Michele Nuzzi

Subject: Attachments:

FW: DRAFT AMA Comments on 2016 physician fee schedule

2015-9-8-AMA Comment Ltr to CMS-Physician Fee Schedule-DRAFT.DOCX

From: evp.grstaff@enews.ama-assn.org [mailto:evp.grstaff@enews.ama-assn.org]

Sent: Thursday, September 03, 2015 10:57 AM

To: PSCHUH@mssny.org

Subject: DRAFT AMA Comments on 2016 physician fee schedule

The AMA's **draft** comments on CMS's proposed 2016 Medicare Physician Fee Schedule rule are attached. The proposed rule was published in the Federal Register on July 15 and can be found at https://federalregister.gov/a/2015-16875. Please note that there could be some changes in our comments as they undergo further review but we do not expect major substantive changes. The comments are due to CMS by 5 pm Eastern Tuesday September 8. They can be submitted electronically to www.regulations.gov. We also recently submitted comments on CMS's proposal to require bundled payments for hip replacements in 75 geographic areas. Comments are due for this proposal on September 8 as well. The AMA's comments on this proposal can be found on our web site at https://download.ama-assn.org/resources/doc/washington/2015-09-01-comment-letter-cms-joint-replacement-payment-model.pdf.



Terri Marchiori Director, Federation Relations 330 N Wabash Chicago, IL 60611 P: (312) 464-5271 terri.marchiori@ama-assn.org



EXECUTIVE VICE PRESIDENT, CEO

September 8, 2015

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program: Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2016 (CMS-1631-P)

Dear Acting Administrator Slavitt:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am pleased to offer our comments to the Centers for Medicare & Medicaid Services (CMS) regarding the proposed rule for calendar year (CY) 2016 to revise the Medicare Physician Fee Schedule and Part B (Proposed Rule), published in the *Federal Register* on July 15, 2015 (80 Fed. Reg. 41,686).

I. Executive Summary

- The AMA fully supports and endorses the **recommendations and comments of the AMA/Specialty Society RVS Update Committee (RUC)** regarding physician work, practice expense, and malpractice relative value units (RVUs) for particular services, the process and methodology for valuing services, and the RUC's additional comments on other issues related to the Proposed Rule. (Page 4)
- The AMA urges CMS to continue to retain the refinement panel process as this is an important element in ensuring the accuracy of valuation of physician services. (Page 4)
- To improve payment for primary care and care coordination, the AMA urges CMS to implement Medicare coverage for six services that are essential to care coordination and collaboration, as well as team-based care: anticoagulation management; education and training for patient self-management; medical team conferences; telephone services; analysis of computer transmitted data; and complex chronic care management services. (Page 5)
- The AMA strongly supports establishing separate Medicare payments for collaborative care.
 AMA discussions with physicians about developing alternative payment models have made it clear that funding for physicians to consult with one another and jointly develop treatment plans

could facilitate substantial improvements in patient care and population health outcomes. We also strongly support Medicare coverage of collaborative care models for patients with common behavioral health conditions. (Page 8)

- In calculating targets for savings from misvalued services, CMS must establish an open, transparent process and should include existing codes which are either being deleted or having utilization changes as a result of the misvalued code project and/or the CPT Editorial Panel process. CMS should also consider as "redistribution" any decisions to begin payment for new services in 2016, including advance care planning and non face-to-face services, which would bring the estimation closer to the required one percent. (Page 10)
- For the **phase-in of significant RVU reductions**, the AMA urges CMS to establish a consistent methodology and an open, transparent process to ensure stakeholders are fully aware of the impact the net target reduction will have on physician payment. (*Page 12*)
- The AMA is very pleased that CMS has proposed to accept the RUC recommendations for
 advance care planning services, and to begin paying for these services in 2016. However, we
 are very disappointed to learn that CMS included the services in the net reduction target for CY
 2016. (Page 13)
- The AMA strongly supports the expansion of telehealth coverage under Medicare consistent with the existing clinical evidence base, including the proposed addition of several prolonged service and end-stage renal disease codes. (Page 13)
- The AMA encourages CMS to retain the regulatory language that the physician supervising auxiliary personnel need not be the same physician upon whose services the "incident to" service is based, as eliminating the language could result in confusion for Medicare providers and contractors. (Page 14)
- The AMA commends CMS for its proposal to provide a separate payment to rural health clinics
 and federally qualified health centers for chronic care management services, but we have
 serious concerns with CMS' proposed technological requirements and believe they should be
 broadly drafted to allow for future changes. (Page 15)
- With respect to appropriate use criteria for advanced diagnostic imaging, the AMA recommends that CMS either seek a delay in implementing this requirement and/or consider various alternatives for starting small and then building up the AUC program over time. (Page 16)
- CMS should postpone new benchmarks or other major programmatic changes for the Physician Compare website until after it establishes the methodology for evaluating performance under the Medicare Access and CHIP Reauthorization Act (MACRA) for the Merit-based Incentive Program (MIPS), makes necessary accommodations for the shift to ICD-10, and addresses issues around invalid and nonconforming data. (Page 18)
- The AMA is very pleased that CMS has not proposed substantial changes in the Physician Quality Reporting System (PQRS) but we remain concerned about the reporting requirements

and offer suggestions to make the program more manageable and encourage greater participation by physicians and other eligible professionals. (Page 26)

- The AMA urges CMS to deem a physician who is participating in a qualified clinical data registry as satisfying the **Meaningful Use (MU) quality requirements**, and we share several concerns regarding the ability of EHR vendors to meet the growing demands around the reporting of **electronic clinical quality measures (eCQMs)**. (Page 33)
- The AMA strongly supports giving primary care physicians the flexibility to improve patient care while lowering Medicare spending through alternative payment models (APMs) such as the Comprehensive Primary Care (CPC) initiative. As CMS considers potential expansion of this model, it should seek to: reduce administrative burdens associated with the current model; offer an expanded array of model designs with increased physician flexibility to redesign the delivery of primary care services; link cost accountability to costs that primary care physicians can influence; and make it clear that all of the CPC participants in such an expansion are participating in an eligible APM as defined in the MACRA. (Page 35)
- The AMA opposes using the quality measure *Percent of PCPs who Successfully Meet Meaningful Use Requirements* (ACO-11) in the **Medicare Shared Savings Program** for **accountable care organizations** (ACOs) and we have concerns about adding the measure *Statin Therapy for the Prevention and Treatment of Cardiovascular Disease* (ACO-42) as CMS in the middle of the three-year contract cycle. (*Page 38*)
- The AMA appreciates that in this proposed rule CMS has decided to "stabilize" the **value-based payment modifier (VM)** program rather than increasing penalties and moving ahead at the pace we have seen in the last few years. However, we believe that significant modifications will be needed under the resource section of MIPS and we urge CMS to help inform those modifications by conducting more in-depth analysis and evaluation of the VM and its underlying **physician feedback reports**. (Page 39)
- The AMA encourages CMS to expand its proposed exception for physician recruitment of nonphysician practitioners, and to issue waivers of the **physician self-referral** prohibitions for certain innovative payment and delivery models. (*Page 42*)
- The AMA strongly supports the changes that CMS proposes in its regulations to eliminate the
 previous requirement for physicians who have opted out of Medicare to renew their opt-out
 status every two years. (Page 44)
- The AMA plans to address issues regarding the MIPS program, including the definitions of the low-volume threshold and clinical practice improvement (CPI) activities, as we begin discussing these issues in greater detail among state and national specialty societies, and particularly in the context of responding to upcoming requests for information as well as next year's proposed rule. (Page 44)
- With strong support from the AMA, MACRA promotes the development of alternative payment models (APMs) and provides incentive payments for physicians who participate in APMs. The AMA offers specific suggestions on key questions in the forthcoming Request for Information regarding MACRA APMs. (Page 44)

- Detailed AMA comments on specific quality measures appear in the following appendices:
 - Appendix A: AMA Comments on Table 22/Proposed Individual Quality Cross-Cutting Measures for PQRS & Available for Satisfactory Reporting Via Claims, Registry & EHR Beginning in 2016 (Page 48)
 - Appendix B: AMA Comments on Table 23/New Individual Quality Measures & Those Included in Measures Groups for PQRS & Available for Satisfactory Reporting Beginning in 2016 (Page 50)
 - Appendix C: AMA Comments on Table 24/Proposed NQS Domain Changes for Individual Quality Measures & Those Included in Measures Groups for PQRS Beginning in 2016 (Page 54)
 - Appendix D: AMA Comments on Table 25/Measures Proposed for Removal from the Existing PQRS Measure Set Beginning in 2016 (Page 55)
 - Appendix E: AMA Comments on Table 26/Existing Individual Quality Measures & Those Included in Measures Groups for PQRS for Which Measure Reporting Updates Will Be Effective Beginning in 2016 (Page 58)
 - Appendix F: AMA Comments on Table 27/Cardiovascular Prevention Measures Group for 2016 & Beyond (Million Hearts) (Page 60)
 - Appendix G: AMA Comments on Table 28/Diabetic Retinopathy Measures Group for 2016
 & Beyond (Page 60)
 - Appendix H: AMA Comments on Table 29/Multiple Chronic Conditions Measures Group for 2016 & Beyond (Page 61)
 - Appendix I: AMA Comments on Table 29B: Dementia Measures Group for 2016 & Beyond (Page 62)
 - Appendix J: AMA Comments on Table 29C: Diabetes Measures Group for 2016 & Beyond (Page 62)
 - Appendix K: AMA Comments on Table 29D: Preventive Care Measures Group for 2016 & Beyond (Page 63)

II. Provisions of the Proposed Rule for the 2016 Physician Fee Schedule

A. Determination of Practice Expense (PE) and Malpractice Relative Value Units (RVUs) and Potentially Misvalued Services Under the Physician Fee Schedule

The AMA fully supports and endorses the recommendations and comments of the RUC regarding physician work, practice expense, and malpractice relative value units for particular services, the process and methodology for valuing services, and potentially misvalued services. We also support the RUC's additional comments on other relevant issues.

B. Refinement Panel

The AMA joins with the RUC is urging CMS not to permanently dismantle the Refinement Panel or the de facto appeal process it offers. CMS indicates the process may no longer be necessary, now that proposed work RVUs are being published in the proposed rule, and available for public comment prior to (and potentially even after) their publication in the final rule. While the AMA and the RUC strongly support shifting the first publication of proposed work RVUs to the proposed rule, we still see benefits in

maintaining an objective, transparent, and consistently-applied appeals process that would be open to any commenting organization. This process affords an important opportunity for outside stakeholders to appeal CMS decisions and provides an additional layer of accountability for CMS' decisions.

Stakeholders have considered the Refinement Panel an appeals process for nearly two decades. As organized by CMS, the panel has been comprised of members from primary care organizations, Medicare contractor medical directors, a specialty related to the commenter, and the commenting specialty. For many years, CMS has deferred to the panel's recommendation in finalizing values. More recently, CMS modified the process to only consider codes for which new clinical information was provided in the comment letter. The agency also began to independently review each of the Refinement Panel recommendations. In many cases, the Refinement Panel supported the original RUC recommendation and the commenter's request, but CMS finalized its proposed value instead.

C. Improving Payment Accuracy for Primary Care and Care Management Services

Medicare Coverage for Six Crucial Services that Support Care Coordination and Collaboration

The AMA appreciates CMS' decision to recognize and pay for transitional care management (TCM) services in 2013 and chronic care management (CCM) services in 2015. We also strongly urge CMS to implement separate payment, beginning January 1, 2016, for six categories of services described below, which have long been recognized to improve care coordination and care collaboration:

- Anticoagulant Management: This is crucial for keeping patients on anticoagulant therapy, including the large contingent of patients with atrial fibrillation, within a safe and effective therapeutic range. Close management is needed to avoid the wide range of potentially life-threatening complications, from blood clots and even pulmonary embolism when doses are too low, to hemorrhages and when the dose is too high. The failure to separately compensate anticoagulation management represents a lost opportunity to address a known health risk with a fairly simple and straightforward solution.
- Education and Training for Patient Self-Management: The inherent value of this service only continues to grow in importance, as every aspect of health care moves to incorporate more patient-centered care at virtually every level.
- Medical Team Conferences: Team-based case simply cannot exist without medical team conferences. The failure to compensate this service is the single greatest impediment to moving toward more team-based care. As health care options and approaches have multiplied exponentially, team-based care is the glue that bonds together all the disjointed pieces to ensure that a patient's care is being coordinated among the multitude of health care professionals, services, and professionals. Many medical schools are moving to include team-based care models in their education of physicians, and the AMA is supporting those efforts through the AMA Accelerating Changes in Education (ACE) program.
- Telephone Services: These services can be a valuable and efficient alternative to face-to-face
 visits for certain patients and in appropriate circumstances. Physicians simply do not have the
 time or resources to engage in these services unless they are compensated, particularly with the
 extra time and effort they must devote to uncompensated requirements under PQRS, the VM,
 MU, etc.
- Analysis of Computer Transmitted Data: These are non face-to-face services that require time
 and effort on behalf of physicians and other health professionals, which should be compensated.

