLFS). CMS has proposed placement of all of the MoPath codes on one fee schedule. The AMA supports placement of the MoPath codes on the PFS for clinical and public policy reasons.[4]

Clinical Considerations

Molecular pathology tests are complex and require professional interpretation of the data generated by instruments to be clinically meaningful. Efforts to improve quality care and patient safety underscore the essential role of physicians in rendering interpretive services in the area of molecular pathology testing services. Currently, and into the foreseeable future, many treating clinicians are not able to interpret the output of molecular pathology tests. These test results require review and interpretation in order to convert data into a clinically useful test result that the treating clinician is able to rely upon in diagnosis and treatment. Furthermore, the results are specific to a particular patient. In short, these tests typically identify "individual normals" for a specific patient. While certain molecular pathology tasks can be performed by non-physicians, these tests are considered sufficiently complex to require the professional involvement of a physician. It is reasonably expected that there will be a deluge of extremely complex molecular pathology diagnostic services into the foreseeable future and the need for physician interpretive services then becomes more important, not less, as suggested by some commentators.

In addition, the notion that a negative test does not warrant review and analysis is simply wrong. Negative results of highly complex tests often warrant as much scrutiny and analysis as those that are not "negative," and can provide information critical to patient care. The analysis is multi-factorial and a failure to review a "false" negative is as problematic and harmful to patients as an inadequate review and analysis of tests that are "positive." Molecular diagnostic services can have a direct and immediate impact on patient care and outcomes. Placing the MoPath codes on the PFS will promote accountability and ensure quality because such a placement will ensure physicians are compensated for the molecular pathology services that they render.

Public Policy Considerations[5]

[4] The AMA supports modification of 42 CFR section 415.130. In addition, the AMA understands that there are situations when interpretation of molecular diagnostics by PhD geneticists is not permitted under the PFS. The AMA supports providing regulatory modifications that allow PhDs to continue to provide such services subject to the supervision of a physician.

[5] Historical legal precedents and current Medicare regulations unambiguously support placement of MoPath codes on the PFS as physician laboratory services payable on the PFS. Medicare regulations regarding payment for physician pathology services are not designed to prohibit payment to pathologists for the professional component of laboratory tests, but instead are meant to define whether pathologist payment should be made under Part A or Part B of the Medicare program. These same regulations are also clearly meant to encompass

Policy-makers and clinicians have been grappling with health care system costs and the associated strategic (and sometimes tough) decisions that result from a need to increase value while improving patient health outcomes. Placement of the MoPath codes on the PFS (grounded in the historical nature of the services provided and clinical considerations, as discussed above) will drive value and innovation, and lower costs. In sharp and marked contrast to the PFS, the CLFS provides for a fixed price that can only be varied through legislative means. The CLFS process does not account for the lowering of costs that are associated with the maturation of technologies and services that reflect increased efficiencies over time. Placement of the MoPath codes on the PFS provides greater benefit to the Medicare program because it safeguards CMS' discretion and control over the costs and prices of molecular pathology services that are predicted to be the fastest growing segment of medical services. The PFS process allows CMS to continuously review molecular pathology services and to take into account changing technology and increased efficiencies as technology is adopted and becomes more widespread. Placement of these molecular pathology codes on the PFS gives CMS a greater ability to control costs over time via PFS payment update processes.

Efforts to improve upon and enhance patient outcomes also weigh in favor of placement of the MoPath codes on the PFS. The lowering of costs over time will ensure greater access to a varied number of molecular pathology services. (In addition, it will ensure that overutilization is not incentivized which may occur without beneficiary co-pays.) This will accelerate uptake and application in clinical practice as the value proposition increases. Simply stated, placement of the MoPath codes on the PFS is the only approach that will ensure the greatest reach of molecular pathology services to the widest number of Medicare beneficiaries who would benefit from such services. At the same time, it will ensure the cost of a few tests will not prematurely arrest the development of less costly, higher value alternatives. Furthermore, as the complexity of the services increases, it will ensure the continued and appropriate recognition of services provided to physicians who translate and interpret the results into information that is comprehensible and relevant to clinical practice and individual patients.

