California Medical Association
Physicians dedicated to the health of Californians

September 2, 2014

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Ave, SW
Washington, D.C. 20201

RE: **Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015**
[CMS-1612-P]

Dear Administrator Tavenner:

The California Medical Association (CMA) appreciates the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) on the proposed 2015 Medicare Physician Fee Schedule. The CMA strongly concurs with the comments submitted by the American Medical Association. We are providing additional recommendations related to the Value-Based Modifier and the Physician Sunshine Act reporting requirements. And finally, with the Congressional enactment of the California Medicare locality reform earlier this year, we look forward to working with CMS next year to ensure its timely implementation in 2017.

CMA emphasizes the following AMA comments below with specific California additions.

- Resource-Based Practice Expense Relative Value Units (RVUs)
- Off-Campus Provider-Based Outpatient Departments
- Improving the Valuation and Coding of the Global Package
- Professional Liability Insurance RVUs
- Medicare Telehealth Services
- Chronic Care Management
- Removal of Employment Requirements for Services Furnished "Incident to" Rural Health Clinic and Federally Qualified Health Center Visits
- Private Contracting Opt-Out
- Reports of Payments or Other Transfers of Value to Covered Recipients
- Physician Compare Website

- Physician Payment, Efficiency, and Quality Improvements—Physician Quality Reporting System (PQRS)
- Electronic Health Record Incentive Program
- Medicare Shared Savings Program
- Value-Based Payment Modifier and Physician Feedback Program

I. Resource-Based Practice Expense (PE) Relative Value Units (RVUs)

A. The Practice Expense Relative Value Methodology is Extremely Important in High Cost States, such as CALIFORNIA.

CMA Supports the Increase from 55-59% for the Practice Expense Impact on California Physician Payments.

We Urge CMS to Continue to Make Improvements to Cover All Direct Physician Practice Expenses.

In 2010, CMS completed a transition to a "bottom-up" practice expense RVU methodology. According to the CMS PE formula in Table 4,[1] to obtain the direct PE RVU, the actual labor, supply, and equipment costs accepted by CMS are first multiplied by a direct budget neutrality adjustment resulting in adjusted labor, adjusted supplies, and adjusted equipment costs, which are then converted into RVUs by dividing them by the current conversion factor. The AMA/Specialty Society Relative Value System/RVS Update Committee (RUC) and CMA have repeatedly expressed concern that this method means that CMS is only paying a percentage of the actual PE direct costs to provide a service. CMS has responded that the purpose of the resource-based PE methodology is to develop RVUs within the overall Medicare Physician Payment Schedule budget neutrality requirements, and prefers to refer to the direct adjustment in their methodology as a scaling factor. The CMA echoes the RUC's concern, while acknowledging that the percent of direct PE costs covered has improved since 2010. In 2009, the direct costs covered were 62.5 percent and then dropped to 50.8 percent in 2010, under the new "bottom-up" PE RVU methodology. In 2011, that percentage dropped further to 50 percent, then in 2012 increased to 55 percent and increased again in 2013 to 60 percent before dropping to less than 55 percent in 2014.

CMA supports the increase in 2015 to 59 percent. We applaud CMS for making this improvement in California physician reimbursement. This is particularly important in states, such as California, with higher than average PE costs. Rent and labor represent more than 59% of California physicians' practice expenses and we urge CMS to continue to make improvements to ensure appropriate and accurate reimbursement.

[1] 79 Fed. Reg. 40,327.

B. Off-Campus Provider-Based Outpatient Department Data Collection Needs to Take Into Account CALIFORNIA'S Unique Laws

In order to understand trends in hospital acquisitions of physician practices, CMS proposes to create a HCPCS modifier to be reported with every code for physician and hospital services furnished in an off-campus provider-based department of a hospital. The modifier would be reported on both the CMS–1500 claim form for physicians' services and the UB–04 (CMS form 1450) for hospital outpatient claims.

We have concerns about the administrative burden that this proposal would impose on physician practices, and strongly urge CMS to rescind this proposal and instead engage with stakeholders to develop alternative methodologies for understanding trends in hospital acquisitions of physician practices. Requiring inclusion of a modifier for each code for services furnished in an off-campus provider-based hospital department would be a significant, unwarranted encumbrance on administrative workflow. There is not sufficient merit for CMS to impose this requirement simply to study hospital acquisitions of physician practices, a trend that is complex and unlikely to be fully understood by the collection of this data.

The CMA would be happy to work with CMS as it evaluates physician practice trends. While hospital employment of physicians is prohibited in California, California has unique laws that allow hospitals to form "1206(l) Physician Foundations" to organize physicians. Our state legal framework must be taken into consideration under this proposal. We are keenly interested in this data but we don't believe that it will be accurately collected in California under the current proposal.

II. Potentially Misvalued Services under the Physician Fee Schedule

A. The CMA applauds CMS' recognition that the AMA RUC is a vital part of the agency's valuation of Medicare services.

Since the inception of the RUC Relativity Assessment Workgroup, the RUC and CMS have identified over 1,700 services through 15 different screening criteria for further review by the RUC. Most recently, the RUC has identified 010-day and 090-day global period services which appear as outliers with regard to the number of post-operative office visits included in the global period. The RUC will review and submit recommendations for these services for the 2016 Medicare Physician Payment Schedule. The RUC has also recommended reductions and deletions for 935 services, more than half of the services identified, leading to redistribution of more than $3 billion. The RUC will continue working with CMS in a concerted effort to address potentially misvalued services. A detailed report of this progress is appended to the RUC's separate comment letter.

B. Improving the Valuation & Coding of the Global Service Package

The CMA supports increasing the accuracy of physician payment and commends CMS for investigating methods to more accurately pay Medicare practitioners for the services they

provide. However, we have serious concerns that the current proposal would not accurately account for physician work, practice expense, and malpractice risk for services performed within the current surgical global period. CMS proposes to transition all 010-day and 090-day global codes to 000-day global codes by 2017 and 2018, respectively. As support for this proposal, CMS references challenges it has experienced in obtaining available data to verify the number, level, and relative costs of post-operative visits included in global packages. CMS also expresses concern that 010-day and 090-day global packages may, in some cases, no longer accurately reflect the post-operative care provided to the typical patient. CMA joins the AMA in recommending that CMS work jointly with the RUC Relativity Assessment Workgroup to collect and review existing, objective data in order to validate bundled post-operative visits. **Given the complications that may arise from these logistical difficulties, we believe that the proposed timeline is simply unrealistic.**

1. **Unbundling Global Service Packages Would Require Separate Reporting (New Codes & Valuation) of Non-E/M Post-Operative Physician Work**

Before finalizing any proposal, CMS should work with the RUC and the CPT Editorial Panel to ensure physicians are accurately paid for vital, routine patient care services that currently have no separate coding or reimbursement. In addition to hospital visits, office visits, critical care visits and discharge day management, there are many other post-operative care services that are also bundled into the 010-day and 090-day global packages. If CMS's proposal is implemented, these other physician services would also need to have their physician work, practice expense, and malpractice risk separately compensated—using either new or existing CPT/HCPCS codes. The Medicare Claims Processing Manual (Chapter 12, Section 40.1) provides several examples of services which are currently bundled into the global surgical package. If post-operative care is unbundled, examples of services that would need to be separately reported include:

- Dressing changes;
- Local incision care;
- Removal of operative pack;
- Removal of cutaneous sutures and staples, lines, wires, tubes, drains, casts, and splints;
- Insertion, irrigation and removal of urinary catheters;
- Routine peripheral intravenous lines;
- Nasogastric and rectal tubes; and
- Changes and removal of tracheostomy tubes.

The CMA commends CMS to the excellent and extensive detailed comments submitted by the AMA about the global services packages. The AMA identifies appropriate issues with the practice expense propsosal, payment for professional liability insurance, the level of office and hospital visits, administrative burden, the impact on multiple surgery, bilateral surgery, and co-surgeon reduction policies, the current RUC review of the 010-Day and 090-Day global period services, data collection and post-operative period validation, the proposed timeline, the adverse impact on patient access and compliance, and the general scope of the entire proposal.

III. Professional Liability Insurance Premiums and Relative Value Units Should be Reviewed Annually

CMS has again proposed improvements under its statutory obligations for the Five-Year Review of the Professional Liability Insurance (PLI) RVUs. We are pleased with several of the proposals introduced in this review cycle, but remain concerned over those that maintain the current, flawed status quo.

A. Annual Review of PLI RVUs

Over the past several years, CMS has made concerted efforts to ensure that services are accurately paid on the Medicare RBRVS. Removing the five-year review of potentially misvalued services has streamlined the review process and provided stakeholders an opportunity to provide comments to CMS in a timely fashion, on services that may be misvalued. In addition, practice expense inputs are updated frequently, with direct PE inputs updated within the RUC recommendations for specific services, and indirect inputs updated each year based on shifting PE percentages for each physician specialty. Given that CMS has modernized its process for updating these two components to reflect the most accurate information available, it seems logical that the third component of physician payment, PLI, should also be updated annually. Instituting a yearly collection of PLI premium data would provide two clear advantages. First, it would base PLI RVUs on the most current PLI premium data available, increasing the reliability and accuracy of PLI payments. Second, it would provide additional transparency for stakeholder comments. Under the current five-year review process, stakeholders have only one opportunity every five years to identify potential problems and/or improvements to a service's PLI RVU. If problems are not addressed in the final rule, then they must wait five years. An annual review would eliminate this problem and allow PLI RVUs to be treated identically to physician work and PE RVUs. **The CMA supports the RUC's recommendation that CMS implement an annual collection and review of PLI premium data.**

IV. Medicare Telehealth Service Expansion Crucial for CALIFORNIA Patients

CMS has proposed further expansion of covered telemedicine services. **Telemedicine services are becoming extremely important in vast states, such as California, where access to care is particularly challenging in rural areas.** The CMA is generally supportive of the agency's proposed inclusion of the following services via telemedicine: psychotherapy services (CPT codes 90845-7); prolonged services (CPT codes 99354-5); and annual wellness visit (HCPCS G0438-9). The CMA and AMA have consistently supported Medicare's proposals to expand access to a telemedicine option for Medicare covered services including last year's proposal to broaden the definition of "originating sites" to include more geographic locations. **The CMA and AMA would welcome the opportunity to collaborate with CMS and other major stakeholders to identify strategies to increase access to telemedicine services while ensuring quality and standards of care consistent with our policy.**

In June of this year, the AMA's House of Delegates adopted a report entitled, "Coverage and Payment for Telemedicine," which contains the most comprehensive and expansive AMA policy statements on telemedicine to date. The report was the culmination of discussions and deliberations by a diverse cross-section of practicing physicians, including many from **California**. As part of a comprehensive top to bottom initial review of the various telemedicine issues considered prior to the preparation of the report, leading telemedicine innovators provided expert guidance, early-adopter physicians provided recommendations concerning the benefits, risks, and best practices, and a number of environmental scans were completed.

Consistent with current Medicare practice and regulation, the **CMA** supports physicians and other health practitioners delivering telemedicine services abiding by state licensure laws and state medical practice laws and requirements in the state in which the patient receives services. The **CMA** advocates that physicians delivering telemedicine services must be licensed in the state where the patient receives services, or be providing these services as otherwise authorized by that state's medical board.