Complex Chronic Care Management Services: The AMA and the RUC have long advocated
for compensating these more comprehensive services for more complicated patients. These codes
were developed with substantial input from a multitude of specialty societies (of physicians and
non-physicians) working in consultation with CMS staff.

The Current Procedural Terminology® Editorial Panel has already defined and given CPT® codes for these services. The RUC has already recommended valuation of those codes, based upon input from the relevant specialty societies. The RUC initially sent comments to CMS in October 2011 supporting Medicare coverage for these services, and we are hopeful that CMS will now be receptive to doing so. These services are designed to support collaboration among and between physicians, non-physician clinicians, and clinical staff, and to support team-based care. They also provide physicians and other providers with the general framework and tools they must have to ensure a high quality of care by focusing their efforts to support ongoing coordination with the patient and evaluation of their status, transitions of care, and streamlining services to avoid complications, costly admissions, and preventable or unnecessary services and procedures. Coverage of the following services will represent a monumental step in the burgeoning movement to reform health care by moving away from the current culture of paying for disjointed, duplicative, and inefficient care:

Type of Service	CPT Code & Description			
Anticoagulant Management	99363 Anticoagulant management for an outpatient taking warfarin, physician review and interpretation of International Normalized Ratio (INR) testing, patient instructions, dosage adjustment (as needed), and ordering of additional tests; initial 90 days of therapy (must include a minimum of 8 INR measurements) 99364 Anticoagulant management for an outpatient taking warfarin, physician review and interpretation of International Normalized Ratio (INR) testing, patient instructions, dosage adjustment (as needed), and ordering of additional tests; each subsequent 90 days of therapy (must include a minimum of 3 INR measurements)			
Education and Training for Patient Self- Management	98960 Education and training for patient self-management by a qualified, non-physician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; individual patient 98961 2-4 patients 98962 5-8 patients			
Medical Team Conference	99366 Medical team conference with interdisciplinary team of health care professionals, face-to-face with patient, and/or family, 30 minutes or more, participation by nonphysician qualified health care professional 99367 Medical team conference with interdisciplinary team of health care professionals, patient and/or family not present, 30 minutes or more; participation by physician 99368 Medical team conference with interdisciplinary team of health care professionals, patient and/or family not present, 30 minutes or more; participation by nonphysician qualified health care professional			
Telephone Services	99441 Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion 99442 11-20 minutes of medical discussion			

Type of Service	CPT Code & Description				
	99443 21-30 minutes of medical discussion				
Analysis of Computer	99091 Collection and interpretation of physiologic data (e.g., ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or				
Transmitted Data	caregiver to the physician or other qualified health care professional, requiring a minimum of 30 minutes of time				
Complex Chronic Care Management Services	99487 Complex chronic care coordination services; first hour of clinical staff time directed by a physician or other qualified health care professional with no face-to-face visit, per calendar month 99489 each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month				

CMS may also consider implementing coverage for additional services. The current covered chronic care management service (CPT 99490) assumes 15 minutes of physician time spent over the course of one month. CMS has proposed that there may be a need to describe and pay for the professional work (of physicians and other qualified health care professionals) that extends beyond the 15 minutes. Specialty societies may also want to propose additional codes, such as one similar to the current CPT code 90785 *Interactive complexity (List separately in addition to the code for primary procedure)*, in an attempt to better describe services that require intensive communication with the family and/or family members. There could also be a new CPT code to describe extensive physician work related to medication management and reconciliation. The CPT Editorial Panel and the RUC have also restructured the former Chronic Care Coordination Workgroup to a new Emerging CPT and RUC Issues Workgroup to develop, in part, a specific response to many of the questions that CMS outlined in the Proposed Rule. We encourage CMS to begin working with the medical community to ensure efficient implementation of any new CPT or G codes to be developed in response to the Proposed Rule.

CCM and TCM Services

The AMA and the RUC agree that Medicare coverage of TCM and CCM services demonstrates a positive step in paying for non face-to-face services that improve the quality of health care provided to patients, while ultimately leading to potential overall savings to the program. CMS has asked the public to comment on potential ways to reduce the administrative burdens associated with reporting the services as well as consideration of data to demonstrate that the more resource-intensive CCM services (CPT codes 99487 and 99489) should be covered.

One potential improvement to reporting the CCM and TCM services would be to allow the physician to file the claim at the point in time that the service is rendered and the requirements to report have been completed. Some physicians are reporting difficulty with their claims processing systems in accommodating the requirement that the physician wait until the end of a 30 day period to file the claim. CMS should reconsider the claims processing requirements to alleviate administrative burden.

The new CCM code, 99490, requires at least 20 minutes of clinical staff time spent in care management activities. Physician practices are required to document this time. Accordingly, CMS should contract with a vendor to collect information on the actual time spent in these activities. These data would support that the time spent is likely bimodal and provide evidence to CMS that the more resource-intensive CCM services (CPT codes 99487 and 99489) should be payable.

D. Establishing Separate Payment for Collaborative Care

The AMA is pleased to respond to the CMS request for comments on collaborative care. CMS discussed four CPT codes, created in 2014, to describe interprofessional telephone/internet consultative services (CPT codes 99446-99449) in this Proposed Rule. CMS is considering separate payment for these services to "account for the resource costs of a more robust interprofessional consultation within the current structure of Physician Payment Schedule payment." The AMA recommends that CMS work directly with interested parties through the CPT Editorial Panel to ensure that the CPT codes are described in a manner that would allow CMS to offer separate payment for the services. The RUC will re-review the codes, as modified, to ensure that the resource costs are appropriately described for CMS consideration.

As CMS notes in the Proposed Rule, the management of patients with multiple chronic conditions, a particularly complicated disease or acute condition, or common behavioral health conditions often requires extensive discussion, information-sharing, and planning between the patient's primary care physician and the specialists who are managing the patient's other conditions. CMS also provides a good example of the need to recognize collaborative care as a separate service when a primary care physician and a neurologist consult with one another about a patient who has Alzheimer's disease plus other chronic diseases. CMS further notes that, in 2014, the CPT Editorial Panel created four CPT codes to describe interprofessional telephone/internet consultative services (CPT codes 99446-99449). Currently Medicare does not provide separate payment to physicians for these codes.

Unfortunately, the lack of funding for interprofessional consultative services under the Medicare physician payment schedule makes it difficult for physicians to take the time to engage in this collaboration. In the CMS example, not only would the primary care physician and neurologist who consult with one another not be paid for the work involved in this joint treatment planning, but they would lose revenue they could have earned from face-to-face patient services. Over the last several years, the AMA has met with physicians from many different specialties about how they want to reform delivery of care for patients with particular conditions to improve quality and coordination while lowering Medicare spending. Each and every new model that specialties have proposed involves interprofessional consultative services that are not supported within the current Medicare payment system:

- Patients with ovarian and endometrial cancer could benefit from fewer repeat operations and complications of surgery as well as improved health outcomes through a team approach in which gynecologic oncologists collaborate with other surgeons, medical and radiation oncologists, and other physicians and health professionals involved in the patient's care.
- Collaboration between cardiologists and primary care physicians in diagnosing and managing
 patients with ischemic heart disease can improve the appropriateness of diagnostic test ordering
 and reduce the risk of heart attacks.
- Patients with diabetes could benefit from reduced hospitalizations through collaboration between endocrinologists and primary care physicians in managing care for this chronic disease.
- Breast cancer patients could benefit from fewer repeat operations and better health outcomes
 through coordination and joint advance treatment planning by the breast surgeon who is removing
 the patient's cancer, the plastic and reconstructive surgeon, and the radiation and medical
 oncologists involved in the patient's care.
- Collaboration between neurologists, emergency medicine, and primary care could help prevent seizures and injuries and complications due to epilepsy, reducing the need for patients to be hospitalized.

- Nephrologists and vascular surgeons could utilize collaborative care for chronic kidney disease
 patients to plan ahead for vascular access using an arteriovenous fistula for hemodialysis, which
 would avoid the need for multiple catheters and reduce infections and other complications
 associated with dialysis.
- Nursing home medical directors and hospitalists could collaborate to manage exacerbations in the long-term care setting and reduce the number of patients cycling between the hospital and nursing home.
- Hospitalists could consult with a thyroid patient's endocrinologist to obtain information about the
 patient's medical history, prescribed medications, recent laboratory data and treatment and
 management options to be considered when the patient is hospitalized with chest pain.
- Primary care and specialist physicians could consult with one another to discuss treatment options
 in response to findings from imaging tests, such as a thyroid nodule found during a CT exam for a
 patient experiencing recurrent severe headaches.

As the foregoing examples illustrate, there are many opportunities to improve patient care by providing separate Medicare payment for physicians to collaborate with one another in their patients' care. These opportunities exist both for individual patients and for populations of patients, particularly when the population is defined as patients who have a particular disease or condition. CMS should make it possible for two or more physicians to collaborate in care planning for an individual patient and also for groups of patients. Using CMS' example of collaboration between primary care and neurology for patients with Alzheimer's and other chronic diseases, this collaboration could either take the form of a primary care physician discussing a particular patient with the neurologist, or it could take the form of a discussion about a population of the primary care physician's patients who all have Alzheimer's and other conditions.

The above examples also show that a Medicare policy decision to provide separate payment for interprofessional consultations should not be limited to primary care physicians or medical specialists. Funding for these services could have a major positive impact on surgical care as well. Finally, it is important that both of the physicians involved in the collaborative care service be able to bill for the service.

Collaborative Care Models for Patients with Common Behavioral Health Conditions

CMS is persuaded that randomized controlled trials have provided evidence that the collaborative care model for patients with common behavioral health conditions (e.g., depression and anxiety) has been successful. In this model (described at http://aims.uw.edu), the primary care office (the PCP and a designated care manager) collaborates with a psychiatric consultant, in managing a population of patients to ensure that patient treatment is effective and to make necessary adjustments in a timely manner to reach individual patient treatment plan goals. Much of this collaboration is performed non face-to-face by the psychiatrist and by the primary care physician's care manager. CMS will consider new codes to describe this collaboration since current codes do not accurately represent the work entailed in this model. The AMA understands that the organizations that represent psychiatry and other mental health professionals will work with the primary care organizations to develop CPT coding proposals in the near future. The AMA strongly supports Medicare coverage of collaborative care models for patients with common behavioral health conditions.

E. Target for RVU Adjustments for Misvalued Services

The Protecting Access to Medicare Act of 2014 (PAMA), enacted on April 1, 2014, established an annual target for reductions in Medicare Payment Schedule expenditures resulting from adjustments to relative values of misvalued codes. Following this, the Achieving a Better Life Experience Act of 2014 (ABLE), enacted on December 19, 2014, accelerated the application of the expenditure reduction target, setting targets of one percent for CY 2016 and 0.5 percent for calendar years 2017 and 2018.

The AMA opposes these specific savings targets imposed by Congress as they are completely unnecessary, particularly in light of the significant work of the RUC and CMS in identifying, examining, and addressing misvalued codes for several years. The RUC and CMS have been engaged in intensive efforts to identify and address misvalued services for many years, long before passage of PAMA and the ABLE Act. CMS has also recognized the RUC's vital role in helping CMS to value Medicare services. Since the beginning of the RUC's Relativity Assessment Workgroup in 2006, the RUC and CMS have identified over 1,800 services through 15 different screening criteria for further review by the RUC. The RUC has recommended reductions and deletions for 1,036 services, over half of those identified, leading to redistribution of more than \$3.5 billion.