CMS Has Received Robust Evidence to Support National Pricing

We strongly urge CMS to adopt the valuations for the MoPath codes supplied by the RUC and CAP. In addition to the information supplied by the RUC and CAP, CMS has taken an additional year to gather information and had the benefit of two robust notice and comment periods where additional information and data have been supplied by stakeholders. CMS has ample documentation to support national pricing.

In addition, we do not support the delegation of CMS' national pricing authority to one regional carrier for most molecular pathology services. CMS has stated in prior meetings

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scientific advances that permit analysis and interpretation of the human body at the subcellular, molecular level, as a subset and extension of the tissue and cellular level.

that it does not direct the actions of the regional carriers. The lack of meaningful and necessary transparent engagement of impacted parties and the larger public by the CMS carrier currently responsible for processing most molecular pathology claims is very concerning. Molecular pathology services are at the vanguard of innovations in patient care. It is contrary to public policy to severely limit input of health care stakeholders—new and established—in this rapidly evolving area. The CMS proposal to delegate pricing to the regional carrier is essentially a proposal to delegate the majority of molecular pathology pricing to one regional carrier. We oppose this unilateral, insular, and non-transparent approach to national pricing and urge CMS to rely upon the information and data provided by numerous stakeholders.

Summary

For all of the foregoing reasons, the AMA urges CMS to place the new Tier 1 and Tier 2 molecular pathology service codes on the PFS. Further, we urge CMS to adopt the RUC-approved technical and professional valuations for these services along with the additional information provided by CAP in order to establish national pricing.

PART B DRUG PAYMENT: AVERAGE SALE PRICE (ASP) ISSUES

Average Manufacturer Price (AMP) Substitution

CMS proposes to leave the threshold for AMP substitutions at five percent "until such time as a change in the threshold amount is warranted." CMS has also sought additional specific safeguards for the AMP price substitution policy.

We support CMS' proposal to prevent the application of the AMP substitution if a drug and dosage form represented by the HCPCS code are reported by the Food and Drug Administration (FDA) on its current drug shortage list (or other FDA reporting tool that identifies shortages of critical or medically necessary drugs) to be in short supply at the time that ASP payment limits are being finalized for the next quarter. However, we urge CMS to further modify this proposal to provide that CMS will not substitute if the American Society for Health System Pharmacists (ASHP) identifies the drug on its shortage list. A manufacturer could delay reporting anticipated or actual shortages to the FDA. (This possibility increases as there are no meaningful penalties for not reporting and some manufacturers may be concerned about FDA scrutiny.) The ASHP list provides a rapid indication of shortage before it deepens. Waiting until the FDA specifies that a drug is in shortage may undermine efforts to avert or mitigate a shortage. We also urge CMS to increase the threshold that would trigger AMP substitution for the reasons discussed below.

Widely Available Market Price (WAMP) Substitution

CMS proposes to leave the threshold for WAMP substitutions unchanged. The AMA agrees that CMS should "proceed cautiously" and "provide adequate notice of [its] intentions" to

make WAMP substitutions. **However, in light of drug shortage concerns outlined below, we urge CMS to increase the threshold that would trigger WAMP substitution and provide a similar requirement that any drug that has been identified as being in shortage would be exempt from substitution.**

Part B Drug Payment Policy & Shortages

The AMA appreciates CMS' effort to avoid deepening a drug shortage of Part B drugs when the FDA has indicated that it is subject to a shortage. Nonetheless, we continue to have concerns that CMS' proposed Part B drug payment provisions are not adequate in light of the serious and, in some cases, life-threatening conditions faced by patients when a Part B drug is in shortage. More broadly, as discussed immediately below, we continue to have concerns that the ASP plus six percent is not adequate to cover the actual Part B drug acquisition costs for small physician practices.