AMA policy outlines the conditions and factors applicable to establishing a valid physician-patient relationship. In addition, the AMA urges CMS to consider other factors that should apply to telemedicine services. For example, the AMA urges CMS to prioritize coverage of telemedicine services that include care coordination with the patient's medical home and/or existing treating physicians. This includes at a minimum identifying the patient's existing medical home and treating physician(s) and providing to the latter a copy of the medical record. AMA policy also provides that:

- Telemedicine services must be delivered in a transparent manner, to include but not be limited to, the identification of the patient and physician in advance of the delivery of the service, as well as patient cost-sharing responsibilities and any limitations in drugs that can be prescribed via telemedicine;
- Patients seeking care delivered via telemedicine must have a choice of provider, as required for all medical services;
- Patients receiving telemedicine services must have access to the licensure and board certification qualifications of the health care practitioners who are providing the care in advance of their visit.
- The patient's medical history must be collected as part of the provision of any telemedicine service;
- The provision of telemedicine services must be properly documented and should include providing a visit summary to the patient;
- Telemedicine services must abide by laws addressing the privacy and security of patients' medical information;
- The standards and scope of telemedicine services should be consistent with related in-person services; and
- The delivery of telemedicine services must follow evidence-based practice guidelines, to the degree they are available, to ensure patient safety, quality of care and positive health outcomes.

The CMA supports Medicare's proposal to expand pilot programs to enable coverage of telemedicine services, including, but not limited to, store-and-forward telemedicine as well as demonstration projects under the auspices of the Center for Medicare and Medicaid Innovation (CMMI) to address how telemedicine can be integrated into new payment and delivery models. As adoption of new telecommunication technologies increases, the CMA and AMA continue to carefully consider and evaluate the impact on patient clinical care and welcomes the opportunity to work with CMS.

V. CMA Supports Payment for Chronic Care Management (CCM) Services

The **CMA strongly supports payment for non-face-to-face chronic care management (CCM) services**. The RUC has worked with the CPT Editorial Panel and the CPT/RUC Complex Chronic Care Workgroup ("C3W") to describe and estimate resource costs associated with these important non face-to-face services. The C3W has advocated for separate payment for other non face-to-face services that are critical components of care management, including team conferences, patient education, telephone calls, and anticoagulant management. In 2013, CMS implemented payment for transitional care management services (TCM) based on the work of CPT and the RUC. In 2015, CMS will begin payment for CCM services for patients with two or more complex chronic conditions that are expected to last at least 12 months or until the death of the patient, and that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. We appreciate the CMS decision to pay for TCM and CCM services and urge CMS to continue consideration of payment for other non face-to-face services.

In the Proposed Rule, CMS discusses nomenclature for a G code originally proposed in July 2013. **The CPT Editorial Panel has created a new code 99490X for 2015 intended to address the CMS proposal, and we urge that CMS use this new CPT code, rather than the G code.**

In addition to implementing the RUC recommendations for 99490X, CMS should also continue to publish, and ideally pay and recognize, the RUC recommended relative values and direct practice expenses for CPT codes 99487 and 99489.

VI. Removal of Employment Requirements for Services Furnished "Incident to" Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Visits

In May 2014, CMS amended the regulations for RHCs to allow nurse practitioners (NPs), physician assistants (PAs), certified-nurse midwives, clinical social workers, and clinical psychologists to furnish their services under contract, so long as at least one NP or PA is employed by the RHC (as required by section 1861(aa)(2)(iii) of the Social Security Act). In similar fashion, CMS is now proposing to allow billing for services "incident to" an RHC or FQHC visit that are furnished by nurses, medical assistants, and other auxiliary personnel who work under contract with the clinic or center, as well as by those who are employees. These changes are designed to provide RHCs and FQHCs with greater flexibility.

The CMA supports this proposal, provided that RHC and FQHC auxiliary personnel are held to the same high professional standards for the quality of their care, regardless of whether they are working under contract or as employees. All members of a physician-led health care team should be enabled to perform medical interventions that they are capable of performing according to their education, training, licensure, and experience to most effectively provide quality patient care. In June 2014, the AMA House of Delegates adopted guidelines for physician-led medical health care teams. Many of the guidelines are quite relevant to the team approach integral to many RHCs and FQHCs:

Patient-Centered:

a. The patient is an integral member of the team;
b. A relationship is established between the patient and the team at the onset of care, and the role of each team member is explained to the patient;
c. Patient and family-centered care is prioritized by the team and approved by the physician team leader;
d. Team members are expected to adhere to agreed upon practice protocols;
e. Improving health outcomes is emphasized by focusing on health as well as medical care;
f. Patients' access to the team, or coverage as designated by the physician-led team, is available twenty-four hours a day, seven days a week; and
g. Safety protocols are developed and followed by all team members.

Teamwork:

a. Medical teams are led by physicians who have ultimate responsibility and authority to carry out final decisions about the composition of the team;
b. All practitioners commit to working in a team-based care model;
c. The number and variety of practitioners reflects the needs of the practice;
d. Practitioners are trained according to their unique function in the team;
e. Interdependence among team members is expected and relied upon;
f. Communication about patient care between team members is a routine practice; and
g. Team members complete tasks according to the agreed upon protocols as directed by the physician leader.

Clinical Roles and Responsibilities:

a. Physician leaders are focused on individualized patient care and the development of treatment plans;
b. Non-physician practitioners are focused on providing treatment within their scope of practice consistent with their education and training as outlined in the agreed upon treatment plan or as delegated under the supervision of the physician leader; and
c. Care coordination and case management are integral to the team's practice.

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Practice Management:

a. Electronic medical records are used to the fullest capacity; and

b. Quality improvement processes are used and continuously evolve according to physician-led team-based practice assessments.

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c. Prior authorization and precertification processes are streamlined through the adoption of electronic transactions.

VII. Private Contracting: Allow Physicians to Opt-Out Indefinitely

We strongly urge CMS to amend its current opt-out policy by allowing physicians to opt-out of the Medicare program indefinitely, and by ending the required submission of an affidavit every two years, in perpetuity. The CMA supports CMS' clarification that the physicians who have validly opted-out of the Medicare program are nevertheless still permitted to write orders and referrals for Medicare beneficiaries. This will assist beneficiaries in receiving the care they need. The CMA fully supports changes, which would allow physicians to opt-out of Medicare without a requirement to reaffirm their opt-out status; and create a safe-harbor period for a physician to remain opted-out of the Medicare program, without penalty or possibility of recoupment, when a physician has mistakenly not reaffirmed his or her intention to be opted-out. The current requirement—that every physician who opts-out of Medicare must re-file an affidavit every two years in order to maintain his or her opt-out status—is unnecessary, is not required by law, and seems completely illogical. No other government program comes to mind, where one has to file a legal document in order to continue not to participate. Most important, this creates an unnecessary burden for these physicians to needlessly submit documentation every two years, and has the potential to catch some physicians unaware, at great peril. Failing to submit such documentation may expose physicians to significant penalties. After the two-year minimum that is required by law, the opt-out period should be effective indefinitely, unless and until the physician chooses to terminate his or her opt-out status.

VIII. Reports of Payments or other Transfers of Value to Covered Recipients
CMA Urges CMS to Retain the CME Exemption Specified in Section 403
CMA Urges CMS to Reverse the Reportability of Reprints

The CMA joins a number of groups in the medical and health care community opposing the provisions in the proposed rule to eliminate the CME exemption for programs provided by accredited and certified CME organizations. We believe the proposed rule will significantly impede physician's ability to both present at and participate in necessary continuing education programs. This clearly was not the intent of the Sunshine Act.

In lieu of the exemption for certified CME programs, the proposed rule creates a new awareness standard for indirect payments that allows exemptions through third party transfers only where an industry donor is unaware of the recipients/beneficiaries before and up to 18 months after the funds are transferred. The CMA joined with the AMA and other state and national medical specialty groups in writing to the Secretary to oppose this standard which we believe is unworkable and would in effect make all CME programs reportable. As the letter states "Our organizations believe that this raises concerns as industry could learn the identities

of speakers/faculty and potential participates after the funds have been transferred through brochures, programs and other publications" as well as other means.

We agree with the comments submitted by the Council of Medical Specialties which state that "as faculty are selected and identified during the planning process by an accredited CME provider, their names are promoted in the activity programming to the intended audience. It is not realistic nor would it be perceived as transparent if faculty names were withheld until the day of the conference. " Their letter goes on to state "CMS has agreed that a grant from a company to an accredited and certified CME provider does not establish a relationship with the faculty, due to the firewall established by strict universal adherence in accredited and certified CME to the ACCME SCS. Therefore, it is not necessary to undermine the recognition of the protection of the faculty by eliminating from the rule mention of the Standards which create the firewall, and replacing them with an arbitrary and unworkable proxy." This same principle applies to conference attendees.

The CMA urges CMS to retain the original provisions in the final rule which exempt CME activities by providers of certified and accredited CME providers who strictly adhered to the firewalls established by the Standards for Commercial Support as promulgated by the ACCME.

Recognizing that CMS needs to address CE programs, we urge the agency to adopt the key provisions of these standards which state that the commercial supporter:

- Does not pay covered recipient speakers or attendees directly;
- Does not select covered recipient speakers or provide a third party (such as a continuing education vendor) with a distinct, identifiable set of individuals to be considered as speakers or attendees for the CE program; and
- Does not control the program content.

In order to strike a balance that acknowledges CMS' concerns while also safeguarding independent CE, we strongly urge modification of the agency's proposal to exclude from the Open Payments Program reporting where the above criteria are met. For those CE programs that are not ACCME certified, we also encourage CMS to look to existing inter-professional coalitions for accreditors of continuing education called Joint Accreditation which has been convened since 2009 and includes the AACME, Accreditation Council for Pharmacy Education and the American Nurses Credentialing Center.

Reporting of Reprints from Peer Reviewed Medical Journals and Text Books

The CMA continues to urge CMS to reverse its decision that reprints from scientific medical journals and medical textbooks are reportable under the Sunshine Act. Over 76 state medical societies and national medical specialty organizations as well as a number of other health care organizations and Members of Congress have contacted the Secretary to urge reconsideration

of this flawed policy. We continue to believe the regulations in this regard are contrary to both the statute and congressional intent. We further believe these rules will potentially harm patient care by impeding ongoing efforts to improve the quality of care through timely medical education.

The Sunshine Act was designed to promote transparency with regard to payments and other financial transfers of value between physicians and the medical product industry. As part of this provision, Congress outlined twelve specific exclusions from the reporting requirement, including *"[e]ducational materials that directly benefit patients or are intended for patient use."* In its interpretation of the statute, CMS concluded that medical textbooks, reprints of peer reviewed scientific clinical journal articles and abstracts of these articles are "not directly beneficial to patients, nor are they intended for patient use." We believe this conclusion is inconsistent with the statutory language on its face, congressional intent, and the reality of clinical practice where patients benefit directly from improved physician medical knowledge.

The importance of up-to-date, peer reviewed scientific medical information as the foundation for good medical care is well documented. Scientific peer-reviewed journal reprints, supplements, and medical text books have long been considered essential tools for clinicians to remain informed about the latest in medical practice and patient care. Independent, peer reviewed journal article supplements, reprints and text books represent the gold standard in evidence-based medical knowledge and provide a direct benefit to patients because better informed clinicians render better care to their patients. It is now clear that the design of the reporting requirement presents a clear disincentive for clinicians to accept high quality, independent educational materials; an outcome that was unintended when the provision was passed into law.

The Food and Drug Administration (FDA)'s 2009 industry guidance titled "Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices" underscores the importance of this scientific peer reviewed information. The FDA noted the "important public health and policy justification supporting dissemination of truthful and non-misleading medical journal articles and medical or scientific reference publications." FDA guidelines for reprints provide that medical reprints should be distributed separately from information that is promotional in nature, specifically because the reprints are designed to promote the science of medicine, are educational, and intended to benefit patients. We believe the Sunshine Act was designed to support the dissemination of this type of educational material.