Cumulative Savings to Date

With estimated total allowed charges of \$88.4 billion for CY 2016, one percent would roughly equate to a net reduction target of \$884 million. According to the regulatory impact section in the Proposed Rule, CMS estimates a net reduction of approximately 0.25 percent of expenditures under the Medicare Payment Schedule for codes under review by CMS under the NPRM timeline. (This reduction target does not account for RUC reviewed services that were not submitted to CMS by the February 2015 deadline for inclusion in the NPRM.) After analysis of the available information published by CMS, the RUC confirmed the agency's published reduction target seems accurate. However, the process for determining the net reduction target remains non-transparent. The RUC's independent calculations came after several conversations with CMS staff and a comprehensive knowledge of the utilization crosswalk assumptions. Individual stakeholders without this knowledge base will be significantly burdened to conduct a reasonable analysis of the net reduction target. Therefore, CMS should establish a transparent process to ensure stakeholders can independently verify the updated net reduction calculations each year.

CMS should take several steps towards establishing a transparent calculation process. First, the agency must publish the dollar figure estimate in each year. In this Proposed Rule, CMS simply publishes an estimated target reduction of 0.25 percent. When estimating such large reductions, small changes, including rounding errors, can result in fluctuations in the millions of dollars. Second, CMS should publish each issue's estimated impact on the net target reduction. CMS could publish this information per CPT code, or identify each family of services and publish a combined impact. While estimating the impact of existing services is straightforward, new codes resulting from the revision of large families of services can be difficult to assess. To ensure the stakeholder community can fairly and accurately calculate the published reduction, CMS should publish the exact target reduction number and individual service-level impacts for each year.

Distinguishing "Misvalued Code" Adjustments from Other RVU Adjustments

CMS discusses several ways to identify a subset of the adjustments in RVUs for a year to reflect an estimated "net reduction" in expenditures. The agency then states "we believe that the best approach is to

Andrew M. Slavitt September 8, 2015 Page 11

define the reduction in expenditures as a result of adjustments to RVUs for misvalued codes to include the estimated pool of all services with revised input values."

The AMA agrees with the CMS proposal to include all services that receive revised input values. This approach is especially appropriate given the amount of work the RUC Practice Expense Subcommittee has done recently to update practice expense inputs, including the film-to-digital migration for imaging services and moderate sedation monitoring time.

The AMA would like to comment on one subset of services that need to also be included in the target reduction- existing codes in which large volume changes occur due to new coding structure. These volume changes could result from coding changes to large families of services and/or the deletion of obsolete codes. Under the current proposal, these existing codes would not be included in the target reduction because inputs are not changing. However, the utilization for these services is changing and should be included as they are related to the activity of either the misvalued code project and/or the CPT Editorial Panel. These codes are identified by the RUC in the utilization crosswalk spreadsheet submitted with each RUC recommendation submission. CMS should include existing codes which are either being deleted or having utilization changes as a result of the misvalued code project and/or the CPT Editorial Panel process.

We would also urge CMS to consider any impact from implementation of payment for anticoagulation management, education and training for patient self-management, medical team conferences, telephone services, analysis of computer transmitted data, and/or complex chronic care management services, as "redistribution" from other services and toward the goal of improving payment for care coordination and care collaboration. For example, it is projected that implementation of the anticoagulant management CPT codes in 2016 would lead to \$230 million in physician payment for these services. The implementation should be factored into redistribution from other services and account for 0.25 percent of the one percent in redistribution mandated by Congress for 2016. These proposals represent the same type of targeted initiatives that have been implemented recently and should be considered as "redistribution" from other physician services, bringing the estimation closer to the required one percent.

RVU Determinations over Three Years

Additionally, CMS discusses the challenges presented by calculating an annual target when changes in values take place over three years: the original value in the first year, the interim final value in the second year, and the finalized value in the third year. The agency proposes to exclude code-level input changes from the CY 2015 interim final values from the calculation of the CY 2016 misvalued code target since the misvalued change occurred over multiple years, including years not applicable to the misvalued code target provision.

The AMA joins the RUC in supporting this proposal for two primary reasons. First, as the agency notes, the year two to year three changes represent an incomplete picture of the redistributive effects from the review of misvalued services. These changes largely represent increases in value to services that, after receiving public comment, CMS had previously proposed to decrease. The vast majority of redistribution happens between year one and year two, where the RUC recommendations are initially reviewed and receive interim final values. Second, because of the nature of these changes, reductions that occurred on an interim final basis for CY 2015 were not counted towards achievement of the target. Thus, accepting

Andrew M. Slavitt September 8, 2015 Page 12

changes resulting from CMS decisions to modify CY 2015 interim final recommendation would distort the overall net impact of the RUC and CMS work on the service level input changes for CY 2015.

Calculating "Net Reduction"

CMS states that the requirement to calculate net reductions implies that both decreases and increases must be considered. The agency also notes that this is the only practical approach given that revising families of services can often lead to both increases and decreases within the same family (e.g., splitting one code into two codes, simple and complex).

When considering the net impact of service-level input changes in a given year, it is important for CMS to understand specific scenarios in which codes under review should not be included in the net reduction target calculation. Below are two examples from the CY 2016 recommendations, regarding the phase-in of significant RVU reductions, as well as the implementation of payment for advance care planning services. In general, however, these examples represent broad concepts that CMS should continue throughout each rulemaking process.

The following two sections also discuss how these items should count toward meeting the targets for revaluation of misvalued services.

New Services without Predecessor Codes

Each year, CPT codes are created for services which reflect new technology and other physician work that are not accurately reportable prior to implementation. These services are outside the scope of any payment initiatives between the RUC and CMS, as described above, and are often billed as Category III codes or unlisted codes. Examples include the transcatheter pulmonary valve implantation code 3347A, the rib fracture fixation codes 21811-21813, and the high resolution anoscopy codes 46001 and 46607. Since codes of this nature are not accurately reportable prior to the creation of new codes, their RVU inputs cannot be considered revisions. Taking into account the lack of predecessor payment and the CMS definition that the target will only consist of services with input changes, net RVU changes that result when new families of services are created should not count towards the target calculation.

F. Phase-In of Significant RVU Reductions

CMS proposes to phase-in over two years refinements that result in a year over year reduction in total RVUs of 20 percent or more. For purposes of calculating the net reduction target, CMS uses the fully reduced total RVUs, not the first year phase-in RVUs. However, for a subgroup of services, CMS proposes to not follow this standard. During review of the radiation treatment services, the agency proposes a change in the equipment utilization rate assumption for the linear accelerator from 50 percent to 60 percent by CY 2016 and 70 percent for CY 2017.

For purposes of calculating the target reduction for CY 2016, CMS uses the 60 percent threshold for these services. The AMA does not agree with this proposal because it creates two separate rules for codes affected by phased-in RVU reductions. As stated initially, CMS must establish an open, transparent process to ensure stakeholders are fully aware of the impact the net target reduction will have on physician payment. Establishing a consistent methodology for codes with phased-in RVU reductions is a necessary component of that mission. CMS should calculate the full impact of the change in the

linear accelerator equipment utilization for radiation treatment services, and any future instances of multi-year phase-in proposals, from the year CMS initially establishes the decision.

G. Valuation of Specific Codes: Advance Care Planning

The AMA is very pleased that CMS has proposed to accept the RUC recommendations for advance care planning services, and to begin paying for these services in 2016.

Treatment for the Misvalued Services Target

However, we are very disappointed to learn that CMS included the services in the net reduction target for CY 2016. The RUC, specialty societies and CMS have worked extremely hard over the past few years to develop several coding solutions that recognize the important components of care management, which lead to better health outcomes for individuals and help reduce downstream costs within the health care system. Services like the TCM and CCM services represent targeted payment initiatives that were specifically created to provide appropriate support for furnishing the best patient care possible.

Given the implicit nature of services like advanced care planning, the AMA and the RUC are disappointed to learn that CMS included these services in the net reduction target for CY 2016. The advance care planning codes represent new services, which are not currently reportable. The RUC estimates that roughly \$4 million will be spent on these services in CY 2016. Creating a scenario in which payment for these services is immediately offset by a reduction in the conversion factor, resulting from not hitting the target, is counterintuitive to the recent work to recognize important care management services. Therefore, CMS should instead estimate the cost of implementation of the advanced care planning services as "redistribution" from other services for CY 2016.

H. Medicare Telehealth Services

The AMA strongly supports the expansion of telehealth coverage under Medicare consistent with the existing clinical evidence base. While CMS has been constrained by statutory restrictions that limit access based on geographic location and sites of service which the AMA continues to advocate for congressional action to remove, the AMA supports the evidence-based approach utilized by CMS to include additional telehealth services. The AMA strongly supports the addition of codes 99356 and 99357 (prolonged service in the inpatient or observation setting requiring unit/floor time beyond the usual service) and the following end-stage renal disease codes: 90963, 90964, 90965, and 90966. We understand that, although these are for home dialysis, the agency has noted that the home is not an eligible site of service for Medicare telehealth services. The agency has concluded that "that many components of these services would be furnished from an authorized originating site and, therefore, can be furnished via telehealth." The agency has also clarified that the required clinical examination of the catheter access site has to be furnished in-person.

The growth and rapid rate of innovation in digital medicine all underscore the need for a review of existing codes and services that would be appropriately delivered via telehealth. To that end, the CPT Editorial Panel has announced the formation of a CPT Telehealth Services Workgroup, which will be chaired by members of the CPT Editorial Panel. The workgroup will be comprised of relevant medical specialties/organizations, payers, industry, and other relevant stakeholders. The workgroup will recommend additions and changes to the CPT code set related to medical services utilizing telehealth technology. The charge of this ad-hoc workgroup is to:

- Recommend solutions for the reporting of current non-telehealth services when using remote telehealth technology (to include but not limited to E/M services). Considerations will include potential new codes, use of current codes without or with modifier, add-on code(s).
- Address the accuracy of the current code set in describing the services provided when telehealth data is reviewed and analyzed, including potential code set revisions and/or education for:
 - o Appropriate code use (e.g., E/M versus data analysis codes);
 - o Potential code development to report analysis of transmitted data;
 - Definition of data types whose interpretation will require differentiation and consideration of separate reporting of current E/M services/codes; and,
 - o Potential new E/M services codes based on emerging new patterns for sites of service.
- Recommend whether any other telehealth service codes should be developed based upon services currently being provided.
- Develop new or modify existing introductory language to guide coding of telehealth services.

The workgroup will also help facilitate discussions with key stakeholders who may wish to bring forward telehealth services applications for consideration. According to the CPT Editorial Panel Ad-Hoc Workgroup Organizational Structure and Processes guidance, all workgroup recommendations will be presented in a Code Change Application(s) for consideration by the CPT Editorial Panel. Participation in the Telehealth Services Workgroup does not preclude the submission of a separately developed code change application for consideration by the Editorial Panel.

I. "Incident to" Proposals: Billing Physician as the Supervising Physician

CMS is proposing to require that a physician or other practitioner who bills for "incident to" services must be the same physician or practitioner who directly supervises the service. CMS is proposing to eliminate the current regulatory language that "the physician (or other practitioner) directly supervising the auxiliary personnel need *not* be the same physician (or other practitioner) upon whose professional service the incident to service is based," and substitute language requiring such services to be "furnished under the direct supervision of the billing physician."

It is our understanding that CMS did not intend to prohibit "incident to" billing by a supervising physician who is not the physician managing the patient's overall care. The proposed modification leaves considerable ambiguity on that question, however, and we are concerned that removal of the sentence in question could be read the wrong way by Recovery Audit Contractors (RACs), Medicare administrative contractors (MACs), etc. CMS needs to retain or modify the language rather than eliminating it.

Specifically, the AMA is concerned that as currently worded, the proposed amendment fails to account for—and risks posing an undue burden upon—group practices and clinics that provide care for a large population of patients undergoing recurring treatment series such as chemotherapy. In such circumstances, it is feasible that the patient's treating physician will not be on the premises for each and every visit, but that another physician in the practice will directly supervise the "incident to" service on those occasions. This arrangement satisfies the current CMS standard that the "incident to" services must be furnished under direct physician supervision. In fact, CMS Form 1500 appears to anticipate this very scenario by having the "rendering provider" number listed in block 24J, and the "billing provider" number listed in block 33A. We fear that the proposed amendment would be read as requiring that blocks 24J and 33A must always be identical, forgoing any possible distinction between the rendering and billing providers.