For the past several years the AMA, along with a number of impacted specialties such as oncology, have expressed concern that ASP plus six percent has resulted in persistent under-reimbursement that impacts small physician practices, in particular. The method for calculating ASP includes discounts and rebates that hospitals, large practices, and group purchasing organizations (but not small practices) are able to negotiate. This has meant that small practices have to administer some treatments at a loss or refer their patients elsewhere. This undermines continuity of care at a critical time for patients and leads to fragmentation of care which carries increased costs. Ultimately, the foregoing hinders efforts to improve patient outcomes. It also drives services into the hospital outpatient department, where both Medicare and beneficiaries pay more.

The problems outlined above have been further exacerbated by the persistent shortages that have emerged since the Part B payment policy change dictated by the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA).[6] Drug shortages have climbed from fewer than 80 in 2005 to more than 250 in 2011. The vast majority of drugs in short supply have been physician-administered generic sterile injectable drugs. IMS reports that over 80 percent of the drugs in shortage have been generic and over 80 percent have been injectables. The IMS Institute found that this "is a small part of the overall medicines market, yet includes a number of critical drugs used in the treatment of cancer, infection, cardiovascular disease, central nervous system conditions and pain." These drugs have a significant impact on patient outcomes. Furthermore, the lack of timely access to these treatments likely has both immediate as well as long-term consequences.

[6] Efforts are underway to fully evaluate the underlying causes that have contributed to the increasing number of drugs in shortage. There does appear to be consensus that the causes are multi-factorial and complex. However, a recent analysis of the MMA policy changes that prompted a reduction of Medicare Part B reimbursements for physician-administered generic drugs, provides some evidence that suggests the policy change may, in fact, be at least one significant contributing cause of shortages for Part B generic drugs. See, Medicare Reimbursements and Shortages of Sterile Injectable Pharmaceuticals, Ali Yurukoglu, July 2012, NBER Working Paper No. 17987, Stanford University, www.stanford.edu/~ayurukog/shortages.pdf.

In an October 2011 report, the HHS Office of the Assistant Secretary of Planning and Evaluation (ASPE), found that "only about 10% of the Medicare Part B volume of injectable oncology services in 2008 consisted of drugs that experienced any shortage at some point over the subsequent 4 years."[7] While 10 percent may appear to be a relatively low number, it belies the far larger costs that ripple through the health care delivery system when a shortage of physician-administered drugs exists. First, patients bear the brunt of the impact as their treatment is delayed or they are treated with inferior alternatives. Second, shortages consume an immense amount of provider time and resources that tax an already overburdened health care delivery system. Physicians and staff are diverted from providing clinical care to locating a drug in shortage, identifying and securing alternatives, and addressing the possible effects of a de-stabilized patient or delayed care. Furthermore, since 2008, the timeframe in which ASPE drew data for its analysis, physicians and patients have seen a steady rise in the number of drug shortages, not less.

In light of the significant and continuing problems presented by shortages in physician-administered generic drugs under Part B, we support policy changes that will lead to greater stability in reimbursement for Part B drugs and efforts to put safeguards in place at the first sign that a drug shortage exists. **We have concerns that the substitution thresholds may be set too low and represent another layer of disincentives to long-term investment in the manufacture of physician-administered generic drugs**. In addition to soliciting comments on the appropriate WAMP and AMP substitution threshold, **we strongly urge CMS to undertake or commission analysis of this issue**.

CERTIFIED REGISTERED NURSE ANESTHETISTS AND CHRONIC PAIN MANAGEMENT SERVICES

CMS proposes to revise its regulations governing the practice of CRNAs to provide that, "[a]nesthesia and related care includes medical and surgical services that are related to anesthesia and that a CRNA is legally authorized to perform by the State in which the services are furnished." Although CMS says it means to make clear by this revision that CRNAs may, if permitted by state law, be reimbursed by Medicare for chronic pain management services, the proposed amendment to the regulatory text is much broader and would allow CRNAs to perform any medical or surgical services related to anesthesia pursuant to state law restrictions, not only chronic pain management. **Because chronic pain management poses potentially serious patient health and safety risks, and because CRNAs do not possess the requisite education and training to manage those risks, the AMA strongly urges CMS to rescind this proposal in its entirety. We are also highly concerned that the proposed regulatory text is far broader than stated in the preamble.**

[7] While the report focused on oncology drugs, the purpose was to better understand the implications of drug shortages more broadly.