As we have commented previously to the agency, there is no transfer of value, as contemplated by the law, to the physician from reprints from scientific peer reviewed medical journal reprints. A physician may have already purchased a subscription to the journal, they may have access to the material for free through an institutional site license or through their group practice or network. It is also critical to underscore that many of the leading medical journals, including the NEJM and JAMA, make research articles available for free after six months on the web. That is anyone, can obtain this information for free after six months on the internet. We

continue to question how CMS can maintain that there is any transfer of value when the information is available for free or the physician has already paid for the information. It is notable that the CMS's guidance on this issue states that the reportable value is determined is the price paid by the industry. We continue to maintain that the final rule is fatally flawed in this interpretation - the value to the pharmaceutical company, eg what they paid, is irrelevant to and not a valid determinant of the value to the physician. At a minimum we urge CMS to eliminate the reporting of reprints from the Sunshine Act as there is no transfer of value as contemplated by the law.

It is important to underscore our overriding concerns with the CME issue and reporting of reprints and textbooks. We continue to be concerned that by misinterpreting the law, CMS is in essence thwarting physician's ability to learn and keep up to date with the most current medical information. By any and all accounts this was not the purpose of the Sunshine Act. In fact Congress purposely included 12 exceptions to the law to ensure that the public reporting did not have a chilling effect on legitimate activities involving commercial support or indirect payments. At the same time, by creating a data base that is overwhelmed with data, which has no context, CMS is making the public disclosure aspect of the law unworkable.

As always we would welcome the opportunity to work with the agency to find a workable solution to these problems. The CMA would like to work with the agency to help ensure its appropriate implementation. Given all the problems to date with the Open Payment system, we continue to ask CMS to delay the publication of the reported information and to rescind the reporting requirements for reprints from scientific medical journals and textbooks.

IX. Physician Compare Website
CMA Urges CMS to Scale-Back the Website Until More Accurate Data Is Applied and Can Be Verified

CMS is proposing a significant number of changes and additions to the Physician Compare website, starting in 2015 or 2016, including plans to:

- In early 2015, publicly report on Physician Compare 20 2014 PQRS measures for individual EPs, collected via registry, EHR, or claims.
- Perform concept testing to test consumers' understanding of each measure under consideration.
- In 2016, make available for public reporting all 2015 PQRS GPRO measure sets across group reporting mechanisms (GPRO web interface, registry, and EHR), for groups of two or more eligible professionals (EPs). All measures reported by Shared Savings Program ACOs would also be available for public reporting on Physician Compare. CMS would select some of these to include on the profile pages, based upon consumer testing and stakeholder input, as too much information can negatively impact consumers' ability to make informed decisions.
- In 2016, publish composite scores by grouping measures according to the PQRS GPRO measures groups, e.g., care coordination, coronary artery disease, diabetes, and preventive care.

- In 2016, include benchmarks for 2015 PQRS GPRO data, using the Shared Savings ACO benchmark methodology. Benchmarks would be calculated using data at the group practice TIN (tax identification number) for all EPs who have at least 20 cases in the denominator, for each percentile from the 30th through the 90th percentiles. A group practice would earn quality points on a sliding scale, with a level of performance based on an average of their scores for each measure group.
- In 2016, begin reporting patient experience data for group practices of two or more EPs who meet sample size requirements and collected 2015 data via a CMS-specified certified CAHPS (Consumer Assessment of Health Providers and Systems) vendor.
- In late 2016, make available for reporting all individual EP-level PQRS measures collected via registry, EHR, or claims. Some would be published on the profile pages, based upon consumer input, and CMS would set benchmarks and calculate composite scores for individual EPs.

The CMA joins the AMA in strong opposition to the multiple proposals to extensively expand the Physician Compare website, as serious and fundamental flaws and errors remain unaddressed. While we appreciate CMS taking a phased approach to expanding Physician Compare, the website continues to be riddled with problems. Until CMS can make timely updates to the demographic data for individual EPs and group practices, we have little confidence in CMS' ability to accurately report performance scores, benchmarks, and composites. It is vitally important that quality information is utilized to improve care and support new delivery and payment models. But this must be done in a manner that is transparent and fair, so that providers and consumers can have confidence in the information that is posted. Recent efforts by CMS to publicly post individual physician data (i.e., the Medicare Physician Data Release and the Sunshine Open Payments Website Data) have been far from ideal and riddled with problems. This has soured the faith of many physicians in CMS' ability to accurately post information regarding the quality of their care.

There are also regular issues regarding the appropriate sample size to allow for correct inferences to be made about an individual physician. The CMA opposes posting individual performance information, and supports continuing to post only group practice performance information for successful reporters. AMA policy adopted at the June 2014 House of Delegates meeting states that "Consistent with the Medicare Improvements for Patients and Providers Act of 2008, the public reporting of quality and outcomes data for team-based care should be done at the group/system/facility level, and not at the level of the individual physician . . ."

CMA policy is consistent with AMA policy. It is based on our past experience in CALIFORNIA with the private payers and a Medicare demonstration project where inaccurate individual physician information was proposed to be publicly disclosed. While CMA supports efforts to improve quality and efficiency and appropriately educate patients, individual physician reporting systems in California were not producing accurate data, mainly due to flaws in the attribution methodology and inadequate risk-adjustment. Fortunately, because of the more advanced internal data systems within California's medical groups, their aggregated data was relatively more accurate but we all agreed that the individual physician-level data would be misleading to the public.

Further, a large percentage of CALIFORNIA'S population are uninsured, ethnically and racially diverse and low-income. These factors have a substantial impact on a physician's "score" and yet none of them were taken into account. Because of the problems with the data, the California private and Medicare data disclosure proposals were appropriately withdrawn by the payers. Even Medicare decided not to publish the individual physician data from the demonstration project as originally planned. CMA has commented extensively on this issue to CMS. It not only impacts the Physician Compare Website reporting program but the outcomes of the Value-Based Modifier payment policies.

In CALIFORNIA, it is essential that physicians who treat older, sicker and poorer patients not be disincented from caring for these most challenging patient populations. Risk adjustment and attribution methods systems that have been used by large insurers or health care organizations may not be adequate to deal with the detail of an individual subspecialist's patients who have numerous co-morbidities and complexities, or a safety net physician caring for patients who have no social support systems. To protect physicians and their frail elderly patients, it is incumbent on CMS to ensure that the attribution and risk adjustment methods are specific for subspecialists and appropriate, that demographic information is taken into account, and that the accuracy of the information is verified before it is disclosed to the public.

CMS must consider the current state of Medicare data collection and aggregation accuracy. Moreover, the agency has yet to put in place a formal appeals process for contesting Physician Compare information and only provides 30 days for an EP to review their information. **Therefore, CMA urges CMS to expand the preview period to 90 days at a minimum. And if an EP or group practice files an appeal and flags their demographic data or quality information as problematic, CMS should postpone posting their information until the issues are resolved.** It often takes medical practices several weeks and sometimes months to register and obtain their PQRS reports and Quality and Resource Use Reports (QRURs). It is also unclear how CMS plans to notify EPs of the preview period for reviewing their pubic ratings. We anticipate problems and backlogs with obtaining reports, as CMS greatly expands all of its quality programs and moves to profile all EPs.

The CMA and AMA support efforts to make medical standards more comprehensible to patients. However, star rankings or similar systems that display disparate quality scores in a simplified graphic result in distorted, inappropriate distinctions of quality for physicians whose performance scores are not statistically different. **Since the overwhelming majority of physicians would likely fall within a small range of average quality, the only information that accurately identifies what is truly valuable to a patient, considering the evolving state of quality measurement, is whether a physician is an outlier.**

CMS also proposes to report measures that meet a minimum sample of 20 patients. However, we are concerned with the accuracy of this sample size and the possibility of incorrect inferences. Acumen, on behalf of CMS, tested measures at the group practice rate using at least 25 measure-eligible cases for a select set of GPRO web-interface measures. Therefore, the results may vary if CMS moves to a sample of 20 patients and reports measures at the

individual level. **We request that CMS test measures and composites with a 20 patient attribution and provide an opportunity for public review and comment on the results.** The Physician Compare Technical Expert Panel (TEP) reports highlight the value in maintaining a consistent measure set for public reporting over time, which is more evidence as to why it is premature to move to reporting benchmarks and composites and reducing the sample size." This is especially confusing if CMS moves forward with its truncated list of measures for 2015 due to the proposal to remove a significant number of measures from the 2015 PQRS program. The information from 2013 and 2014 will be very different from the information based upon 2015 quality measures.

While we are supportive of composite measures, the composites, both as a whole and those newly proposed, have not been tested. Only individual measures have been reviewed and tested. It is inappropriate to simply assemble individual measures into a composite, and then assume they remain valid and measure practices accurately. There are also existing limitations in the evolving methodologies for risk-adjustment, attribution, and aggregation which greatly affect the performance score of a group and/or EP. Acumen specifically highlights in its testing of the Diabetes Mellitus (DM) composite results that when risk adjustment is expanded to include race, income, and region type, that predicated performance rates differed from actual performance rates on the group practice level. TEP members also highlight that case-mix adjustment will be critical when reporting at the individual EP level.

We urge CMS to move forward with expanding its risk adjustment methodology to incorporate race, income, and region type. The lack of adjustment can lead to inaccurate and misleading conclusions about quality and performance measurement. This could, in turn, lead to increases in disparities in health care. A simple examination of performance scores without adjustment for patients' socioeconomic and/or sociodemographic situation ignores a number of factors that are believed to influence quality and cost of care. For example, economic and cultural status can affect health status, impede ideal communication between the patient and the physician, and hamper the patient's desire and/or ability to follow a given treatment plan. Ignoring these factors could lead to the conclusion that physicians and practices that serve low income patients provide lower quality care than those serving high income patients, when the difference in scores could actually be due to differences in patient mix rather than differences in quality of care provided. To hold physicians accountable if outcomes differ for these patients without accounting for the factors that contribute to that difference would unfairly penalize physicians for factors outside of their control. This also runs the risk of unfairly penalizing those physicians who treat a number of socio-disadvantaged patients.

We also advocate for enhancing the transparency of the process by providing the opportunity for the public to comment on the deliberations of the Physician Compare TEP and to regularly engage with interested stakeholders, especially medical specialty societies. Currently, the public has no opportunity to participate and comment on the TEP's recommendations. With Hospital Compare, CMS conducts monthly to quarterly calls with the affected stakeholders, engages in discussion with them regarding plans for expansion, and informs them of the latest

release of information. The AMA and CMA would be happy to convene something similar with the specialty societies, state societies and CMS.

CMS also seeks comment on whether to post specialty society measures on Physician Compare, or link to the websites of societies with non-PQRS measures and proposes to post QCDR (qualified clinical data registry) measure data from 2015. We defer to the specialties to determine how specialty society measures and QCDR measures are best suited for reporting. We also provide more detailed information on publicly reporting QCDR measures in the following section of our comments.