The AMA believes that if CMS adopts the proposed amendment, it should further specify that physicians and other practitioners in the same group practice or clinic are considered as one entity for purposes of linking billing and supervision. Otherwise, the current proposal may eliminate necessary flexibility within group practice arrangements and thereby prove unduly restrictive. The AMA believes that the extant regulatory framework better reflects the reality of group practice and facilitates team-based care.

III. Other Provisions of the Proposed Regulations

A. Chronic Care Management (CCM) Services for Rural Health Clinics and Federally Qualified Health Centers

The AMA commends CMS for its proposal to provide a separate payment to rural health clinics (RHCs) and federally qualified health centers (FQHCs) for CCM services, as part of the RHC and FQHC benefit. As proposed, an RHC or FQHC may bill once per calendar month for at least 20 minutes of qualifying CCM services by a physician, nurse practitioner, physician assistant, or certified nurse midwife, to patients with multiple chronic conditions that pose a risk of death, acute exacerbation or complication, or functional decline. Payment will be based upon the Physician Fee Schedule (PFS) national average non-facility payment rate (\$42.91 per beneficiary in the first quarter of 2015), and subject to beneficiary notification, consent, coinsurance, and deductibles. CCM services could be initiated during a comprehensive Evaluation/Management (E/M) service, Annual Wellness Visit, or IPPE.

In January of this year, CMS began paying under the PFS for CCM services as described and billed under CPT code 99490. The AMA, the CPT Editorial Panel, and the RUC have long supported payment for CCM services, and the CPT/RUC Chronic Care Coordination Workgroup worked with national medical specialties over several years to foster the development of CPT codes and value recommendations for both CCM and TCM services.

We are happy to join the chorus of those who have already expressed support for payment to RHCs and FQHCs for CCM services in the public comments regarding the May 2014 FQHC PPS final rule. We agree this will support the Affordable Care Act's goal of furnishing integrated and coordinated health services. Furthermore, it will help ensure that the rural and low-income individuals served by RHCs and FQHCs, who may have limited options and resources, can receive the ongoing care and attention they need and deserve between their clinic appointments.

We are also pleased by CMS' statement that "The CPT code descriptor sets forth the eligibility guidelines for CCM services and will serve as the basis for potential medical review" (page 41794) and we support the proposal to waive the RHC and FQHC face-to-face requirements when CCM services are furnished.

Technological Requirements

Health information systems do not coordinate care for patients with chronic conditions; physicians and other health professionals do that. Therefore, while we appreciate the proposal allowing RHCs and FQHCs to bill for CCM services, the AMA has serious concerns with CMS' proposed technological requirements. Interoperability and electronic exchange of medical information currently face significant cost and technological barriers that prevent physicians, despite their best efforts, from seamlessly transmitting and recording patient information. Such requirements should be encouraged but not mandated as a part of billing for CCM services. In particular, we disagree with the proposals that an

electronic care plan be made available 24 hours a day and seven days a week as this unrealistically fails to account for system maintenance, down-time, change in EHR vendor, or the event of technological glitches and cyber-attacks. At the very minimum, CMS should provide for exceptions in the event of any of these circumstances. In addition, physicians have highlighted significant problems and usability concerns with the clinical care summaries, which can extend to well over 40 pages and fail to arrange data in useful formats. We therefore discourage mandating that these summaries be used for CCM services before these problems are resolved. Finally, we worry that adding very prescriptive technological requirements may stifle innovation and prevent the use of technology that is more appropriate and tailored for chronically ill patients. Accordingly, any technological requirements for CCM services should be broadly drafted to allow for future changes and advancements over time.

B. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

As a first step in the implementation of a provision in the Protecting Access to Medicare Act of 2014 (PAMA) that will require physicians to consult appropriateness use criteria (AUC) prior to ordering certain services, CMS has laid out the ground rules it will use to choose which AUC sets could be used to meet the requirement. The specific criteria, clinical decision support mechanisms that incorporate the criteria, and the rules surrounding how physicians choose, document and use AUC products will be taken up in the 2017 rulemaking process. As a result, physicians will not have known what they must do to comply with the new requirement until a final 2017 rule is published in November 2016 and until the list of clinical decision support systems or other products they can use is published sometime after that. It will be virtually impossible for many practices—especially if they are small and unaffiliated with a larger system—to incorporate consultation of an approved set of appropriateness use criteria in the few weeks remaining before PAMA's January 1, 2017 implementation deadline.

The AMA supports the use of AUC to inform physician decision-making and appreciates CMS' effort to lay out a foundation for this complex new requirement within the idealistic deadlines envisioned by Congress. We also agree with many of the premises and policies proposed in the rule. However, we have serious reservations about CMS' ability to implement and physicians' ability to incorporate such a significant change within the extremely short turn-around time envisioned in this proposed rule. We therefore recommend that CMS seek a delay in implementing this requirement and/or consider various alternatives for starting small and then building up the AUC program over time. Also, rather than waiting another year for public comment on the 2017 physician fee schedule rule, CMS should issue a request for information regarding the additional decisions that are needed to bring the AUC program on line. Our comments on specific provisions in this Proposed Rule follow.

Scope of the Program

Because PAMA specifies only that initial criteria are to be directed at advanced imaging services, CMS has considerable latitude in determining what conditions and for which modalities consultation will be required. In discussing its proposed approach, CMS observes that there are two schools of thought regarding how rapidly to roll out the program with one school arguing for a "comprehensive library" of criteria and the other calling for an approach that focuses on "a few priority clinical areas." The proposed rule suggests that the agency will take a flexible approach that would allow physicians to choose between competing sets of AUC and clinical decision support mechanisms. However, only a narrow list of AUC would be approved for the purpose of identifying outlier physicians who would be required to get prior authorization effective January 1, 2020.

The AMA is very pleased that CMS intends to base outlier identification on a narrow set of conditions where there is wide agreement on clinically appropriate treatments. We also support CMS's decision to qualify AUC developers and endorsers rather than qualifying each individual AUC set. These positive features notwithstanding, we cannot endorse an approach that gives physicians less than eight weeks lead time to choose and implement a clinical support system that suits the needs of their patients and practices, will meet the AUC requirement and can be integrated into normal workflow. Compliance with the law may require new contracts and licenses, legal reviews, modified work flow patterns, and EHR updates that cannot be completed in the time allotted, especially by small rural practices and by the primary care physicians who will be heavily impacted by the new rules. Medicare itself may not be ready either, since verifying AUC consultation may require claim form changes that CMS may not be able to complete prior to January 1, 2017.

Rather than proceeding down the track laid out in the rule, CMS should either seek Congressional authority to postpone AUC implementation or significantly limit its initial application. To this end, we recommend that initial implementation should focus on large health systems that meet CMS's criteria for provider-led organizations that are qualified to develop, modify or endorse AUC. These groups presumably will already have some experience with AUC consultation and are most likely to have built the criteria into their electronic health records, which the proposed rule suggests is the most effective and efficient way to integrate AUC into daily practice. As an alternative, CMS could consider limiting AUC to just a few conditions using the process laid out in the rule for identifying priority clinical areas based on prevalence, utilization, cost and strength of the evidence.

Applicable Settings

In the definitions section, CMS states that consultation with AUC will be required of physicians in all outpatient settings, including emergency departments (EDs). We note that while the law calls for application of AUC in all hospital outpatient settings, including the emergency department, it also created an exception for emergency services. This is a distinction without clear boundaries that will force ED physicians in the midst of identifying and treating critical and potentially life-threatening illnesses to first distinguish between cases that require AUC consultation and those that do not. Resulting treatment delays could exacerbate crowding in many emergency departments and have devastating consequences for some patients such as those where a stroke is suspected and timely diagnosis and intervention is imperative.

Prior to imposing the AUC consultation requirement in emergency departments, CMS therefore will clearly need to work closely with emergency physicians and the organizations that represent them to identify a modified approach. Possible options might include requiring AUC consultation only after a diagnosis has been reached, applying the mandate to a very limited set of conditions that are not generally true emergencies, creating a separate outlier identification process for emergency physicians, or delaying implementation of mandated AUC in the emergency department until more experience is gained with required AUC consultation in other settings.

Eligible Entities

As stipulated by the PAMA, CMS would only approve appropriateness criteria that are submitted by entities that are provider-led, which the proposed rule defines as national professional medical specialty societies or organizations comprised primarily of providers and actively engaged in the practice and delivery of health care. Any criteria that these entities developed, modified, or endorsed would count as

meeting the PAMA requirement if the organization met specified requirements regarding review of the evidence, methodology employed, composition of the team that put the AUC together, and transparency regarding their process and team.

The AMA generally favors CMS' proposals for defining provider-led entities and establishing the process they must follow in order to have their AUC product deemed to meet the PAMA mandate. There are several areas, however, where clarification and/or expansion are needed:

- Because Medicare typically refers to hospitals and facilities as providers and physicians as suppliers, language clarifying that provider-led organizations could include physicians should be added to the definition.
- We have some concerns that a provider-based entity might "endorse" or modify insurer
 guidelines that have not gone through the rigorous process that CMS is proposing. To that end,
 we would appreciate some more explicit language regarding the endorsement or modification of
 another organization's criteria. We would also like to ensure that the multidisciplinary team
 developing or selecting AUC includes <u>practicing</u> physicians in the field to which the AUC will
 apply.
- While we believe some flexibility with regard to conflicts of interest is appropriate, some categories of conflict should probably be prohibited, not just disclosed on a developer's website.

C. Physician Compare Website

The AMA believes it is premature for CMS to consider or implement a new benchmark or other major programmatic changes for Physician Compare at this time. CMS has proposed to implement a benchmarking methodology for displaying quality information on Physician Compare profile pages for individual physicians and group practices starting in 2016. The information would be based on measures reported through the PQRS program. CMS also proposes to continue to make available for public reporting on Physician Compare all individual EP and group practice measures following the year the measures are reported. We recommend that CMS not move forward with such changes. Rather, we urge CMS to focus its current efforts on preparing Physician Compare for the MIPS program, making adjustments due to adoption of ICD-10, and addressing current issues around invalid and nonconforming data. Any changes adopted at this time are likely to be temporary and short-lived, confusing patients and increasing physician's already considerable administrative burden. In addition, PQRS data does not lend itself well to public reporting, as it was designed as a pay-for-reporting, not public reporting, program.

We are also concerned with CMS' ability to move forward given major problems with the underlying accuracy of the data posted on Physician Compare and CMS' inability to provide timely data and feedback to physicians. We do greatly appreciate the agency's efforts to date to improve the accuracy of the data. Unfortunately, problems continue to arise, such as the recent incident with invalid 2014 PQRS EHR data that affects a significant percentage of eligible professionals. Based on the AMA's calculations, we believe one-quarter to one-third of PQRS participants are affected. This invalid PQRS data underscores the challenges with the program at this time, and the fact that the physician data is not ready to be made publicly available through Physician Compares. CMS should dedicate its resources and efforts to ensuring that data can be captured and reported across varying electronic tools before publicly reporting more robust information on Physician Compare.

ICD-10 takes effect on October 1, 2015, but CMS has agreed to a transition period of flexibility in the level of specificity of reporting, to allow physicians and other providers to adjust to this wholesale change in the way they report diagnoses and procedures. There is great uncertainty as to how the conversion to

ICD-10 will affect the underlying benchmarks of reporting quality measures under PQRS, cost and quality composite measures and performance score under the VM, and compliance with MU.