Patient Safety

As CMS notes in the proposed rule, chronic pain management is an evolving field, the available interventions to treat chronic pain have been expanding, and the health care community continues to examine the appropriateness and effectiveness of these many and varied treatment techniques and modalities. Given the varied and emerging nature of these chronic pain management procedures, it is difficult to understand why CMS proposes to expand the scope of practitioners who may perform such procedures beyond physicians, whose additional and specialized training makes them far more qualified than other practitioners to assess the clinical risks and benefits of such procedures.

CMS should consider that many of the chronic pain management procedures at issue have significant patient health and safety risks. Many interventional chronic pain management procedures are administered at the high levels of the spinal column, and risks include allergic reactions, infections, bleeding, nerve damage, spinal cord injuries, brain stem infarction, and death. Further, drugs that are associated with interventional pain procedures (like neurolytic agents and particulate steroids) can cause serious complications like reduced blood flow, paraplegia, stroke, and death. Spinal cord stimulations via electrical pulse generators also have serious risks, including epidural hemorrhage, hematoma, infection, spinal cord compression, paralysis, leakage of spinal fluid, infection, and numbness or pain below the level of implantation. Epidural steroid injections carry risks of infection, numbness of the bladder, bleeding, and nerve damage.

Education and Training

Caring for patients with chronic pain requires a broad understanding of diagnostic evaluation, behavioral management, rehabilitation, pharmacologic therapy, and interventional pain treatment. Recognizing the significant medical issues associated with pain management, the American Board of Medical Specialties has created a pain medicine sub-specialty, which CMS has recognized since 2003. To develop this expertise and avoid exposing patients to unnecessary harm, physicians who specialize in pain medicine complete four years of medical school, four years of anesthesiology residency or residency training in physical medicine and rehabilitation, neurology or psychiatry, as well as a one-year multidisciplinary fellowship in pain medicine and examination for board certification. Physicians who are board-certified in pain medicine have thus undergone extensive training in the diagnosis and treatment of patients with chronic as well as acute pain problems.

Conversely, CRNAs do not possess the requisite education or training to perform many of the chronic pain management techniques contemplated in this rule. CRNAs complete a nursing degree, work for a year in an intensive care setting, and participate in a 30-month training program. There is no board or accreditation program for nurse anesthetists who seek to perform chronic interventional pain management techniques. Indeed, nurse anesthesia educational programs are not required to provide any clinical experience in pain

management, though a mere 10 cases of acute and/or chronic pain management are recommended as part of the clinical experience.[8]

While several state legislatures have recently debated the scope of CRNA practice generally, state legislatures that have specifically considered scope of CRNA practice as it pertains to interventional chronic pain management have overwhelmingly determined that only physicians may perform these services independently.[9]

Similarly, courts that have considered the issue have determined that CRNAs lack the education and training to perform interventional pain management procedures. For example, testimony in a Louisiana Court of Appeals case (that the Louisiana Supreme Court declined to hear) noted the lack of guidelines necessary to assess the competency, skill set, abilities, and training needed for nurse anesthetists to begin performing interventional pain management procedures.[10] During the litigation, the president-elect of the American Association of Nurse Anesthetists (AANA) acknowledged that there are no guidelines for assessing the competency, skill set, abilities, or training needed for CRNAs to begin performing interventional pain management procedures. Rather, she opined that a CRNA should be allowed to perform these procedures once the CRNA has had the "necessary education, training, and feels like they have the necessary skills." In that case, the court concluded that the practice of interventional pain management is not within the scope of practice of a nurse anesthetist, and is solely the practice of medicine.