X. Physician Payment, Efficiency, and Quality Improvements—Physician Quality Reporting System (PQRS)

CMS is proposing changes in several key areas of PQRS, particularly the requirements for the 2017 PQRS payment adjustment. By statute, CY 2015 is the first year when no PQRS incentives are available under the program. The year 2015 also serves as the performance year for the 2017 payment adjustment of two percent, which will apply to eligible professionals (EPs) who do not satisfactorily report data on quality measures. CMS continues to maintain a two-year look-back period for satisfactorily reporting data on quality measures to avoid a penalty. CMS also proposes to remove a significant number of measures from the PQRS program due to CMS considering the measures as "topped out;" having no identified measure steward; or due to changes in recommended guidelines. CMS maintains all of the reporting options for 2015 (claims, registry, qualified clinical data registry, group practice reporting option, GPRO web interface, and EHR), which we support. **These options help the multitude of practice arrangements in California from the solo-small practices to the very large medical groups.**

We agree with CMS' decision to maintain the claims-based reporting option for 2015 and urge CMS to maintain the option for future years as it continues to be the most popular reporting option and one that small physician practices depend upon. As CMS considers alterations to try to meet the varying needs of newly electing participating EPs, it is imperative that CMS take into consideration the simultaneous and compounding demands of rapid changes in health care delivery systems and the effects upon physicians. We continue to remain concerned that the growing complexity of PQRS and yearly program changes pose a significant barrier to participation for many physicians and successful participation for physicians who have experience in the program. Monitoring the yearly changes to the PQRS reporting options, measures, measures groups, and physician group participation options requires an overwhelming layer of administrative burden that is extremely costly and resource intensive. For some physicians, this is simply not feasible and probably leads to the continually low PQRS participation rate. According to the last year of data that CMS has provided the public on PQRS participation rates, only 36 percent of eligible professionals participated in PQRS for 2012.

If physicians are not considered to successfully report in PQRS, Meaningful Use (MU), and the Value Based Payment Modifier (VM), in 2015 for 2017 penalties, they are potentially subject to a two percent PQRS adjustment, a three percent MU adjustment, and a four percent VM

adjustment, plus an additional two percent adjustment due to sequestration, for a total 11 percent cut in reimbursement in 2017. The maximum cumulative penalties (with sequestration) in 2015 total five and a half percent, increase to eight percent in 2016; 11 percent in 2017; and 12 to 13 percent (or greater) in 2018 and 2019. These penalties far exceed the maximum penalties that hospitals can receive under the hospital quality and value based purchasing programs. At the same time, physicians are implementing EHR systems and must transition to ICD-10 by October 1, 2015, which could have serious repercussions for successful reporting and CMS' ability to accurately process claims. **Therefore, we urge CMS to institute stability into these programs by not changing requirements on a yearly basis and by scaling back on reporting requirements.**

We also urge the Administration to work with AMA and CMA to push Congress to adopt the bipartisan, bicameral Medicare payment reform legislation, S. 2000/H.R. 2015 which would reform the penalty structure outlined above and institute upside physician bonuses for participation. We strongly urge policymakers and regulators to create incentives for physicians to improve quality and efficiency rather than penalties that deplete physician resources and completely discourage participation.

At a minimum, PQRS requirements should stay the same for three years. We believe three years is an appropriate timeline as physicians are not provided a PQRS Feedback Report until six months after the close of the previous reporting period. For example, a physician who participated in 2013 PQRS is not provided a PQRS Feedback Report until approximately September of 2014. At that point, the physician or practice is well into the next reporting cycle when they learn of potential errors, and whether they will receive a payment adjustment for 2015. Based on this timeline, the first opportunity EPs may have to correct their mistakes and successfully report is 2015. An additional year of stability is necessary so that physicians can have the opportunity to learn and follow standard quality improvement protocols, such as the Plan, Do, Study, Act (PDCA) method. Furthermore, multiple studies and editorials have seriously questioned the ability of pay-per-performance programs to improve quality of care in the long term.[2]

A. Proposed 2015 PQRS Reporting Changes

CMS proposes to increase the number of measures that must be reported via the claims and registry-based reporting mechanisms to avoid a payment adjustment, from three to nine measures, as well as the number of measures in a measure group. These nine measures must cover at least three of the National Quality Strategy (NQS) domains and must include two measures from the newly proposed cross-cutting measure list. CMS indicates that these changes are necessary to further the goal of aligning CMS' various quality reporting programs.

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[2] Caroll, A.E. "The Problem with 'Pay for Performance' in Medicine." *New York Times*, July 28, 2014.
Jha, A.K, Joynt, K.E., Orav, E.J., and Epstein, A.M. "The Long-Term Effect of Premier Pay for Performance on Patient Outcomes." *New England Journal of Medicine*, Vol. 366, No. 17, April 26, 2012.
Serumaga, B., et al. "Effect of Pay for Performance on the Management and Outcomes of Hypertension in the United Kingdom: Interrupted Time Series Study. " *British Medicine Journal*, Vol. 342, No. 108 (2011).
Werner, R. M., Kostad, J.T., Stuart, E.A. and Polsky, D. "The Effect of Pay-For-Performance in Hospitals: Lessons for Quality Improvement." *Health Affairs*, Vol. 30, No. 4 (2011); 690-698.

Increasing the current reporting requirements threefold and requiring the reporting of two cross-cutting measures when physicians have still not seen their data for successful participation in 2013 or 2014 is an unreasonable leap and disregards the realities of the existing PQRS measure portfolio. The availability of measures to meet the needs of varying specialties and subspecialties becomes even more problematic as CMS proposes to remove a significant number of measures for 2015. Many specialties, particularly those that are procedure-based, continue to struggle in identifying meaningful clinical quality measures to report, e.g., pathologists, urologists, neurosurgeons, and other subspecialists. **Therefore, the AMA opposes the increase from three to nine measures due to the unavailability of meaningful measures relevant to every specialty and the dramatic reduction of measures available to report.** Until there are a clinically significant number of measures that are relevant to every individual specialty, it is contrary to the intent of the PQRS program to require every EP to report on nine measures, of which two must be from the cross-cutting measure list. For instance, CMS proposes to remove several ophthalmology measures, leaving only six eye care measures in the program, and only four non-cataract eye care measures. Due to sub-specialization within ophthalmology, it will be nearly impossible for ophthalmologists to find nine measures to report on. This dramatic change and reduction in available measures will create an undue burden on a physician's ability to report on meaningful measures that actually improve care.

It is imperative that CMS maintain the options of reporting three measures or electing reporting via administrative claims to avoid the 2017 PQRS penalty. Since 2015 is the first year the VM will apply to all physicians, regardless of practice size, it behooves CMS to give physicians more flexibility in avoiding the penalty, as CMS works to fix methodological issues with the VM program and physicians work to better evaluate the PQRS measure portfolio and reporting options, as well as work on developing clinically relevant measures available through EHR and registry reporting modalities. Reinstating the administrative claims option will provide an additional gateway for physicians and other EPs to participate in and achieve PQRS and VM penalty avoidance.

While we very much support CMS maintaining the claims-based reporting option and understand CMS' goal to move away from claims-based reporting, we are concerned with the number of measures eliminated for reporting through claims. The sudden elimination of reporting specific measures through claims will leave a significant gap in the measure portfolio. We are aware of certain specialties now left without any measures through the claims reporting option. This proposal will disproportionately affect certain specialties and physicians who are unable to participate through a registry and/or adopt certified electronic health record technology (CEHRT). Many specialties also are unable to participate through the Group Practice Reporting Option (GPRO) web-interface, since the measures are focused on internal medicine, and reporting is required on every measure on the GPRO list.

Based upon what has been published in the Proposed Rule, the AMA has submitted additional comments related to the AMA-PCPI measures which CMS has proposed as "cross cutting," as well as the proposed addition, domain change, removal, and changes in reporting modalities for PQRS 2015. These comments have been broken down into relevant tables and can be found attached to the AMA letter in Appendices A-E.

B. Program Alignment

The CMA and AMA appreciate the agency's efforts to further align CMS quality programs, but we continue to believe the effort falls short, and the vast majority of physicians must report multiple times to avoid payment adjustments. In order for MU quality reporting to count towards PQRS, a physician must take into consideration the following detailed rules and requirements:

- PQRS quality measures must be reported for a full year, as opposed to 90 days, so first year MU participants must report twice;
- Regardless of calendar year, the first year of participation in MU only requires 90 days of reporting;
- In 2015, MU requires reporting through Version 2014 Certified Software;
- Some of the MU eCQMs include "look back" or "look forward" periods requiring data outside of the PQRS and VM reporting periods. If CMS cannot calculate a performance rate for that electronic clinical quality measure (eCQM), a physician would be subject to both PQRS and VM penalties;
- Measures reported through the PQRS Qualified Clinical Data Registry (QCDR) option must be part of the MU program;
- The QCDR must be certified by ONC; and
- For MU, it is acceptable to report zeroes on measures (including not having any denominator-eligible patients for any of the measures for which their EHR is certified). This is not permissible for the PQRS EHR reporting option or any other option under PQRS. If a physician does not have any data on Medicare patients (i.e., none of their Medicare patients fall into the denominator of any of the quality measures for which their EHR is certified), then the physician needs to report separately for PQRS.

To truly streamline reporting, physicians who successfully participate in PQRS, regardless of the reporting mechanism, should be deemed as successfully meeting the MU quality measure requirements, and vice-versa. **We also urge CMS to reduce the number of quality measures required to report until there are enough eCQMs that work for all physician specialties.** As stated above, we recommend that CMS only require physicians to report on three measures to be considered successful and avoid a payment adjustment. This also resolves part of the alignment problem due to physicians currently having to report on measures in MU that are not applicable and report zeroes in the denominator for satisfactory participation, which PQRS does not consider successful reporting.

CMS would be acting within its statutory discretion by permitting MU reporting to satisfy PQRS reporting, starting in 2015. Section 1848(k) of the Social Security Act (42 USC 1395w-4(k)) sets the general requirements for the "quality reporting system" that became PQRS. It requires the use of consensus-based quality measures, and grants the Secretary discretion to decide how quality data is submitted, including submission via Medicare claims. "Such data shall be submitted in a form and manner specified by the Secretary . . . which may include submission of such data on claims . . ." Section 1848(a)(8) of the Act governs PQRS payment adjustments

starting in 2015. It states that EPs must satisfactorily submit data on "quality measures for covered professional services" to avoid such adjustments, but it does not specify or require quality measures (or quality reporting) developed specifically for PQRS. **We believe these provisions allow CMS to use MU measures and reporting, to satisfy the requirements of PQRS reporting.**

C. Selection of PQRS Quality Measures for Meeting the Criteria for Satisfactory Reporting for 2015 and Beyond

According to statute, the Secretary is allowed to use measures not endorsed by the National Quality Forum (NQF) in the PQRS program if the medical topic for which a feasible and practical measure has not been endorsed or adopted by a consensus organization identified by the Secretary. **The AMA continues to support the agency's ability to use non-NQF endorsed measures in the PQRS program.**

As in previous rules, CMS once again states that there should be no special restrictions on the type or make-up of organizations developing physician quality measures. However, the AMA and CMA disagree. We support the development of quality measures through a multi-stakeholder, public and transparent process, which maintains certain processes to ensure that measures are meaningful to users, uphold national standards, and harmonize with existing measures in widespread use. A frequent criticism of the AMA-convened Physician Consortium for Performance Improvement® (PCPI®) is that its process is not sufficiently inclusive, and one reason PCPI is now undergoing an evaluation of its governance structure. The AMA views measure development in similar fashion to the development of clinical practice guidelines. The recent IOM report, *Clinical Practice Guidelines We Can Trust,* specifically states that guidelines should be developed through a multi-stakeholder process. The same perspective and standards should apply to the development of quality measures. In addition, standardized measures (using standardized specifications) can be used to compare results nationally, which is especially important as CMS proposes to expand reporting on Physician Compare and considers financial penalties.

As the field of measure developers expands, there is an increased risk of un-harmonized measures and duplicative efforts. Providing incentives to coordinate efforts and co-produce Clinical Quality Measures (CQMs) are prudent considerations as well. It is imperative that measure developers have the necessary expertise with CQM standards currently in use (e.g., Quality Data Model, HL7 (Health Level 7) HQMF eMeasure) and are involved in national efforts focused on the future direction of health care standards.