Physician Compare will also become the major site for public information regarding performance under the MIPS program. The MIPS adjustments that begin in 2019 will likely be based upon performance in 2017. CMS has only just begun to solicit general input on its methodology for MIPS performance evaluations, and the actual methodology will be fleshed out in rulemaking for the 2017 Medicare Physician Fee Schedule. Physician Compare needs to be ready for these changes:

Major Changes Affecting Physician Compare	Effective Date	
CMS reported major issues with invalid 2014 PQRS data for many EPs.	August 2015	
ICD-10 implementation takes effect	October 1, 2015	
MACRA requires integrating public data release on physician services with Physician Compare	January 1, 2016	
Groups may do quality reporting via qualified clinical data registries (QCDRs)	January 1, 2016	
CMS must finalize the MIPS Measure Development Plan	May 1, 2016	
GAO report & recommendations due on reducing burden of quality measures of multiple payers	October 16, 2016	
2017 Physician Fee Schedule final rule will establish MIPS reporting period & requirements	November 2016	
VM applies to all physicians & physician groups	January 1, 2017	
Start of first MIPS performance period, with new reporting by "virtual groups"; CPI activities; and MU policies subject to change.	January 1, 2017	
Final patient relationship categories & codes for MIPS resource use are due	April 2017	
Final care episode & patient condition codes for MIPS resource use are due	November 2017	
End of physician feedback reports	December 31, 2017	
EPs must receive their MIPS adjustment factor at least 30 days in advance.	December 1, 2018	
MIPS adjustments replace PQRS, VMB, and MU, with new: performance evaluation & scoring; flexible category weights; "virtual groups" scored together; & extra bonus for "exceptional performers." EPs include physicians, dentists, podiatrists, optometrists, chiropractors, PAs, NPs, CNSs & CRNAs.	January 1, 2019	
MIPS resource use counts 10 percent & quality counts 40 percent.	2019	
MIPS resource use counts 15 percent & quality counts 35 percent.	2020	
MIPS scores must consider improvement in quality & resource use (optional for MU & CPI activities).	2020 & after	
MIPS resource use & quality each count 30 percent.	2021& after	
MIPS may expand to include social workers, psychologists, dietitians, nutritionists, PTs, OTs, speech pathologists & audiologists.	2021 & after	

Timing of Posting Measures

The AMA believes that CMS should allow at least three years of reporting a measure, prior to its being publicly posted on Physician Compare. CMS proposes to continue to make available for public reporting on Physician Compare all individual EP and group practice measures in the year following the year the measures are reported. For QCDR reporting, CMS proposes to continue to make available for public reporting on Physician Compare all individual EP-level PQRS QCDR and non-PQRS measure data

Andrew M. Slavitt September 8, 2015 Page 20

that have been collected for at least a full year, as well as new group practice level QCDR PQRS and non-PQRS measure data that have been collected for at least a full year.

The AMA supports allowing for at least three years of measure data collection prior to public reporting to allow for more robust and meaningful data to be collected on performance. This will allow physicians enough time to address any problems regarding how data is reported and captured provided that data has been validated and received without submission errors. One year of data represents a limited snapshot of performance, instead of a more meaningful trend over time.

Self-Nomination by QCDRs

Under the Proposed Rule, the QCDR would be required to declare during self-nomination if it plans to post data on its own website and allow Physician Compare to link to it or if the QCDR will provide the data to CMS to public report on Physician Compare. We support CMS' proposal for QCDRs to declare if they plan to post data on their own website and allow Physician Compare to link to it, or if the QCDR will provide the data to CMS to report on Physician Compare. Some QCDRs will want to publicly report on their own website but others, such as those who do not have the resources to create their own public report, may choose the Physician Compare option instead.

Physician Compare Benchmarking

CMS is proposing to adopt a new benchmark based upon the "Achievable Benchmark of Care" (ABCTM) to assign star ratings on Physician Compare. The ABC methodology might create achievable benchmarks and could potentially be superior to the current construct of arbitrary star ratings, and has been used in other performance improvement programs. **However, we cannot support the selection of a benchmark methodology at this time.** CMS should not adopt a benchmark for Physician Compare until the agency has (a) finalized and fully informed all EPs of the particularly methodology under which their performance will be scored for the MIPS program, and (b) proposed for public comment how the ABC methodology would be applied in the context of MIPS. In fact, the proposed ABC benchmark would be based on a "pared mean" of the best performers, while the performance threshold for the MIPS program is defined by statute as reflecting the mean or median performance of all EPs for a prior period. We are concerned physicians and other EPs will literally be held to two different sets of standards, potentially conflicting.

If CMS does choose to move forward, we would like to highlight some ambiguities that should be clarified, regarding implementation of the ABC methodology. The example CMS provides lacks sufficient detail in the context of the PQRS program. The example also does not include the adjusted performance mean (APM), but the developers of the methodology use an adjusted performance fraction (APF). It is also not clear how CMS will apply the ratings in conjunction with the benchmark. Will the stars be based on the 20 percent increments CMS currently utilizes for star ratings with a benchmark listed somewhere nearby? Or does CMS plan on applying the stars based on where performance falls in relation to benchmarks? The second method doesn't mean that 5 stars = 100 percent. Rather, the practices that fall above the benchmark could achieve the 5 star rating. Based upon the AMA's analysis of what was provided in the Proposed Rule, the majority of physicians will be rated somewhat consistently when comparing the current 5 star ratings with the ABC methodology, regardless of whether the APM or APF is included.

Analysis of Proposed Changes to Physician Compare

Current 5 Star Rating System

• Characteristics: (1) Uses true performance rates (unadjusted); (2) Does not include any samples of less than 20 patients; and (3) Stars are received in each 20 percent increment.

Eligible Professional	Denominator	Performance Score	Benchmark	Star Assigned
Physician A	10	N/A	N/A	N/A
Physician B	30	27%	N/A	**
Physician C	50	50%	N/A	***
Physician D	150	93%	N/A	****
Physician E	200	76%	N/A	****

ABC with Benchmarks Only

- Characteristics: (1) Uses true performance rates (unadjusted); (2) Benchmark is determined using the top-ranked eligible professionals (EPs) whose denominator represents at least 10 percent of the overall number of patients on which the measure was reported.
- Assumptions made: (1) CMS will continue to the policy of only including samples of 20 patients or more; (2) Stars are received in each 20 percent increment with the benchmark reported beside individual results.

Eligible Professional	Denominator	Performance Score	Benchmark	Star Assigned
Physician A	10	N/A	76%	N/A
Physician B	30	27%	76%	**
Physician C	50	50%	76%	***
Physician D	150	93%	76%	****
Physician E	200	76%	76%	****

If the stars are provided in increments based on the benchmark for that measure (indicating that five stars are those EPs who achieved the benchmark or higher), ratings would appear as follows:

Eligible Professional	Denominator	Performance Score	Benchmark	Star Assigned
Physician A	10	N/A	76%	N/A
Physician B	30	27%	76%	**
Physician C	50	50%	76%	****
Physician D	150	93%	76%	****
Physician E	200	76%	76%	****

If the adjustment is used, the AMA has identified one potential problem if a physician has a small reporting denominator with a high exclusion rate. We are not aware of how often this may happen but it can impact a performance score and subsequently associated stars. The articles CMS cites do not describe how the authors addressed the issue. It is possible that they did not encounter this since most of the calculations were at the practice level and small numbers may not have been an issue—or they did not include measures that used exclusions. Therefore, we request before CMS moves forward with finalizing policy, to first run a few simulations with the opportunity to comment with data from previous years and see whether it looks similar to the AMA's analysis.

The following table outlines how small reporting denominators with high exclusion rates could impact performance scores if adjusted:

Reporting Denominator	Numerator	Exclusions	Performance Score	APF Numerator	APF Denominator	ADF Performance Score
25	25	0	100.0%	26	27	96.3%
25	15	10	100.0%	16	17	94.1%
25	5	20	100.0%	6	7	85.7%
25	13	0	52.0%	14	27	51.9%
25	8	10	53.3%	9	17	52.9%
25	3	20	60.0%	4	7	57.1%
25	6	0	24.0%	7	27	25.9%
25	4	10	26.7%	5	17	29.4%
25	1	20	20.0%	2	7	28.6%
75	75	0	100.0%	76	77	98.7%
75	37	38	100.0%	38	39	97.4%
75	5	70	100.0%	6	7	85.7%
75	37	0	49.3%	38	77	49.4%
75	18	38	48.6%	19	39	48.7%
75	3	70	60.0%	4	7	57.1%
75	19	0	25.3%	20	77	26.0%
75	9	38	24.3%	10	39	25.6%
75	1	70	20.0%	2	7	28.6%

Check Mark for High Tier for the Value-Based Payment Modifier (VM)

We also believe including a green check mark on a profile page indicating a physician achieved one of the high tiering categories is misleading as a substantial number of physicians do not have sufficient data to qualify for a high tier category. For example, in 2012, 42 percent of groups with more than 25 practitioner did not receive a Quality and Resource Use Report (QRUR), primarily because CMS did not have enough data to calculate a score. Under this proposal, these groups would all be considered "average" even though CMS has no idea if they are actually good, bad, or "average." This will not be apparent to patients and lead to incorrect assumptions about physicians by the public. Additionally, the 2012 and 2013 Quality and Resource Use Reports (QRURs) show that EPs with a higher percentage of patients with multiple chronic conditions tend to receive lower ratings under the VM.

Linking Utilization Data to Physician Compare

The AMA has provided CMS with recommendations to improve the validity and accurateness of its Medicare Part B utilization data. Specifically, we have requested that physicians be allowed to submit corrections where the data is inaccurate or outdated; however, CMS has not yet permitted changes or established a process to correct the published information. Given this concern with the accuracy of the utilization information, we believe CMS should not link this data to the Physician Compare website. We believe doing so would be in violation of the Physician Compare statutory requirements that the Secretary include a process to assure the data is statistically valid and reliable and that physicians have a reasonable opportunity to review their individual results before they are made public. Linking to another web page without following these appropriate safeguards is simply skirting the rules and requirements of the Physician Compare web page.

We also continue to ask that CMS include a robust outline of the limitations of the utilization dataset before further publishing it or linking it to other information. These safeguards include highlighting that the utilization data may not be representative of a physician's entire population, are not risk-adjusted, the count and cost of services may be misleading, and that billed charges are not the same as payment to a physician.

Including Open Payments Data on Physician Compare

CMS also requested comment on whether individual physician Open Payment Program data should be available on Physician Compare. The AMA does not support the inclusion in Physician Compare of any data that have not been validated for accuracy by a covered recipient. Though the Open Payment Program was established to increase transparency in the financial interactions of physicians and manufacturers of drugs, devices, and medical devices, CMS has not implemented adequate measures to ensure the accuracy of the data submitted by the industry. Specifically, CMS has not required manufacturers to provide data they report to the government to physicians prior to submitting it to CMS, in order to resolve disputes. Furthermore, the agency does not require manufacturers to notify or alert physicians when a transfer of a covered item is subject to reporting. For the first reportable year of the Open Payments Program, CMS refrained from publicly releasing one-third of the data due to concerns about its accuracy. The agency never provided a clear explanation of the problems with the withheld data. More importantly, while the agency has indicated that physicians would have an opportunity, albeit very short, to review the submitted data before it is made public, the actual process for registering and disputing the reporting has been time consuming, confusing, and fraught with technical problems. As a result, only five percent of physicians have independently validated their Open Payments data. Only data that have been independently validated by physicians should be available on Physician Compare.

Acceptance of Medicare Advantage

CMS' proposal to include Medicare Advantage plan acceptance on the Physician Compare profile page is also concerning. While CMS has recently committed to improving the accuracy of MA provider directories in a timely fashion, this is an area where there has been a high degree of error.

Additional Operational Principles for Physician Compare

The AMA appreciates the modifications that CMS has made to improve the data and operability of Physician Compare, and we urge the Agency to consider the following operational principles in guiding further improvements and modifications.

Updating Demographic Data: The current disclaimer that it may take up to six months to correct information on Physician Compare is completely unacceptable, especially if CMS moves forward with expanding the website. We urge CMS to commit to updating data within four weeks of being notified.

Appeals Process and Preview Period: The AMA continues to urge CMS to implement a more robust appeals process for contesting Physician Compare information, and to expand the preview period for an EP to review their information beyond the current 30 days to 90 days. 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 widely notify EPs of the preview period for reviewing their public ratings. We anticipate potential problems and backlogs with obtaining reports, as CMS greatly expands all of its quality programs and moves to profile all EPs.

Ensuring Statistical Validity under ACA: As CMS itself noted in the Proposed Rule, section 10331(b) of the Social Security Act requires Physician Compare, to the extent practicable, to incorporate the following safeguards: "computer and data infrastructure and systems used to support valid, reliable and accurate reporting activities;" processes that ensure "that data made public are statistically valid, reliable, and accurate, including risk adjustment mechanisms used by the Secretary;" and processes that ensure "a robust and accurate portrayal of a physician's performance" as well as "appropriate attribution of care" among multiple physicians and other providers. These are the areas which we believe should be the priorities of Physician Compare as we approach the upcoming transition to the MIPS program for quality reporting.