Some Medicare contractors also agree that CRNAs are not appropriately skilled to perform interventional pain management for patients with chronic conditions. For example, Noridian Administrative Services and Wisconsin Physician Services (WPS), which combined serve 19 states, declined to use Medicare funds to pay CRNAs for chronic pain management services. The contractors concluded that the assessment skills required for the evaluation of chronic pain and development of a plan of care were "not part of the CRNA training curricula."[11]

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[8] Council on Accreditation of Nurse Anesthesia Educational Programs, Standards for Accreditation of Nurse Anesthesia Educational Programs (Jan 2012).

[9] Missouri House Bill 682 (2012), which was signed June 18, 2012, states that only physicians should be able to perform certain chronic pain management services, including nerve ablation, percutaneous precision needle placement in the spinal column under fluoroscopic guidance, laser or endoscopic discectomy, surgical placement of intrathecal infusion pumps, or spinal cord stimulators. Tennessee Senate Bill 1935 (Pub. Ch. 961) (2012), requires direct physician supervision of any advanced practice registered nurse or physician assistant who performs any invasive procedure involving any portion of the spine, spinal cord, sympathetic nerves of the spine or block of major peripheral nerves under the spine. The Oklahoma Interventional Pain Management and Treatment Act (59 Okla. Stat. Ann. 650) (2010), requires CRNAs who administer lumbar intra-laminar epidural steroid injections or peripheral nerve blocks to do so only under the direct supervision of a physician board-certified in interventional pain management or its equivalent, and allows only physicians to perform certain other interventional chronic pain management procedures (e.g., nerve ablation, percutaneous precision needle placement within the spinal column with placement of drugs such as analgesics, laser or endoscopic diskectomy, intrathecal infusion pumps, spinal cord stimulation). Iowa Administrative Code 13.9 (2010) defines interventional chronic pain management as the practice of medicine.

[10] Spine Diagnostics of Baton Rouge, Inc. versus Louisiana State Board of Nursing. (4 So.3d 854, 2008-08-13 (La.App. 1 Cir. 12/23/08).

[11] Noridian. *CRNA Practice and Chronic Pain Management, Revised*. See http://bbnor.noridian.com/Bulletins/Medicare_Part_B/Medicare_B_News/Medicare_B_News_Issue_273_October_6_2011_/CRNA_Practice_and_Chronic_Pain_Management_-_Revised___.htm. WPS Medicare. *Certified*

In describing its rationale for expanding CRNA scope of practice to include pain management and any other services authorized under state law, CMS contends that state scope of practice laws are only "one parameter" it uses to define services that can be furnished and billed by non-physician practitioners. However, no other justifications for this significant change in policy are laid out in the rule.

CMS does acknowledge in the rule that "simply because the State allows a certain type of health care professional to furnish certain services does not mean that all members of that profession are adequately trained to provide the service." However, the proposed rule then provides that "CRNAs practicing in States that allow them to furnish chronic pain management services are responsible for obtaining the necessary training for any and all services furnished to Medicare beneficiaries." Medicare patients deserve better. CMS should consider the patient health and safety implications of this policy that exposes Medicare patients to unnecessary risks and should not implement it.

For the foregoing reasons, we urge CMS to rescind its proposal to expand the scope of CRNA practice to include chronic pain management and other services.

ORDERING OF PORTABLE X-RAY SERVICES

We urge CMS to rescind its proposal to permit portable x-ray services to be ordered by a non-physician practitioner. Non-physician practitioners generally do not possess the requisite clinical knowledge to determine how to diagnose an illness, how to utilize x-rays as part of the diagnosis and treatment of a patient, how to interpret an x-ray, how to plan a course of medically appropriate follow-up treatment, or how to determine when an x-ray is medically necessary and should be ordered.

There are also outstanding program integrity concerns regarding portable x-rays that would be exacerbated as a result of CMS' proposal. As CMS notes in the proposed rule, the OIG recently published a report entitled *Questionable Billing Patterns of Portable X-Ray Suppliers* (OEI-12-10-00190). That report found that even though federal regulations at 42 CFR § 410.32(a) and 486.106 clearly state that portable x-ray services must be ordered by a doctor of medicine or osteopathy to be eligible for Medicare coverage, Medicare paid at least $6.6 million for portable x-ray services that were ordered by non-physicians, and therefore not covered, in 2009.