The AMA and CMA also request, and believe it advantageous, to include a comprehensive list of the finalized measures for 2015 in the CY 2015 Physician Fee Schedule Final Rule. It is unreasonable to shift the burden on EPs to have to refer to multiple sources just to clarify current PQRS policies and measures, particularly given the inherent complexity of the program. This also raises a considerable risk of confusion and error in reporting. **The AMA also requests that a comprehensive measure list be included in every future proposed rule, to provide a**

complete picture of what is proposed for the following year's PQRS program on which payment is dependent.

The AMA and CMA support the continued development of guidance materials to further assist EPs to identify suitable PQRS measures for their specialty/care setting. We receive many questions from prospective participants asking how to determine which measures they should report on for PQRS, and believe CMS' approach to provide documents with this guidance and information will prove to be very beneficial for the EPs. It would be prudent and more beneficial for EPs if CMS published these materials prior to the start of the reporting period, so that EPs can have ample time to prepare for reporting and can select the reporting option most suitable for their practice.

1. Measures Proposed for Removal Beginning in 2015

We recognize CMS' desire to raise the bar on quality reporting. However, we believe it is premature, short-sighted and unjustified to remove a measure as "topped out" simply because it has a high performance rate, particularly when the EP reporting rates within the PQRS program are so low. We are also concerned with the significant gaps that will be created in the measure portfolio due to the number of measures CMS proposes for removal in 2015, without any advanced warning to physicians or measure owners. Based upon 2012 data:

- Only 31 percent of EPs were able to participate successfully in PQRS;
- 75 percent of measures had a successful reporting rate below ten percent; and
- 33 percent of measures had a reporting rate below one percent.

Classifying any given measure as having a high performance rate when the overall reporting rate is less than one-third of all EPs, is not based upon an accurate picture of actual performance. This does not provide a representative sample of the nation's EPs. Since PQRS is now a program that applies penalties, we anticipate that the number of physicians who participate will increase significantly, which will likely have a great impact on the performance rates of all measures.

The AMA also does not believe that performance rates alone provide a valid reason to consider a measure "topped out." Removal from PQRS of any measure as "topped out" must be based upon consideration of several factors, including reporting rate and performance rate, at a minimum. A higher reporting rate or threshold may be indicated before decisions are made on measures based solely upon performance rates. Additionally, high performance rates (close to 100 percent) on some measures among reporting EPs may be partly attributable to intensified improvement efforts motivated by the reporting opportunities. Therefore, removal of these measures from PQRS may result in a drop in performance as well as the quality of care. CMS also states in the rule that many of the "topped out" measures are process measures, and the agency would like to move away from process measures in general. However, process

measures play a very important role in improving care as well as in fostering and measuring good outcomes.

Finally, we propose a three-year phase out period for any new measures being removed to allow for the submission of new measures within the current Call for Measures timeframe to prevent gaps in the measure portfolio. The proposed timeframe is also consistent with our call for three years of stability in CMS' quality programs to allow EPs time to adjust to changes in programs and make improvements in their practice. Under the current process for incorporating new measures into physician quality programs, CMS requires a measure developer to submit a measure two and a half years prior to the start of the program year. To consider a measure for the 2017 PQRS program, CMS had to receive the measure information by June 30, 2014—a gap of two and a half years. Prior to the requirement of MAP review, it took only six to 12 months for a measure to be included in a CMS program. With the EHR Incentive Program, the delay is even worse since CMS operates on a three-year rulemaking cycle as opposed to yearly with PQRS and the VM. We were also informed by CMS that the agency must have already received measures for the yet to be released Stage 3 EHR Incentive Program Proposed Rule. CMS needs to be realistic in setting goals for its program and consider its operating cycle, which causes a huge delay in incorporating new measures into programs.

2. Measures Groups

In the CY 2014 Physician Fee Schedule proposed rule, CMS proposed to increase the number of measures that may be included in a measures group from a minimum of four measures to a minimum of six. CMS did not finalize the proposal for CY 2014 and stated that it would work with measure developers and owners of these measures groups to appropriately add measures to measures groups containing only four measures. **However, once again, CMS is proposing to increase the number of measures that may be included in a measures group from a minimum of four measures to a minimum of six. Once again, we do not support this, as CMS has not worked with measure owners and developers over the last year to ensure the appropriate measures are part of a measures group.**

We appreciate CMS maintaining the measures group reporting option and believe it is a meaningful option for reporting since it follows a continuum of care. However, CMS has offered no evidence or rationale to support expanding measures groups by including two additional measures to groups with less than six measures. In fact, many of the measures groups which CMS is proposing to revise have been tested and endorsed by the NQF. The proposed revisions may make the group statistically invalid and/or alter the quality measurement process. For instance, a measures group that includes only one condition-specific measure does not seem to be a meaningful measures group in the context of the PQRS program. More specifically, the proposed "asthma" measures group no longer seems to be meaningful since it includes only one measure that focuses on asthma, as the other asthma specific measures have been proposed for removal beginning in 2015. If measures groups can be generic for all but one of the measures they include, this widens the possible number of measures groups that could then be created, undermining the purpose of creating a measures group reporting option.

D. PQRS Qualified Clinical Data Registries

For 2014, CMS added a new qualified clinical data registry (QCDR) option whereby EPs may report the measures used by their QCDR, instead of those on the PQRS measure list. EPs meet the criteria for satisfactory participation by reporting on a least nine measures to the registry covering at least three of the NQS domains, and report each measure for at least 50 percent of the EP's applicable patients. At least one of the measures must be an outcomes measure. For 2015, the second year of the QCDR reporting option, CMS proposes to modify the requirements by requiring that an EP must report on three outcomes measures. If three outcomes measures are not available, the EP must report on two outcomes measures and at least one measure related to resource use, patient experience of care, or efficiency/appropriate use.

The AMA opposes CMS' proposal to modify the requirements for the QCDR option for 2015 and advocates for CMS to gradually incorporate QCDR requirements. We continue to believe the QCDR requirements are too stringent, and CMS' plan to modify the requirements in only the second year of this option is simply too aggressive. The AMA disagrees with the high bar which CMS proposes and continues to advocate for a gradual incorporation of QCDR requirements. QCDRs need a period of stability to allow those that are currently qualified to make minor adjustments. Clinical data registries that have yet to become a QCDR also need time to meet CMS' requirements. Since the QCDR is still a new PQRS participation option, the AMA recommends that CMS only make small, incremental changes in QCDR requirements while early experience is gained and evaluated. **It is premature to require the reporting on three outcomes measures and/or two resource use or patient experience of care measures before QCDRs have had the opportunity to gain experience with the program.** As QCDR stewards and EPs become more comfortable with the requirements of the QCDR program, they will be able to focus more of their resources on innovation.

In general, medicine is currently developing tools to help physicians adopt and incorporate systems of learning into their practice, which will improve quality of care, provider workflow, patient safety, and efficiency. Capturing data through a registry allows for its collection and tracking across care settings and disease states, inpatient and/or outpatient settings, acute episodes or chronic diseases, surgical versus nonsurgical interventions, and resource-intensive versus relatively inexpensive therapies. Quality measurement must move beyond single episodes or "snapshots" of care, which focus solely on clinicians and individual patients, to a learning system with a broad focus. Utilizing third-party registries provides an opportunity to evaluate the care provided within an entire specialty, as well as at the individual physician level. However, if CMS moves forward with its QCDR proposal, this will hinder registry progression and quality improvement activities occurring outside of Medicare. CMS' overly ambitious performance program requirements hinder the ability of physicians to tailor programs to their practice. We recognize that a number of registries qualified to become a QCDR in 2014, but this should not be a signal for CMS to raise the bar after only one year of existence. Registries have devoted substantial effort and resources to become QCDRs, and incorporate enough outcomes measures so that all subspecialists within a specialty could report on at least one.

While the AMA appreciates the flexibility in a QCDR's ability to select measures to capture on behalf of its members, these multiple requirements are simply coming too quickly. If a QCDR wishes to submit quality measures data for the 2017 PQRS payment adjustment, it must provide the information to CMS by March 31, 2015. Reporting on meaningful and scientifically valid outcomes and resource use measures requires capturing data with a significant sample size. It is not something that can be turned around in six months, especially for low volume specialties.

1. Program Alignment and Electronic Interoperability Issues

We are disappointed that CMS did not address in the rule issues around QCDR reporting for satisfactorily meeting quality requirements for the MU program. This represents a missed opportunity for CMS to align reporting requirements for PQRS and EHR Incentive programs and make the programs meaningful for physicians. Alignment of quality reporting efforts is essential to reduce practical and economic burdens on individual physicians and physician groups. Physicians will still be forced to report the same quality measures that are established in the EHR Incentive Program. The measures within the EHR program are also extremely limited for specialists, so most specialists have to report separate measures to satisfy PQRS and EHR Incentive program requirements. We urge CMS to promote flexibility in its performance program requirements so that physicians participating in a QCDR can receive credit for multiple quality improvement activities.

The proposed criterion for QCDRs to report quality measures within the MU Program is simply not feasible. Essentially, QCDRs must have the ability to electronically specify their measures. As CMS has discovered, this is not a simple task and not all quality measures lend themselves to electronic specifications. In addition, QCDRs must go through the MU modular Certified Electronic Health Record Technology (CEHRT) process which assumes that an EHR is interoperable with a registry. We do not believe certification vendors are set up to certify or understand clinical data registries. Finally, requiring QCDRs to go through the CEHRT process will force registries to meet qualification requirements for both PQRS and EHR Incentive programs. Within PQRS, QCDRs will have to meet standards for certifying both the PQRS registry and the QCDR process. The intention behind section 601(b) of the American Taxpayer Relief Act of 2012 (ATRA) was to provide physicians with greater flexibility to report on and receive credit for their quality improvement activities relevant to their practice and patients. The QCDR EHR Incentive program requirements do not allow for the true utility and purpose of registries, or the evolution of the quality measurement process.

It would be more advantageous and assist with registry evolution and participation if CMS focused its efforts by working with the Office of the National Coordinator for Health Information Technology (ONC) to develop a single standard so that EHRs are interoperable with registries. EHR code extraction is not available for the vast majority of clinical data registries and the registry objective within MU continues to miss the mark. The proposed Stage 3 objective only requires a CEHRT EHR to transmit to one registry, and does not recommend a standard. CMS needs to play a greater role in facilitating the use of clinical data registries by encouraging the development of standards for sharing/transmitting data between EHRs and

registries. Presently, practices are forced to manually enter data into a registry because no streamlined process exists, and because of the proprietary nature of health information technology (HIT) products. This existing data-sharing process is particularly challenging for solo and small practices, and prevents many from participating in registries. Finally, the manual data-entry process requires a full-time or half-time employee, which is an added cost that most practices cannot easily absorb.

The current certification requirements also fail to address the need for bi-directional exchange for national clinical data registries or clinical data standardization for any other purpose. EHR vendors charge providers to map and transmit data from an EHR to a registry. The ability to transmit clinical data to national clinical registries using standardized data definitions will assist physicians and health care systems to move to a more advanced state of quality measurement. **CMS should work with ONC to require EHR vendors to provide clinical data in a standard format backed by standardized data definitions.** Providers that have purchased EHR systems should not have to incur the cost of middleware vendors mapping and transmitting the data. CMS should also engage with the physician community, including the AMA, so that the clinical content of this work is accurate and widely adopted.