Notice of Chosen Methodology: EPs and group practices should be afforded at least two years' advance notice before any benchmark methodology takes effect, to afford practices the opportunity to prepare and change workflows and implement a quality improvement strategy. The AMA also recommends that CMS distribute prototype reports to individual physicians and practices ahead of the methodology taking place. We envision this similar to the QRURs CMS distributed to practices ahead of the VM taking place.

Individual vs. Group Reporting: As noted above, section 10331 of the ACA requires any public reporting of performance information to be statistically valid and reliable. We believe that CMS should only continue to report at the group practice level and not at the individual EP level. The AMA continues to have serious concerns about the accuracy and validity of reporting information about individual physicians and other EPs, versus group practices, on Physician Compare. A likely foreseeable problem CMS will run into when moving from group level reporting to individual is having an adequate sample size to make a statistically valid comparison between physicians and practices. As noted above, CMS is already grappling with this issue under the VM program, where even among practices of 25 or more practitioners, more than 40 percent of practices did not have enough data calculate performance scores.

Star Ratings: The AMA supports efforts to make quality performance standards more comprehensible to patients, but we have serious concerns about star ratings and simple graphics, which can easily mislead

Andrew M. Slavitt September 8, 2015 Page 25

patients. Star ratings can impose artificial, arbitrary divisions between physicians with very minor differences in quality. Often the issues with accurately reporting measures are related to incorrectly coding or a physician's or vendor's inability to implement changes at the start of the reporting period. For instance, CMS only finalizes PQRS policy by November 1, leaving all parties about two months to implement changes and update workflows before the new performance year begins on January 1.

Minimum Patient Sample: The AMA is concerned with CMS' proposal to utilize a sample size of 20 patients for testing of performance measures because such a small sample size often has relatively low reliability. For the VM, CMS had to increase the All-Cause Readmission measure sample size from 20 to 200 and is now proposing to increase the sample size for the Medicare Spending Per Beneficiary measure from 20 to 100 episodes to increase reliability. Even with the higher thresholds, these measures achieved only a moderate reliability rating. So although the AMA supports an increase in the thresholds, we believe that any publicly reported data should be based on a larger sample in order to ensure that ratings reflect true differences in performance rather than random variation. We also would like to point out that 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, CMS should test individual measures by reporting mechanism and composites with a 20-patient attribution and provide an opportunity for the public to review and comment on the results to ensure they are reliable and valid.

Reporting Mechanisms: We are glad to see CMS accept the AMA's suggestion that comparison between EPs and/or group practices should only be based on the same mechanism which an EP or group practice used for reporting. For instance, if an EP participates in PQRS via claims, they should only be compared with other EPs who reported via claims. However, the AMA is also concerned with the accuracy of comparison of practices who report the same measure but through different EHR vendors. Current challenges with electronic quality measures (eCQMs) and associated electronic reporting mechanisms have led to widespread skepticism around the associated results, which is probably a significant barrier to widespread e-reporting. It is unknown whether required data elements for selected eCQMs can be efficiently and accurately gathered across EHR vendors and in the health care provider workflow. To diffuse this problem, there is a need for field testing to identify whether new and existing eCQMs and CMS' implementation guides produce valid outcomes across EHR vendors. CMS has also pointed out that results may vary across EHR systems and that no two EHRs report and calculate the results of eCQM uniformly. Therefore, CMS should hold off on posting EHR reported quality data until the mentioned challenges are resolved and the physician community feels comfortable with the results that come out of eCQMs. The AMA also strongly recommends that CMS publicly share the process and methodology for data validation to allow practices the opportunity to review and determine which reporting option to select.

Risk Adjustment: CMS should expand its risk adjustment methodology to incorporate race, income, and region type to avoid inaccurate conclusions about quality and performance measurement that could unfairly penalize physicians who treat a number of socio-disadvantaged patients. While case mix may not play a role in certain structure and process measures, risk adjustment must occur for measures that are not fully within the control of the measured provider(s). When factors such as patients' socioeconomic and sociodemographic situations are ignored, this can lead to the erroneous conclusion that physicians and practices who serve low-income patients provide lower quality care than those serving high-income patients. The differences in these scores may actually be due to differences in patient mix, rather than in the quality of care provided. Holding physicians accountable for different outcomes, without recognizing the patient factors that contribute to those differences, unfairly penalizes them. CMS' contractor,

Andrew M. Slavitt September 8, 2015 Page 26

Acumen, encountered this problem when testing the Diabetes Mellitus measure composite now part of the GPRO web-interface. Acumen tested the DM composite with expanded risk adjustment including demographic and regional characteristics (i.e., race, region, region type, household income, and home value), and the results differed from the original performance assessment.

Stakeholder Input and Communications: It would be beneficial and enhance the transparency of Physician Compare for CMS to allow public comment on the deliberations of the Physician Compare Technical Expert Panel (TEP). Currently, the public has no opportunity to participate and comment on the TEP's recommendations. CMS should also engage regularly with physicians and other stakeholders. With Hospital Compare, CMS conducts periodic calls with affected stakeholders, discussing plans for expansion and notifying them in advance of the release of information. The AMA would be happy to convene something similar with the specialty societies and CMS.

D. Physician Quality Reporting System (PQRS)

The AMA urges CMS to reduce the reporting requirements to three measures and eliminate the requirement of reporting on one cross-cutting measure, to encourage more EPs to participate in PQRS and to reset the reporting burden to a more reasonable level.

The AMA is very pleased to see that CMS has not proposed substantial changes to the 2016 PQRS program. For the first time in three years, CMS has instituted stability by not changing the program requirements and by maintaining all of the reporting options for 2016 (claims, EHR, registry, qualified clinical data registry, group practice reporting option, and GPRO web-interface). For the last three program years, the AMA has urged CMS to avoid continual increases in the requirements while physicians are still struggling to comply with the current requirements. We continue to hear from physicians that the complexity of the program—such as the number of measures a physician must satisfy and CMS' continued direction to remove measures it considers as "topped out"—poses significant challenges for physicians to comply and meaningfully participate. Monitoring these changes in the context of competing and compounding demands physicians face, such as Meaningful Use (MU), the Value Modifier (VM) and ICD-10, and now transitioning to APMs and the MIPS program, requires an overwhelming layer of administrative burden that is costly and resource intensive. For some physicians, this is simply not feasible and leads to the continually low PQRS participation rates. According to the last year of data that CMS has provided the public on PQRS participation, only 469,755 EPs successfully participated in 2013, which equates to an approximately 38 percent success rate with the program, while 51 percent of eligible professionals participated.

In addition, CMS repeatedly insists on arbitrarily tying PQRS requirements to three national quality strategy (NQS) domains, without supporting evidence to demonstrate that this leads to improved care. In fact, this may actually be hindering quality improvement efforts, by diverting attention away from focusing on areas that have a greater impact and are more tailored to meet the needs of a physician's patient panel. A recent Commonwealth Fund survey found that half of the nation's primary care physicians view the increased use of quality-of-care metrics as potentially troubling for patient care.¹ Therefore, we urge CMS to take a new look at the construct of the PQRS program, especially as we transition from the PQRS program to the MIPS.

¹ The Commonwealth Fund and The Kaiser Family Foundation, Primary Care Providers' Views of Recent Trends in Health Care Delivery and Payment, August 2015. http://www.commonwealthfund.org/publications/issue-briefs/2015/aug/primary-care-providers-views-delivery-payment. Accessed 08-26-15.

We also continue to remain concerned with CMS' direction of eliminating many of the claims based measures when claims based reporting continues to be the most popular reporting option and one that small physician practices depend upon. We believe it is premature and shortsighted for CMS to reduce the number of measures that may be reported through claims when electronic quality reporting has come to pose a significant challenge for EHR vendors and for CMS. Due to the significant number of errors with submitting and calculating 2014 eCQMs, CMS has determined that the data are not valid or reliable and must automatically deem over 80,000 physicians as successful for purposes of avoiding a payment adjustment in 2016 or receiving a 2014 incentive. CMS has indicated for future years that if the data are submitted with errors by a vendor on behalf of a physician, that CMS will potentially not accept it, thus leaving a physician on the hook to receive a penalty. We are greatly concerned with this approach when physicians make the good faith effort to comply and must utilize certified electronic health record technology (CEHRT). Furthermore, this points to a larger problem with the certification program and the need for CEHRT to more closely address quality measurement data capture and reporting.

It is important to keep in mind that if physicians are not considered to successfully report under PQRS, MU, and the VM for the 2016 performance period, then in 2018 they are potentially subject to a total penalties of ten percent or even higher, plus an additional two percent adjustment due to sequestration.

Requirements for the PQRS Reporting Mechanisms

One of CMS' goals is to report data on race, ethnicity, sex, primary language, and disability status. A necessary step toward fulfilling this mission is the collection and reporting of quality data stratified by these five data elements. CMS intends to require the collection of the data elements within each of the PQRS reporting mechanisms. The agency is not proposing in this Proposed Rule to require the collection of these data elements, but is seeking comment in regards to the obstacles that providers and vendors may face in collecting and reporting these attributes. CMS also seeks comment on whether there is a preference for a phased in-approach. The AMA and Physician Consortium for Performance Improvement (PCPI) have historically supported and continue to support collecting and reporting demographic data along with quality measure data. This allows for the stratifying of quality measure results to evaluate differences in measure scores that are due to disparities or other relevant differences. The proposed set of demographic data provides a basic set of data elements to form the foundation of risk stratification efforts. In order for such data to be used and analyzed, it has to be collected for a substantial period of time to be significant.

The AMA also believes these data are essential for identifying disparities and initiating subsequent quality improvement activities. However, education and training will be required to ensure that cultural bias does not influence the collection of these data. For example, race and ethnicity information entered into a health information technology (IT) or registration system should be reported by the patient, rather than by a member of the practice or hospital registration team making an assumption of a patient's race or ethnicity.

Per CMS' specifications, AMA-PCPI developed measures, as well as eCQMs in federal programs, include supplemental data elements of race, ethnicity, administrative sex and payer. The code sets used to capture administrative sex and payers are "ONC Administrative Sex" and "Source of Payment Typology," respectively. Race and ethnicity data elements are specified using the Centers for Disease Control and Prevention (CDC) Race and Ethnicity codes, which are the standard recommended by the Health Information Technology Standards Committee in 2011. **The AMA supports the expansion of**

these code sets to allow for greater granularity, as proposed in the Office of the National Coordinator for Health Information Technology (ONC) 2015 Edition HIT Certification Criteria and urges CMS to make these categories consistent across all programs. In our experience, the collection of demographic data has not been problematic, as it is generally part of a standard workflow and is an MU objective. However, this data may not be captured in a uniform fashion across sites. Standardization in the collection of these elements will be essential to ensure meaningful comparisons across providers and sites.

Regarding collection and reporting of disability status, we do anticipate challenges in consistent definition and collection of this data element. As discussed in the MU rule, "Many commenters agreed with the need to incorporate disability status in EHR technology. However, it was also clear that several of these commenters varied in their definition of disability with interpretations that ranged from physical, mental, occupational, and economic disability ..." We support the standardization and expansion of disability codes to reflect more granularity and encourage harmonization of code sets across all CMS programs. CMS should look to EPs and any other vendors for additional insight. The National Quality Registry Network (NQRN®) is uniquely positioned to serve as the convener of these essential stakeholders to achieve consensus around the definitional and operational challenges associated with the collection of these demographic data, including disability status.

Furthermore, the AMA supports streamlined collection of these demographic data and encourages the PQRS program to be streamlined with requirements put forth in the ONC's 2015 Edition Health IT Certification Criteria and with MU program requirements. Streamlining requirements allows for meaningful collection of demographic data and also eases reporting burden moving forward as the MACRA legislation is rolled out and the MIPS program is implemented in 2019. Collecting this information in a standardized fashion will minimize the burden and ensure uniform capture of information.