OIG recommended in that report that CMS collect the $6.6 million in overpayments for portable x-ray services rendered in 2009 that were ordered by non-physicians, and implement procedures to ensure that CMS pays for portable x-ray services only when ordered by a physician and establish appropriate controls. In its August 4, 2011 response, CMS concurred with these recommendations, indicating that it was in the process of revising its *Medicare*

Registered Nurse Anesthetist (CRNA) Practice And Chronic Pain Management. See http://www.wpsmedicare.com/j5macparta/resources/provider_types/crna-pain-management.shtml.

Benefit Policy Manual to be consistent with regulations that would preclude Medicare from paying for portable x-rays not ordered by a doctor of medicine or osteopathy. Therefore, CMS' proposal to permit portable x-ray services to be ordered by a non-physician practitioner is contrary to CMS' prior view on this issue, and its rationale for this reversal is unclear.

Although growth in utilization of Medicare imaging services has declined significantly in the past few years, policymakers continue to express concern about excessive test ordering and to question its medical necessity. In fact, as revealed in the proposed rule, CMS is already considering a number of potential policies to avoid overutilization and abuse in the ordering and provision of portable x-rays. In light of these concerns, a proposal to expand authority to order x-rays to non-physicians seems especially ill-timed.

Should CMS proceed to adopt its proposal anyway, we strongly urge that any new program integrity requirements such as 100 percent prepayment review, audits, certification of necessity, and documentation directives be targeted only to those practitioner groups where there is evidence of abuse. Physicians are already overwhelmed by paperwork and documentation requirements. It does not make sense to adopt a policy that enhances concerns about potential abuse and overuse, and then addresses that concern by adding yet another form, or more requirements, that take up time that could be better spent on patient care.

We also note that CMS has had prior experience with increased utilization as a result of extending the scope of practitioners permitted to perform x-rays. For example, CMS' Demonstration of Coverage of Chiropractic Services under Medicare from 2005–2007 expanded the scope of services reimbursable as chiropractic services. For patients with neuro-musculoskeletal diagnoses, the number of beneficiaries who utilized any expanded chiropractic services increased by 62 percent within the four demonstration regions, while remaining stable in comparison areas. One of the four principal expanded services utilized was spinal x-rays. The Medicare Part B cost for reimbursements for chiropractic services increased by about 78 percent in demonstration areas, due to increases in both the number of beneficiaries receiving expanded services and the total reimbursements per user. The interim cost impact was an average increase of $180 per expanded chiropractic user beyond the cost per standard care user, per each six-month span. Should CMS decide to move forward with this plan, CMS should certainly adjust the Sustainable Growth Rate to reflect this change in policy.

We do not accept the notion in this proposal that because state law authorizes a certain procedure to be performed or ordered by a certain practitioner that Medicare should, in effect, "get out of the way." In fact, we concur with CMS' statement in another section of the proposed rule that "simply because the State allows a certain type of health care professional to furnish certain services does not mean that all members of that profession are adequately trained to provide the service."

Nor do we agree that the proposed changes are needed simply to standardize Medicare's rules for ordering portable or stationary x-rays. Instead, CMS should determine whether its current rules for ordering a stationary x-ray are appropriate prior to extending those rules to portable equipment. For example, some of the practitioners (psychologists) who would now be eligible to order both portable and stationary x-rays under CMS' proposal seem far less likely to ever use an x-ray in the course of their treatment than certain other practitioners who still would not be able to order an x-ray under the proposed rule. Accordingly, CMS should not adopt policies that are deferential to state scope of practice policies without a thorough review of the patient health and safety implications of such policies.

To ensure patient health and safety, and in consideration of the recent program integrity and utilization concerns of both OIG and CMS, we urge CMS to rescind its proposal to permit portable x-ray services to be ordered by a non-physician practitioner.

Finally, we strongly support Part B coverage of the Hepatitis B vaccine for high risk groups, specifically persons with diabetes. This provision promotes positive patient outcomes and quality.

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

Sincerely,

James L. Madara, MD