E. EHR Reporting Option

For 2015, CMS proposes to modify the criteria for satisfactory reporting by individual EPs (to avoid the 2017 PQRS payment adjustment) to require the reporting of individual measures via a direct EHR that is CEHRT, or an EHR data submission vendor that is CEHRT. The EP would report nine measures covering at least three of the NQF domains. If the EP's CEHRT does not contain patient data for at least nine measure covering at least three domains, then the EP would be required to report all of the measures for which there is Medicare patient data. An EP would be required to report on at least one measure for which there is Medicare patient data. **We seek clarification as to whether the MAV process would apply to EPs who chose to report through the EHR reporting option.** If so, we are concerned that an EP may believe they only have one measure for which there is Medicare patient data, but get captured in the MAV process. In addition, does this change (to requiring an EP to report on at least one measure where there is Medicare patient data) apply to EPs who only want to meet MU? Or only EPs that want to align their quality reporting with PQRS, MU and the VM? If this does apply to MU, would an EP that does not have any denominator-eligible patients still have the ability to report zeroes and satisfy their quality requirements? It is unclear whether this proposed change resolves part of the alignment problem between PQRS and MU.

F. Group Practice Reporting Option

For 2017, CMS proposes to modify the requirements for group practices that chose to participate in 2015 PQRS through a registry. Group practices that choose to report using a qualified registry and select to participate in the GPRO for the 2017 PQRS payment adjustment would be required to report at least nine measures, covering at least three of the NQS domains. Of these measures, if a group practice sees at least one Medicare patient in a face-to-face encounter, the group practice would report on at least two measures from the cross-cutting

measure set. As indicated above, we do not support the requirement of having to report two cross-cutting measures due to CMS' proposal to eliminate such a significant number of measures from the program. We believe that group practices, especially specialty practices (e.g., ophthalmology, emergency medicine) will have difficulty finding two measures that work for the group. **CMS should scale down the number of required measures to three, consistent with our recommendation on individual reporting to allow specialty group practices the option to participate through GPRO. We also recommend that group practices who report through a registry be able to report measures groups.** Measures group reporting is a popular option for specialists.

In addition, many CALIFORNIA medical groups are urging CMS to provide more transparency related to the methodology in developing the performance scores. While they support performance measurement and quality reporting in general, they would ask that more information be provided to them to better understand their ratings.

G. CMA Supports the Use of the Clinical and Group- Consumer Assessment of Healthcare Providers and Systems (CG-CAHPS)

The Proposed Rule singles out the CG-CAHPS survey as the most appropriate instrument for physician groups and individual physicians to measure patient experience under the PQRS and VM programs. The CMA and AMA continue to support the use of the CG-CAHPS survey as one means of measuring the patient centricity of a medical practice. However, there are other survey instruments available, which also provide actionable feedback to physicians that can inform their actions and contribute to high quality care in everyday practice.

We are disappointed to learn that CMS will no longer bear the cost for administering CG-CAHPS through a CMS certified survey vendor, especially since it is a requirement for GPRO practices of 100 or more EPs. Since CMS requires CAHPS to be administered through a CMS-Certified Survey vendor, rather than a vendor of the practice's choosing, administration of CAHPS becomes more of a burden, especially for practices that have already implemented CAHPS. We are also concerned with the cost to implement and administer the survey given that CMS will only allow for administration through a CMS-Certified Survey vendor, which may also stifle competition.

CMS also proposes for the 2018 payment adjustment to require group practices comprised of 25 or more EPs that are participating in GPRO to report and pay for the collection of the CAHPS for PQRS survey measures. **The AMA opposes CMS' proposal to move in this direction due to the reasons mentioned above for group practices of 100 or more EPs**. Besides cost, the implementation of CAHPS is extremely burdensome on a practice, especially a small private practice with limited resources that are subject to a 12 to 13 percent payment adjustment and who may just be beginning to participate in PQRS. In addition, response rates are typically low. We have received feedback from providers that patient compliance is very difficult to obtain, and expressing concern with ample sample size for CMS to make a fair assessment of a practice. The collection of CAHPS data may also lead to survey fatigue by patients due to the requirement and inclusion in the Medicare Shared Savings Program and Inpatient Quality

Reporting program. Patients do not know the difference between the CG-CAHPS, Surgical-CAHPS, and Hospital-CAHPS surveys, and this will only become more problematic if the requirement expands. A patient managed for a chronic condition by multiple group practices will be bombarded with filling out lengthy and highly subjective surveys.

If CMS moves forward, practices should not be held liable or penalized for lack of patient compliance, which is beyond their control. CMS should only require a group practice to report on three measures since implementation of CAHPS is so resource intensive and cumbersome. It also needs to be acknowledged that with all experience surveys, regardless of survey type, patients' opinions vary based on cultural and regional differences.

H. Informal Review

CMS proposes to modify the payment adjustment informal review deadline by two-thirds, from 90 to 30 days from the release of the PQRS Feedback Reports. While we support having an informal review process in place, **we do not support CMS' change in timeline for requesting an informal review to only 30 days.** The process for accessing a PQRS Feedback Report is extremely cumbersome and historically has been rife with problems. Sometimes it takes 30 days just for an EP or group practice to obtain a PQRS Feedback Report, not to mention the time needed to analyze the report and assess whether to request an informal review. We are also concerned that the Quality Net Help-Desk will be bombarded with calls and emails requesting assistance since we are now strictly in a PQRS and VM penalty phase. In addition, CMS communications channels for notifying EPs on the availability of PQRS Feedback Reports are not streamlined. For example, in 2013, the AMA was only made aware of the release of the 2012 PQRS Feedback Reports about four to six weeks after their release. CMS specifically highlights in the rule that the agency relies on specialty societies to educate physicians on the quality programs, but the AMA, CMA, state societies and specialty societies cannot provide timely updates to its members if CMS does not adequately notify its partners. Furthermore, we do not believe the proposed deadline would allow physicians to make more timely correction of reporting errors. CMS specifically states they would only allow resubmission of data that was submitted using a third-party vendor, qualified registry, EHR data submission vendor, or QCDR reporting and would not allow resubmission of data submitted via claims, direct EHR or GPRO web interface. Therefore, any identified errors resulting from the Informal Review process would be on the vendor side and not with the EPs reporting incorrectly, which does not allow an EP to internally analyze their data and potentially contest incorrect calculations by CMS.

We also urge CMS to allow EPs and groups to contest their PQRS payment adjustment if they believe there were calculation errors due to ICD-10 transition. ICD-10 begins on October 1, 2015, during the last three months of the PQRS reporting period. It is more than likely there will be calculations errors by CMS, physicians, and third-party vendors due to the transition.

XI. Transition to ICD-10

The CMA welcomes the opportunity to work with CMS to address foreseeable problems with transition to ICD-10. The ICD-10 transition is scheduled to occur on October 1, 2015, and there

are serious potential implementation issues for how ICD-10 will affect PQRS, VM, and MU. After that date, as stated in the 2015 Hospital Inpatient Prospective Payment System (IPPS) final rule, CMS plans to collect non-electronic health record-based quality measure data coded only in ICD-10. CMS highlights its concern that the transition to a new coding system may have unintended consequences for quality measure data denominators, statistical adjustment coefficients, and measure rates. The AMA and CMA echoe these concerns, but we are also concerned that CMS has not addressed ICD-10 with respect to Medicare Part B and CMS' plan for handling physician quality measures in programs such as PQRS, VM, and MU. The IPPS rule only provides details on non-electronic quality measures for hospitals—and does not discuss possible issues around physician eCQMs. **We hope that CMS will, in the 2015 Physician Fee Schedule final rule, discuss its plans for dealing with the transition**, and fully explain both the rationale for having the baseline year vary from the performance year, and the codes that will be used to perform calculations. Physicians need information to successfully make the transition.

CMA also strongly urges CMS to test submission of all measures with updated ICD-10 specifications prior to the deadline, and to hold physicians harmless if CMS and vendors cannot accurately accept and calculate the measures. The difficulties around the ICD-10 transition present another reason why penalties need to be modest. CMS should exempt physicians from all penalties if CMS cannot accurately calculate measures due to the transition.

We are most concerned about the effects of ICD-10 on VM measures, as measure calculations and associated costs will vary depending upon the utilization of ICD-9 or ICD-10. There are several ways that CMS could handle the transition, outside of exemptions. CMS could consider an alternative reporting period of 90 days for the 2015 PQRS and VM programs. Or create a reporting period that only uses ICD-9 (Jan. 1-Sept. 30) or ICD-10 (Oct. 1-Dec. 31) or maintain the current structure, but the AMA perceives problems with calculations when the baseline is coded differently from the performance year. CMS cannot assume that evaluations and comparisons under ICD-10 will be the same as those under ICD-9. We foresee unintended consequences for measure denominators and measure rates. Transitioning the VM program to the ICD-10 system could significantly alter how measures are scored between the baseline and performance periods. **We, therefore, urge CMS to run both the baseline data and the performance data using ICD-9-CM and ICD-10-CM (using crosswalk software) and make the results of the testing public. This would also assist with determining whether the crosswalks are valid since we have no knowledge of the potential repercussions.**

However, instituting a shortened reporting period in 2015 would prevent foreseeable problems with capturing measures correctly due to the ICD-9/ICD-10 transition, since physicians would only be reporting on measures that include ICD-10. This would also allow physicians an additional opportunity to avoid 2017 payment adjustments and appropriately plan for ICD-10 transition, as well as be in line with 90-day reporting for first year MU participants. A 90-day period also provides EPs the opportunity to obtain and review their 2014 PQRS Feedback Report to determine whether they made mistakes with their reporting and correct the errors for 2015. CY 2014 was the first year of payment adjustments so it is even more critical for CMS to allow physicians to have an opportunity to evaluate their mistakes and make corrections.

CMS only has to look back to the 2013 PQRS program where it provided multiple PQRS reporting periods for avoiding the 2015 PQRS penalty

We also suggest that CMS consider how it plans to account for claims that must be resubmitted with a service data prior to October 1, 2015, and how the agency plans to handle appeals. We understand that CMS will need to be able to continue to accept ICD-9 codes in order to accommodate these situations. Services that fall into these categories should be included for quality reporting purposes.

Congress left it up to HHS to define the "quality reporting period" for PQRS penalties in 2015 and beyond. Section 1848(a)(8) of the Social Security Act requires a PQRS adjustment "if an eligible professional does not satisfactorily submit data on quality measures for covered professional services for the **quality reporting period** for the year (as determined under subsection (m)(3)(A) . . ." Section 1848(a)(8) also states that "The term 'quality reporting period' means, with respect to a year, a period specified by the Secretary." There is no explicit requirement that the "period specified by the Secretary" has to be an entire year. Moreover, the phrase "with respect to a year" logically refers to the year in which penalties would apply; otherwise, Congress could have said that the "quality reporting period" means a "prior year" specified by the Secretary, instead of a "period specified by the Secretary." The referenced subsection (m)(3)(A) (of section 1848) says "an eligible professional shall be treated as satisfactorily submitting data on quality measures for covered professional services for a reporting period (or, for purposes of subsection (a)(8), for the quality reporting period for the year) if quality measures have been reported" in the number specified, for "services of such professional furnished during the period . . ." Again, the term "for the year" refers to the year that penalties will apply, as differentiated from the quality reporting period**.**

XII. Electronic Health Record (EHR) Incentive Program

CMS is proposing that beginning in CY 2015, EPs would not be required to ensure that their certified electronic health record technology (CEHRT) products are recertified to the most recent version of the electronic specifications for clinical quality measures (CQMs). **While the AMA and CMA appreciate CMS instituting flexibility with respect to CEHRT, we are concerned that this proposal will not resolve the EHR certification problem as EPs are required to use CEHRT for all the other MU objectives.**

CMS also proposes that if errors are discovered in the July 2014 release of the electronic clinical quality measures (eCQMs), the PQRS program would revert back to the version of each measure that immediately precedes that release. **However, the AMA strongly discourages using specifications when a more current version exists**. Each year during the annual update process for eCQMs, measure developers review each measure to ensure that it aligns with industry standards for electronic measurement, and captures acceptable clinical practices based on clinical guidelines. Especially in the context of the release of the updated version of the Quality Data Model (QDM) version 4.1, as well as HQMF (Health Quality Measures Format) eMeasure Release 2 (HQMF R2), which is used to create logic for a measure, we believe the approach to adopt an old version of measure specifications to report could be detrimental.