In terms of a phased approach, using the assumption that the demographic information would be captured electronically, we do not anticipate that the additional collection of one or two data elements would require an additional burden that would outweigh the benefit of having access to that information. We do not think that a phased approach is necessary in this case, assuming all data elements are captured electronically and harmonization across all programs support the needed level of granularity. Collecting this information for one or two measures could be more complicated than collecting the information for all measures.

We do support a timeline that adequately gives EPs, CMS and health IT vendors an opportunity to build the elements into their workflow, perform testing to ensure that the data collected are valid and reliable, and that there is agreement on a single standard for reporting (Office of Management and Budget (OMB) versus CDC categories) and sufficient time to educate the community of EHR users. The OMB uses OMB categories plus a separate category for "other." The CDC value set captured as a supplemental data element is aligned with the OMB categories. Therefore, we suggest that CMS use "CDC" as this is how the supplemental data elements are recommended from the workgroup that developed them.

Proposed Changes to the Requirements for the QCDR

CMS proposed adding a new qualified clinical data registry (QCDR) option, starting in 2014, whereby EPs may report the measures used by their QCDR, instead of those on the PQRS measure list. Per MACRA, CMS is required to create an option for EPs participating in the Group Practice Reporting Option (GPRO) to report quality measures via a QCDR. In accordance with this mandate, CMS proposes that QCDRs have the ability to submit quality measure data for group practices, in addition to individuals, starting in 2016. QCDRs often offer physicians a much more relevant way of participating in PQRS, and we support efforts to make this alternative reporting mechanism as widely available as possible. However, we request that CMS give QCDRs the flexibility to determine whether group practice-level reporting is even relevant and appropriate for the registry's target population and for the registry to determine if they are prepared to collect and report group practice level data to CMS. Group practice-level reporting should be an option for QCDRs and not a mandate.

Data Validation Requirements

CMS proposes to require several new items to a QCDR's validation strategy for 2016. While they appear reasonable, we defer to entities that act as a steward of a QCDR, as they are the most appropriate to comment. As a general matter, EPs and group practices should not incur liability for a negative payment adjustment based upon problems with vendor performance, so long as the vendor utilized has been deemed by CMS. We would also like to highlight a concern we have heard from physicians and QCDR stewards about insufficient timelines to respond and comply with audits of the data requested by CMS and its contractors. We have heard the turnaround time is too short given the data often need to be repackaged in a way to comply with the request and thus cannot be turned over instantly. Therefore, CMS and its audit contractors need to set clear and realistic timelines for responding to such requests.

<u>Proposed Criteria for Satisfactory Reporting by Individual EPs for the 2018 PQRS Payment Adjustment</u>

As noted above, the AMA strongly supports CMS' proposal to refrain from making substantial changes to the 2016 PQRS program. We are particularly pleased that CMS continues to maintain the popular and widely-used claims-based reporting option. However, we remain concerned that the requirements are overly stringent and there is a lack of sufficient measures by reporting modality, which are hindering physician participation and leading to the feeling that the PQRS program is a check-the-box exercise.

We are also concerned with CMS' continued requirement of reporting on a "cross-cutting" measure for individual physicians who participate in PQRS via claims or qualified registry and see one Medicare patient in a face-to-face encounter. Many specialties do not find the list of measures that are classified as "cross-cutting" relevant or applicable to the care they provide. Also, for certain specialties, such as radiologists and pathologists, CMS' definition of face-to-face encounter does not take into consideration the type of care they provide. For instance, pathologists have a small number of procedural encounters such as fine needle aspirations (FNAs) and bone marrow biopsies that result in face-to-face encounters and make them eligible to report a cross-cutting measure. However, none of the cross-cutting measures are applicable to pathologists. Therefore, the AMA asks CMS to define face-to-face encounters using only the codes in the denominator of the cross-cutting measures. It is very confusing to include codes that do not appear in the cross-cutting measures as there is no way to report on the cross-cutting measures even if a physician bills certain CPT codes. As an alternative, we request for CMS to work with the

AMA and the affected specialties to develop an appropriate definition that takes into consideration physicians who do not treat patients in the traditional sense of face-to-face encounters.

Proposed Criteria for Satisfactory Reporting by Group Practices Participating in the GPRO

CMS does not propose major changes to the GPRO in 2016, except for proposing to require practices of 25 or more who report through the GPRO web-interface to have to report on the CG-CAHPS (Clinician and Group Consumer Assessment of Healthcare Providers and Systems) survey through a certified survey vendor. For the 2015 reporting year:

- Only groups of 100 or more who are registered in GPRO are required to report CG-"CAHPS for PQRS survey."
- Groups of two to 99 could elect the "CAHPS for PQRS survey" to supplement some of the PQRS measures.

The AMA opposes the proposed 2016 requirement that groups of 25 or more who elect to participate through the GPRO web-interface have to report measures via the "CAHPS for PQRS survey" using a certified survey vendor. We also continue to oppose the requirement for practices of 100 or more. There is a growing body of evidence, as highlighted in a recent Hastings Center Report, that patient experience surveys can have repercussions that impede rather than enhance the quality of care. While patient-satisfaction surveys have a valuable place in evaluating health care, "there are significant dangers in tying them to publicly reported ratings and accountability, as they often depend more on patient perceptions that are subject to potential manipulation than on good medicine," as highlighted in the Hastings Report. The AMA understands there is a difference between patient experience and satisfaction, but the definition and difference are not well understood. Therefore, the AMA has significant concerns with the level of measurement for assessing patient experience in PQRS and publicly reporting the information on Physician Compare.

Furthermore, mandating the "CAHPS for PQRS survey" for groups of 25 or more essentially takes away one viable reporting option for smaller, multispecialty practices. It also creates uncertainty in terms of the mechanism a group practice should sign up for with CMS, as the GPRO registration deadline occurs prior to a practice being notified as to whether they have an adequate sample to report CAHPS. CMS is proposing to allow groups that have registered in the GPRO to report via an alternate option and still be successful should their chosen GPRO reporting mechanism become unavailable. However, this does not provide practices back the time and resources expended to secure a certified survey vendor. CMS needs to provide groups with the certainty that they can report the "CAHPS for PQRS survey" in a statically valid manner before requiring them to expend resources to potentially meet this requirement. In addition, the cost to implement and administer the CAHPS may be prohibitive for many small practices, especially in the light of all the other mandates practices must comply with, such as MU. If CMS moves forward, at the very least CMS needs to provide more vendor transparency regarding the cost of administering the survey and make the survey optional.

The AMA also urges CMS to provide better outreach and disclosure regarding the cost to administer the "CAHPS for PQRS" survey through a CMS certified vendor, as well as the length of the survey. The "CAHPS for PQRS" survey currently has 80 questions and is 12 pages long without a cover letter,

² Alexandra Junewicz and Stuart J. Youngner, "Patient-Satisfaction Surveys on a Scale of 0 to 10: Improving Health Care, or Leading It Astray?" Hastings Center Report 45, no. 3 (2015): 43-51. DOI: 10.1002/hast.453.

compared with the CG-CAHPS (Clinician & Group Consumer Assessment of Healthcare Providers & Systems) survey instrument which has only 31 core questions and the HCAHPS survey (for hospitals) which has only 32 core questions. In addition, the decision tree used to direct patients through the "CAHPS for PQRS" survey is confusing and discourages them from completing the survey. CMS also has done very little to educate providers and groups on the major differences between each CAHPS instrument; the purpose of the "CAHPS for PQRS" survey in defining quality; the methodology used to determine the patients who are eligible to receive the survey; and how the results of the survey would impact reimbursement. CMS needs to do more to educate groups and providers of how this survey fits into the overall rubric of federal quality reporting.

Proposed 2016 PQRS Quality Measures

New Individual Quality Measures Proposed for 2016

The AMA has concerns with CMS classifying the following measure as registry reportable:

Cognitive Impairment Assessment Among At-Risk Older Adults: Percentage of patients age 80 years or older at the start of the measurement period with documentation in the electronic health record at least once during the measurement period of (1) results from a standardized cognitive impairment assessment tool or (2) a patient or informant interview.

This measure was developed as a de novo EHR measure and the AMA does not recommend that the specification be adapted for PQRS registry reporting. Should CMS wish to finalize this measure for inclusion in the 2016 PQRS program, we recommend it only be included as a measure for EHR reporting.

Measures Proposed for Removal Beginning in 2016

We recognize CMS' desire to raise the bar on quality reporting, but believe it is premature and short-sighted to continue to remove measures considered "topped out" when the reporting rates within PQRS are quite low. We support the removal of measures when the clinical evidence has changed, but we are concerned with the growing gap that has been created in the measure portfolio due to the number of measures CMS removed in 2015 and slated for removal in 2016. Going forward, we urge CMS to provide 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. Under the current process for incorporating new measures into physician quality programs, CMS requires a measure developer to submit a measure almost two years prior to the start of the program year. With the EHR Incentive program and for use as an eCQM, the delay is unspecified since CMS has not updated the list of quality measures since it finalized the Stage 2 Meaningful Use rule. Even then it was minimally updated. CMS has also stated they have no plans to update the MU program with new quality measures, until 2017 at the earliest. Therefore, CMS must be realistic in setting goals for its program and consider its operating cycle, which causes a huge delay in incorporating new measures into programs.

We once again request that CMS provide measure owners with more detailed analysis of the use of their measures so they can work to develop the next generation of measures and/or improve performance with its measures. Aside from what is published in the PQRS Experience Report (last released for the 2013 program) and any information a measure owner might request from CMS on specific measures for the purposes of submissions to the NQF, measure owners are not provided any more detailed information about the use of their measures in the PQRS program. The Experience Report also does not provide

Andrew M. Slavitt September 8, 2015 Page 32

measure stewards with enough level of detail that might be helpful to determine the utilization and usefulness of their measures. Therefore, we once again request for CMS to provide stewards with information on average performance rate, standard deviation, quintiles, etc., at a minimum.

For additional AMA comments on some of the individual measures that are listed in CMS Tables 22 through 29D, please see Appendices A-K.

Informal Review

The AMA continues to remain concerned with the length of time to file a PQRS Informal Review. We believe the 30-day timeline, upon the release of PQRS Feedback Reports is too short. We urge CMS to extend the timeline from 30 to 90 days upon the release of the PQRS Feedback Reports. The process for accessing a PQRS Feedback Report is extremely cumbersome and historically been rife with problems. For instance, with the 2014 interim PQRS Feedback Reports, CMS has had to take them offline several times, lasting longer than 30 days. Often it takes an EP or group practice 30 days just 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 also urge CMS to extend the deadline as there are instances where CMS defaults to the Informal Review process when CMS has issues with data received from a physician or group practice data. For example in 2014, there were several issues related to practices' GPRO registrations where group practices and individual physicians were unable to submit their PQRS data successfully. While we appreciated CMS looking into the problem upon the close of the 2014 submission period, CMS opted to a default resolution of requiring the affected practices to file an Informal Review when the review period opens up in 2015. However, the problem primarily stems from the fact that a physician or practice cannot change their PQRS registration.

We are also concerned about the numerous issues with the 2014 EHR data that many EHR vendors submitted on behalf of physicians. CMS has indicated for future program years that CMS may not accept the bad data and automatically default to deeming a physician as successful for meeting PQRS. If CMS changes its stance in 2015 and in future years, a significant number of physicians would have to potentially file an Informal Review.

Unfortunately, given the linked nature between PQRS, the VM, QRURs, and public reporting on Physician Compare, filing an informal review may have downstream repercussions. Many of the scenarios are honest mistakes and physicians are making the good faith effort to participate in the PQRS program successfully, but now may be deemed unsuccessful and/or poor performers when that truly is not the case. Under current policy, if a practice or physician files an Informal Review, their PQRS information within the VM is considered "average." Classifying a practice or physician as "average" may become problematic if a practice is considered high cost or low quality for purposes of the claims based VM measures. If the practice is high cost or low quality and deemed "average" on PQRS, they may be subject to a VM penalty. This also raises the question as to whether practices will also have to file a separate Informal Review for the VM. If that is the case, there are several outstanding questions and issues to consider:

 CMS can take up to 6 months to respond back to a PQRS appeal. It is quite possible by the time CMS gets back to a physician or practice as deemed successful in PQRS the VM Informal

- Review period would have closed. Therefore, there is a need for an extended VM Informal Review period too, especially if a practice must file a separate VM Informal Review.
- CMS has stated that if there is inadequate PQRS information or no PQRS data, the physician will
 have an incomplete QRUR. Does CMS have plans to re-issue a QRUR for the physician or
 practice with the updated information? If not, this defeats the purpose of physicians having
 access to detailed information to improve and coordinate the care they provide.