There are many changes to these data standards that impact future versions of the eCQM specifications. Once the measures incorporate QDM 4.1, which is scheduled for release in July 2015, measures will have a very different structure. If in future PQRS program years, specifically with the EHR reporting modality, an error is found, CMS is essentially suggesting that a version of the measure that is no longer supported should be implemented which is inconsistent with program goals. **Reverting back to an older version of a measure will requires users of the measures, including EPs and EHR vendors, to support two versions of a single standard (e.g., HQMF, QDM), thus increasing the burden on these stakeholders and creating the possibility for substantial confusion and errors.**

XIII. Medicare Shared Savings Program

A. Proposed Changes to the Quality Measures

1. Controlling the Burden of Quality Measurement

We support efforts by CMS to retire measures that are duplicative or no longer useful, to replace measures that are outdated, and to change to measures that are more likely to address important quality goals. However, this should occur without a net increase in quality measures over time.

It is important to ensure that Accountable Care Organizations (ACOs) are not achieving savings by inappropriately withholding or limiting care that Medicare beneficiaries need. However, adding more quality measures does not necessarily mean better protection for beneficiaries, and indeed, the more quality measures there are, the less impact any individual measure will have. Moreover, too many quality measures can make the program too burdensome for physicians, deter physician participation in ACOs, and thereby deny patients the benefits of better care coordination.

The proposed regulations retire or replace eight measures but add 12 new ones, resulting in a 12 percent increase in the number of measures. CMS asserts that this will not increase the burden on ACOs because the new measures would be calculated by CMS using administrative claims data or patient survey data. However, in order for an ACO to improve performance on any measure, it will need to collect its own data relevant to that measure, and if the measure is being computed by CMS from claims data, the ACO will also need to analyze the calculations done by CMS to verify their accuracy, reconcile them with the ACO's own data, and determine appropriate actions. Consequently, adding any new measure, even if computed from claims data, will increase the burden on ACOs with no compensation for that additional time.

However, focusing only on changes in the total number of measures underestimates the burden that is created by changes in the underlying measures. Changes in measures require ACOs to shift focus to different aspects of clinical care, change data collection and analysis systems, etc. Under the Proposed Rule, more than one-third of the new set of measures would be different from the current measures, which would create a significant burden for ACOs. Frequent changes in quality measures are a recipe for failure of this Medicare program. Instead of continuously moving the goal posts, CMS should be working to provide more stability for

Medicare ACOs by setting quality standards for the entire three-year agreement period and only changing them during that time if both CMS and the **majority of ACOs** agree the change is needed.

2. Truly Rewarding Higher Quality

If CMS wishes to expand the number of quality measures or to make quality improvement into a primary goal for the ACO program, then it should provide a higher share of savings to ACOs than under the current MSSP rules. Today, the *maximum* share of savings that ACOs can receive is 50 percent in Track 1 and 60 percent in Track 2. That share is reduced if *any* of the quality measures fall below the highest performance level. The more quality measures that are added, the less likely it is that the ACO will receive the maximum share of savings. Yet the more quality measures an ACO needs to pursue, the more it will need to spend in order to improve quality and the greater the financial losses it will likely incur, particularly in areas where the fee-for-service system either fails to pay for high-value services (e.g., chronic disease management) or reduces providers' revenue when quality improves (e.g., fewer readmissions), or both. So the ACO is in a Catch-22; the more quality measures it pursues, the higher its costs and lower its revenues will be, but it will be less likely to receive shared savings to offset those costs and losses. Moreover, increasing the share of savings given to ACOs will not necessarily reduce the amount of savings to the Medicare program. It is quite possible that CMS would obtain more savings for the Medicare program *in total* if increasing the proportion of savings given to ACOs creates a greater incentive for providers to participate in the shared savings program and for ACOs to find ways to generate savings.

Nothing in the Affordable Care Act requires that ACOs receive such a small share of the savings they generate for Medicare. Once sufficient savings have been achieved to assure CMS that the savings were not due to random variation, an ACO could be paid 70 percent, 80 percent, or 90 percent of the savings and they would still reduce net spending for the Medicare program. If CMS wants to encourage improvements in quality, particularly in areas of patient care where such improvements are difficult to achieve, then it should *increase* the share of savings above 50 percent or 60 percent for those ACOs that achieve higher quality.

B. Future Quality Measures

We believe that quality measures should be primarily designed to *protect* beneficiaries from inappropriate reductions in services by ACOs. Quality measures should focus on the kinds of services where a lack of care today would not result in more expensive care within the timeframe of an ACO contract, such as preventive care services. If CMS wants quality measures to *improve* care for beneficiaries, then the measures should focus on areas where (a) CMS believes that Medicare beneficiaries are receiving poor care today and (b) it is feasible for an ACO to make changes in care that would improve care in those areas using the limited resources available in the shared savings program. As noted earlier, if the goal is quality improvement—rather than preservation of current quality—then the shared savings formula needs to be restructured to ensure that adequate resources are directed to providers to achieve this.

C. Electronic Health Record (EHR) Reporting

If the use of EHRs and HIE (health information exchange) will improve quality of care, improve care coordination, reduce duplicative services, etc., then the Shared Savings Program gives ACOs a natural incentive to use them, and there is no need for the program to separately require or incentivize the use of the technology. If ACOs find that EHRs and HIEs are the most effective way to improve quality, then reporting quality measures through EHRs will also become the simplest approach to reporting. Rather than requiring EHR-based reporting, CMS should give providers the option to report through EHRs. If they do not report through EHRs, rather than assuming that this is due to resistance that has to be overcome through mandates, CMS should seek input from providers to determine whether there are barriers to reporting through EHRs or whether the EHRs are not providing adequate value for quality improvement efforts.

E. Standards in Subsequent Performance Periods

A performance standard for a quality measure should not be continued into a second or a subsequent participation agreement, if there have been any significant changes in the specifications used to calculate the measures. An ACO's performance level on quality measures will vary depending on how the measures are calculated. Moreover, there are serious problems with the attribution methods currently used in the Shared Savings Program that we hope will be addressed in future regulations. Improvements in attribution could result in significant changes in ACO's performance on some or all of the measures, making it inappropriate to continue using benchmarks based on previous, flawed attribution methodologies.

F. Timing for Updating Benchmarks

We agree that ACOs need to have stable benchmarks in order to plan quality improvement interventions and predict the impact on their shared savings payments. However, if the specifications for a quality measure change, then the benchmark for that quality measure should be updated immediately so that the ACO's performance on the measure and the benchmark are comparable.

G. Rewards for Quality Improvement

We support modifying the quality performance formula to explicitly recognize and reward improvement on quality measures as well as the attainment of high performance. However, if CMS wishes to create greater incentives for quality improvement, then ACOs need to receive a higher share of savings than under the current MSSP rules, rather than simply receiving bonus points for improvement under the current formula. Even if CMS retains a lower share of savings, it would still be spending less than it would have otherwise. Moreover, CMS may well be able to save more in total than it would by retaining a higher share of savings, and it would likely see more significant quality improvements on a broader range of measures.

XIV. Value-Based Payment Modifier and Physician Feedback Program CMA Opposes CMS' Acceleration of an Unproven Program

In this Proposed Rule, CMS accelerates a rapid and risky expansion of the ACA-mandated Value Modifier (VM) with proposals to double both the number of physicians affected and the size of the penalties they could incur. We acknowledge that the extension of this untested concept to additional physicians in small or solo practices was required by law. However, we have repeatedly urged CMS to seek a modification in that directive. **The CMA is extremely troubled by the agency's continued failure to conduct a rigorous impact analysis of its VM framework before proceeding recklessly with plans to increase the VM penalty from two percent to four percent, leaving some practices vulnerable to total Medicare payment cuts of 11 percent in 2017.**

CMA has aggressively voiced our concerns with the implementation of the value-modifier in prior years. As stated earlier, in CALIFORNIA, it is essential that physicians who treat older, sicker and poorer patients not be disincented from caring for these most challenging patient populations. Based on our experiences in California, risk adjustment and attribution methods systems that have been used by large insurers or health care organizations are not adequate to deal with the detail of an individual subspecialist's patients who have numerous co-morbidities and complexities, or a safety net physician caring for low-income, racially diverse patients who have no support systems. To protect physicians and access to care for frail elderly patients, it is incumbent on CMS to ensure that the attribution methods and risk adjustment methodology are appropriate and specific down to the subspecialist physician, that demographic information is taken into account, and that the accuracy of the information is verified.

What little analysis has been conducted is based on a period when the PQRS program that underpins the VM was far less rigorous than it is today, potentially underestimating the number of physicians who will face penalties under the current program. What data we do have suggests that the modifier discriminates against Medicare's frailest patients and their physicians. Studies to date have not attempted to gauge the combined impact of PQRS, VM and other penalties on vulnerable practices. Numbers cited in the NPRM to justify the rapid adoption and escalation of VM penalties focus on "average" impacts. **They fail to provide reasonable assurances that the VM will not routinely penalize certain categories of patients and physicians.**

There are also serious questions about the efficacy of the VM, which shares the flaws of many of the current approaches to measuring and assigning accountability for health care spending, as outlined in a recent paper by Center for Healthcare Quality and Payment Reform President Harold Miller.[3] These include the assignment of accountability based on aggregate costs rather than those services that a particular physician or group actually had control of, failure to incorporate prescription drug costs, the inability to distinguish between appropriate and

[3] Miller, H.D. "Measuring and Assigning Accountability for Healthcare Spending." Center for Healthcare Quality and Payment Reform, August 2014. http://www.chqpr.org/downloads/AccountabilityforHealthcareSpending.pdf

inappropriate spending, and inadequate adjustment for patient risk and structural differences in costs. Moreover, as CMS' own studies have shown, even medical groups of 25 or more often have inadequate data from which to draw conclusions about costs and/or quality. How then can the VM be applied with any confidence to even smaller groups and solo practitioners?

Coupling the seriously flawed VM concept with a shortage of time and resources for CMS outreach to the more than 1.1 million practitioners (to whom CMS wants to apply the VM), and the aggressive VM expansion envisioned in this rule, is inappropriate to say the least. Some of Medicare's sickest patients could lose access to their doctors, some physicians could be driven out of business, and the government will have diverted scarce resources from other payment and delivery reforms that have a far better chance of achieving a more value-based health care system.

As noted in our comments on the 2014 Physician Fee Schedule proposed rule, the Administration wisely chose to delay the ACA's employer mandate rather than proceed without adequate structure and outreach. **We strongly urge that CMS adopt a more cautionary and realistic approach to the VM as well.** Ideally, this would include a request to Congress for authority to adopt a more targeted approach. At the very least, the agency should slow the VM's expansion and provide a more stable environment as the VM is implemented. It is disconcerting and confusing for practices to be subject to rules which were in place in a performance year that occurred two years earlier, but were replaced in the following year.

The CMA and AMA specifically oppose:

- **increasing the VM penalty from two percent to four percent;**
- **mandating participation in the tiering competition; and**
- **continuing the use of cost and outcome measures that have never been tested for use in physician offices.**

A. Trouble Signs

As noted above, what little data we do have raises serious concerns. At several points in the rule, CMS offers reassurance that based on their 2012 cost and quality data, only 11 percent of physicians would have incurred a VM penalty. This means that a minimum of 90,000 physicians and 35,000 other practitioners would face penalties of up to four percent. This does not even include those physicians who incur a penalty because neither they nor their group successfully participated in PQRS. Without more information on the expected PQRS failure rates, it is impossible to estimate the total number of physicians who will face the four percent VM penalty and what proportion of those will also face a PQRS penalty. **However, the number of penalized practitioners is potentially considerably larger than 125,000, and with a four percent penalty, a significant number of these practitioners may choose to reduce the number of Medicare patients in their practice, particularly if they are facing other penalties as well.**

An evaluation of the 2012 QRURs that contain the data used to compute payment adjustments under the VM is cause for further concern. In the report, Mathematica Policy Research found

that among medical groups with 25 or more practitioners, **the groups most likely to incur penalties are comprised mostly of primary care physicians, who have the sickest patients.** Specifically, among groups with patient risk scores in the highest quartile or at least 80 percent of their physicians providing primary care, one in four—or roughly three times more than the average for all groups—were scored as having low quality. With respect to cost, about one in three of the groups with high risk patients and a primary care focus fell into the high cost category—compared to only eight percent of all groups of 25 or more. In a similar vein, data published in the 2014 proposed rule found that **physician specialties, such as oncologists and geriatricians, who typically treat patients with multiple and/or very serious conditions were more likely to be seen as having high aggregate costs per patient than other physicians.**

As noted above and in past CMA comments on this issue, most private payers have limited the use of pay-for-performance programs to certain specialties and certain conditions. We do not believe it is feasible or cost-effective to expand the concept to small practices. The 2012 QRUR Experience Report reinforces that view with its finding that **among groups of 25 or more, one-third had no Medicare patients attributed to them, and another nine percent did not have enough Medicare patients attributed to them to compile a report.** These were primarily groups in which at least 50 percent of the physicians were in the same specialty. After modification of the attribution methodology proved unsatisfactory, the agency resorted to simply calling all of these practices "average." It seems likely that the failure to meet minimum patient attribution numbers will be even more pronounced as the VM is expanded to smaller practices, which raises important questions. **What is the point in wasting CMS and physician resources on an empty report? Would it not be more productive to target these resources on improving both the content and timeliness of reports for a smaller number of conditions and practices? Based on our past experience in California, CMS should significantly scale back this program. Again, we urge CMS to appropriately incent physician practices rather than establish an aggressive and unrealistic set of penalties that will drive physicians out of the Medicare program.**

In response to specific issues and questions raised in the Proposed Rule, we offer the following views:

B. Structure of the VM/Two Category Approach

CMS is proposing to retain a two-step structure that divides physicians into two groups: those who did comply with PQRS reporting requirements, and those that did not. Non-compliant practices would automatically receive the maximum four-percent penalty. Those who did comply would be placed in a mandatory competition or "tiering" process where their cost and quality is compared to that of other successful PQRS participants—which could result in a four-percent penalty, a two-percent penalty, no adjustment, or an as yet undetermined bonus.

While the AMA has never supported the VM, we agree that if there is to be a VM, basing its quality component on PQRS is a reasonable approach. We do not object to a second step where groups can compete for bonus money at the risk of finding themselves facing a penalty instead. However, we believe it is counterproductive to mandate participation in a tiering

competition where physicians who fulfilled the PQRS reporting requirements are at risk for the same penalties as practices that did not. It is also irresponsible to apply penalties to practices that have done their best to comply with PQRS requirements, but were scored as having high costs and/or low quality because the risk and specialty adjustments and overlapping cost measures employed in the VM disadvantage practices that treat Medicare's frailest patients. The proposed exemption from negative adjustments in the first year a practice is subject to the VM is better than nothing, but ultimately insufficient to compensate for all the methodological problems that plague the VM.

We are also concerned that some physicians will incur penalties in the tiering process, simply because CMS had insufficient data to judge them on. The agency's solution for these groups is to default them into the "average" tier but groups could still incur a two-percent penalty if they had enough data to be scored for one category but not the other. Other groups with sufficient data for both cost and quality could potentially offset a bad score on one component with a good score on the other. But groups defaulted into the "average" tier for one component or the other would not have that opportunity. In our view, it is unfair to disadvantage these groups simply because the VM methodology does not work for them. To resolve the issue, **CMS should go back to making tiering <u>voluntary</u> for all practices**.

C. Maximum VM-Related Penalty

We understand that CMS officials may feel the need to respond to critics who argue that physicians will never participate in Medicare's value-based purchasing programs unless they face substantial penalties for not doing so. **However, as previously stated, CMS' proposal could lead to an 11 percent payment cut for many practices—and is just as likely to drive physicians out of Medicare as into the various value-based incentive programs.** A far better motivation would be to put more effort into improving the PQRS program, dealing with the array of methodological issues that plague the VM, and creating feedback reports that provide data that is timely, reliable, and relevant to daily practice. It is also worth noting that many of the practices that will be subject to 2016 VM adjustments, based upon their performance in 2014, <u>have still never received a QRUR</u> and have no idea what is coming. We sincerely hope that additional resources and outreach will be made available when the program doubles in size.

D. Application of the VM to ACOs

CMS' decision to reverse its own policy of exempting ACOs and other alternative payment and delivery models approved by the CMMI, is both disappointing and unnecessary. The NPRM suggests that the policy reversal stems from a rigid interpretation of the legislative language stipulating that the VM should apply to ALL physicians in 2017. **We do not believe that Congress intended such a broad interpretation. These practices are already subject to quality improvement requirements and cost-saving incentives set by CMMI. Bringing them under the VM umbrella is duplicative, unnecessary, and counterproductive.** If CMS officials believe the agency needs additional authority to continue the current VM exemption for new models of care, the Administration should seek that authority from Congress. We note that based on a

comprehensive SGR replacement bill they approved earlier this year, the three Congressional committees with jurisdiction over Medicare are likely to view such a request favorably.

If CMS moves forward with the inclusion of the ACOs in the VM program, CMA recommends the following:

1. That CMS extend the protection for all groups of 1-9 EPs from the penalties (downside risk) until at least the payment adjustment in year 2020.
2. That CMS provide participating EPs with the relevant data for all their Medicare patients;
3. All EPs who participate in Shared Savings ACOs are voluntarily eligible for VM payments that recognize their quality and efficiency scores to the same extent as if they were not in an ACO. Otherwise, physicians will be disincented from joining ACOs.

E. Treatment of Non-Assigned Claims for Non-Participating Physicians

We support the decision to exempt non-assigned claims from payment cuts triggered by the VM and request that this policy also be applied to penalties tied to PQRS and MU of health information technology.

F. Quality Measures in the VM

As noted in our comments on the 2014 proposed rule, the CMA generally supports the alignment of VM and PQRS quality measures. But we are concerned that the simultaneous expansion of PQRS requirements and VM penalties will increase the risk of physicians incurring penalties for both programs due to misunderstandings or unresolved problems surrounding the expanded PQRS requirements. Moreover, we continue to believe that due to the ever-changing nature of both the PQRS program and the VM, as well as potential problems related to the upcoming transition from ICD-9 to ICD-10 diagnosis codes, physicians should continue to have the option of avoiding penalties under both programs by asking CMS to calculate quality and cost data from administrative claims measures.

G. Process for Correcting the VM

The CMA and AMA appreciate CMS' decision to develop a process that would permit physicians to contest various aspects of the calculations used to compute their particular VM adjustment. We agree it is desirable to align the PQRS and VM correction process, although we hope the final rule will further clarify how and when this process is to occur. Our general view is that dates for correcting this and other data being collected on physicians should occur at a set time each year. Physicians should not be expected to continue checking various web sites at various times of the year simply to determine whether they need to take action. Given the complexity of the VM and the length of time it takes CMS to compile the data, it seems highly unrealistic to expect physicians to review and contest the data within a 30-day period. For 2015, we would prefer the proposal to extend the process through the end of February rather than ending it on January 31. Other elements that should be considered in the correction process include the accuracy of patient attribution and risk adjustment. Based upon experience to date, we are

concerned as to whether questions related to this process can be adequately handled through a help desk.

H. Modifications in the Total Per Capita Cost Measures

As currently constructed, the overlapping cost measures used in the VM will punish physicians repeatedly for the treatment of a subset of patients with multiple chronic diseases and acute conditions who require more frequent hospitalizations than the average patient. It is little wonder that practices treating high risk patients fared poorly in the 2012 QRUR evaluation. Rather than focusing on minor issues, CMS needs to reconsider the use of multiple measures which are all heavily influenced by the same patient population.

That said, the AMA would also like to register some concern regarding the proposals to modify the calculation of the five per capita cost measures and the three claims-based outcome measures. As noted earlier, we are troubled by CMS' failure to make adequate adjustments for differences in patients' socioeconomic status. On the other hand, we see the adoption of two other modifications in the cost and outcome measures as premature.

The first of these would modify the process of attributing patients to a practice by including care provided by nurse practitioners (NPs), physician assistants (PAs), and clinical nurse specialists (CNSs) in the initial determination of which group provided the plurality of primary care to a given patient. This approach ignores the fact that a large percentage of NPs, PAs, and CNSs are not actually providing primary care, but instead work in various specialty practices and areas. This assumption has ramifications well beyond the calculation of Medicare cost measures, including the adjustments that are made for a group's specialty composition. Under this proposal, specialty practices that include non-physician practitioners would be expected to show lower costs than those that did not include the non-physicians, potentially discouraging team-based practices that include both specialists and non-physician practitioners.

The CMA and AMA therefore recommend that CMS withdraw this proposal until the agency has studied its impact on group benchmarks and other unintended consequences.

I. Hospital-Based Physicians

The CMA and AMA continue to support proposals that would enable hospital-based specialties to tie their VM adjustments to the performance of the hospital or hospitals where they work. We appreciate CMS' efforts to work through the technicalities of such an approach and to consult with physicians. The process is obviously complicated and could potentially benefit from a work group consisting of representatives of relevant physician organizations, CMS staff in charge of the VM, and the contractors that are assisting in its development. In general, we favor an approach that is voluntary and flexible enough to accommodate the wide array of practice arrangements that exist between hospitals and the hospital-based specialties. It is preferable to have an approach that would accommodate the many physicians and physician groups which have arrangements with multiple hospitals. It would not be appropriate to force them to choose a single facility. Requiring that the majority of its services must be hospital-

based in order for a group to be eligible for this option seems reasonable. But the 90-percent threshold mentioned in the Proposed Rule is far too high.

J. Physician Feedback Reports/Quality and Resource Use Reports

The CMA appreciates CMS' efforts to make the QRURs more informative and actionable. However, we are worried that the agency may be relying too heavily on these reports to warn physicians that they face substantial payment cuts if they do not participate in PQRS and do well in the VM tiering process. Experience with earlier QRURs suggests that very few physicians are actually reviewing them, but it is hard to fault them for that when more than 40 percent of groups of 25 or more practitioners would have received only a single page report saying that there was not enough data to calculate their cost and quality score. To have gotten to this point in the process, they will have had go through a tedious process of creating an account that allows them to gain access to the portal where CMS will post the QRURs. Understandably many physicians, especially those in small practices with limited administrative staff, will give up before they get this far. We understand that CMS also intends to send emails or letters informing physicians about the VM. We would like to see a fuller discussion of the agency's outreach plans in the final rule.

XV. Conclusion

We greatly appreciate the opportunity to share the CMA's views and to fully concur and reemphasize the comments submitted by the AMA. The CMA contact is Elizabeth McNeil, Vice President, Federal Government Relations, CMA, emcneil@cmanet.org; 415 310 2877.

Sincerely,

Richard E. Thorp, MD
President