Furthermore, we also urge CMS to allow EPs and group practices to contest their PQRS payment adjustment if they believe there were calculation errors due to the transition to ICD-10. It is more than likely, given the 2014 PQRS EHR data issue around calculation and reporting, that there will be errors by CMS and third-party vendors due to the transition to ICD-10.

E. eCQM and Certification Criteria and EHR Incentive Program—CPC Initiative and Medicare MU Aligned Reporting

While CMS does not explicitly address alignment between satisfactory PQRS and MU quality requirements, the AMA would like to once again highlight an ongoing concern we have in regards to vendors' ability to meet the growing complexity of quality measures, especially as MIPS and APMs are implemented. We already know CMS and the EHR vendors are struggling to adhere to standards related to the capture and reporting of process measures that have been in place for several years. As we move away from strictly process measures to outcomes, resource use, patient reported and appropriate use measures, there needs to be an administrative process in place to ensure that vendors update their systems to incorporate new data elements, as well as to ensure that eCQMs can be exchanged, captured and transmitted within the EHR, as we explain in more detailed below in regards to eCQM and certification. Therefore, we are concerned with CMS' proposal and indication in the EHR Incentive Program Stage 3 Proposed Rule to move away from attestation of CQMs to electronic reporting by 2018. We urge CMS not to move forward with its proposal until the health IT infrastructure includes the elements or addresses the problems indicated below:

- Standardized clinical data terminologies to allow information in the EHRs/registries to be exchanged and captured seamlessly;
- Developed standards to appropriately capture electronic quality measures within the EHR
- Sufficient CMS infrastructure to accept electronic transmission of measures (the only way for CMS to accept eCQMs now is through electronic generation of files);
- Module certification for registries to report CQMs; and
- Ensuring CQMs are part of the MU program and included by vendors.

We are also concerned with physicians' ability to satisfy QCDR participation to meet MU quality requirements, as well as the proposed registry requirement in the EHR Incentive Program MU 2015-2017 Modification and Stage 3 Proposed Rules. Currently, if a physician would like to receive credit for participation within a QCDR for MU quality, their QCDR must be certified and the measures must be part of the eCQM measure list. However, as we pointed out earlier in our comments, CMS has not updated the eCQM list for years and stated in the Stage 3 proposed rule that CMS has no intention to update the eCQM measure list until 2017 with no indication what year it would take effect. The more meaningful outcomes oriented measures are often reported through a QCDR and cannot always be captured within the EHR due to the lack of EHR functionality and interoperability. Therefore, we urge CMS to deem a physician who is participating in a QCDR as satisfying MU quality requirements.

Andrew M. Slavitt September 8, 2015 Page 34

Actively engaging with a QCDR is a form of quality improvement that should be sufficient to satisfy quality reporting without requiring duplication of efforts.

In addition, the 2015 CEHRT proposed rule does not include certification standards for connecting EHRs with clinical registries. The rule only addresses standards with EHRs and public health entities. We note, however, that the solution is not to require QCDRs to employ or use CEHRT. Connecting a registry with CEHRT is cost prohibitive. Many EHR vendors have not yet achieved interoperability with these systems, or outright refuse to connect or include all of the relevant measures given their focus on implementing MU requirements. Essentially, vendors do not have to be accountable to meet the connectivity between QCDRs and EHRs, yet physicians and patients must be assured that the necessary tools are available to support and assist with care.

eCQM and Certification Criteria

We appreciate CMS' attempt to lessen the reporting burden on physicians by proposing to require technology to be certified to the Quality Reporting Document Architecture (QRDA) Category I and III standards and the optional CMS "form and manner" guidance. While this is intended for future health IT seeking the 2015 Edition of CEHRT, we are concerned with the continued variances in implementation guides (IGs) between QRDA I & III, consolidated clinical document architecture (C-CDA), and CMS' form and manner requirements.

We are aware that EHR vendors who wish to support both QRDA and C-CDA standards must establish concurrent technical methods to accommodate differences between the way patient data are managed when applied to the QRDA for CMS quality reporting and the C-CDA standard for data exchange between physicians. Part of the issue can be attributed to the variability between the timing of Health Level Seven (HL7) balloting for QRDA I & III, C-CDA, and CMS' form and manner guidance updates. We understand that the process of update publication, balloting, and comment resolution is necessary for the right consensus among standards development organization members. This process can be lengthy and serves to improve the draft standard over time. However, vendors must support data exchange with a variety of health IT products using the C-CDA draft standard as part of the CEHRT requirement. There are already well-documented issues with variability between vendors implementing C-CDA IG (e.g., for things like summaries of care) and the resulting lack of functional interoperability we see today. In addition, we feel it is necessary to point out that there is also significant concern with the effort to support CMS' form and manner requirements in addition to HL7's QRDA IG and the resulting data discrepancies that may lead to patient safety issues.

For vendors to support data exchange and CMS quality reporting they must often rely on CMS' IG to explain methods and workarounds so that data may be bifurcated for both purposes. However, we have heard that this fork in the data pathway may not always be correctly reconciled. EHRs may need to report quality data in the format that CMS stipulates for reporting and in a separate format for care summaries and exchange. However, the difference between C-CDA conformance and CMS' QRDA IG means data adjusted to comply with the CMS version of the QRDA report is less likely to be properly structured in the C-CDA and may not be present in routine transfers of clinical care. As an example, clinically significant reasons for an exception in a patient's treatment should be available to other providers also caring for that patient. However, this information may not come across if the original data are manipulated for QRDA formatting. If the data are managed by the EHR in different ways to support two different formats, the EHR may be reported to CMS correctly, but C-CDA conformant summaries of care sent to other physicians may not include the exception reasoning. Thus, other

physicians may not be aware of the exception and might mistakenly and incorrectly treat the patient without knowing why the referring physician avoided that treatment in the first place. Requiring C-CDA, QRDA, and CMS' form and manner conformance is excessive for vendors and variations in IGs means that information has to be modeled differently for reporting and direct patient care. While CMS' intent maybe to simplify reporting, the proposed approach could lead to patient safety issues. We therefore recommend that CMS and HL7 should align standards before further programmatic requirements are finalized. We recommend that CMS embrace the spirit of interoperability and only establish requirements that both QRDA and C-CDAs can handle without complex IGs or workarounds. We further recommend that ONC's health IT certification process expressly test for tight conformance to any standard required by CMS.

F. Potential Expansion of the CPC Initiative

The AMA strongly supports giving primary care physicians the flexibility to improve patient care while lowering Medicare spending through APMs such as the CPC initiative. The AMA recommends that as CMS considers potential expansion of this model, it should seek to: reduce administrative burdens associated with the current model; offer an expanded array of model designs with increased physician flexibility to redesign the delivery of primary care services; link cost accountability to costs that primary care physicians can influence; and make it clear that all of the CPC participants in such an expansion are participating in an eligible APM as defined in the MACRA.

The AMA is pleased to respond to the CMS request for comments on potential expansion of the CPC initiative. We have heard from a number of physician participants in this model that it has allowed them to substantially improve their patients' care, and that there are features of the model that should be adopted more widely throughout the health care system.

At the same time, concerns have been raised that this model is still largely fee-for-service and, as such, physicians are limited in the degree of innovation they can implement within the model. In addition, requirements for physicians participating in the model to provide five comprehensive primary care functions, demonstrate progress through nine annual Milestones, and report on nine of 13 eCQMs can impose a heavy administrative burden on practices. This is particularly the case for small and independent practices, which lack resources to invest in the practice transformation needed to meet CPC requirements.

In addition, there are serious problems with the reporting of eCQM data through the form and manner CMS has specified for CPCI sites. In order to comply, participants must report eCQMs through the group reporting option and standard (QRDA III) and through a certified EHR. QRDA III is the standard for the CPCI sites that vendors must use to submit data to CMS. However, the functionality of eCQM data submission is not part of CEHRT, as CEHRT does not address the capture or reporting of eCQM data (at the individual or group level), nor is group reporting a requirement for the MU program. As a result of this fundamental disconnect, there were significant errors with the 2014 eCQM data that vendors submitted on behalf of CPCI participants. In fact, 93 percent of the data submitted through the QRDA III standard was recently determined to be unreliable by CMS.³ Furthermore, due to the requirement falling outside of MU and CEHRT, practices must separately obtain and pay for this functionality, either by purchasing this as an add-on from their vendor, or from a third party, so the participants can comply with

³ Centers for Medicare & Medicaid Services. Electronic Health Record Vendor Summit. Presentation August 20, 2015, Windsor Mill, MD 21244.

the CPCI program. Consequently, this results in additional costs. For a more detailed explanation on the issues around eCQM reporting and CEHRT, see the preceding section of these comments.

As CMS weighs potential expansion of the CPC initiative, current participants in the model face an uncertain future. CMS should make clear that the current model will be extended as it considers future expansion. If the CPC model is to be expanded with new practices, CMS should sustain the current enhanced payment model to allow newly participating practices to invest in their primary care transformation efforts. As there is currently no plan in place for how existing CPC practices will carry on their care management funding beyond year four of the CPC Initiative, CMS should act quickly to clarify that this payment model will be extended indefinitely to assure current participants they will continue to be supported in the benefits they provide to patients and the substantial changes they have made to their practices. CMS should also make it clear that participants in an expanded CPC model will qualify for the annual five percent lump-sum payments that will be available under MACRA beginning with services furnished in 2019.

Finally, it is inappropriate to demand that primary care practices reduce the total cost of care for their patients or for the patients in an entire state or region in order to maintain adequate payment levels for the services they delivery to their patients. Payments to physicians for services that patients need should not be tied to "shared savings" and payment models which require physicians to generate savings in order to receive adequate payment place both patients and physician practices at risk. Well-designed APMs should provide adequate financial support for appropriate care and ask physicians to take accountability for avoiding both overuse and underuse of appropriate treatment.

PROBLEMS WITH HOW "SHARED SAVINGS" PAYMENT MODELS FUNCTION	HOW DESIRABLE ALTERNATIVE PAYMENT MODELS SHOULD OPERATE
 Physician practices only receive higher payment for improved care management if they can reduce total spending. 	 Physician practices should receive adequate payment to cover the costs of high-value patient services.
 Physician practices delivering appropriate care receive little or no additional revenue to support high-value services and may be forced out of business. 	 Physician practices delivering appropriate care are able to continue operating and showing other practices what is possible from high performance.
 Physician practices that have been delivering unnecessary services or failing to avoid complications can receive large bonuses that may exceed what is needed for high-value care. 	Physician practices that have been delivering unnecessary services or failing to avoid complications must improve care in order to receive higher payments.
 Physician practices could achieve savings and bonus payments by stinting on care as well as by reducing overuse and complications. 	Patients are protected because any savings are generated by delivery of appropriate care.
 Physician practices are placed at financial risk for costs they cannot control and for random variation in spending. 	Physician practices are only accountable for services and costs they can control.

Offer Multiple Models

In contrast to the CPC initiative, the Bundled Payments for Care Initiative offers multiple models from which applicants may choose and a variety of procedures or conditions on which they may focus. As CMS considers CPC expansion, it should likewise expand the models available to participating practices. As discussed in the AMA comments on advanced primary care in March, one CPC alternative model would be the Patient-Centered Primary Care (PCPC) payment system developed by a group of primary care physicians, specialists, employers, unions, and health plans in West Michigan with assistance from the Center for Healthcare Quality and Payment Reform. In this model, a primary care practice could elect to be paid under the PCPC system rather than the current system. The PCPC payment system has two components: a monthly "Core Primary Care Services Payment" for providing preventive services and chronic disease management, as well as service-based payments for other services. For any group of patients who are enrolled and paid for under the PCPC payment system, a primary care practice could expect to see at least 50 percent of its revenues coming from the monthly Core Primary Care Services Payment, significantly more than is provided under the current CPC monthly payment.

There are four different levels of the Core Primary Care Services Payment based on whether the patient has one of four chronic diseases (asthma, congestive heart failure, COPD, or diabetes) or significant risk factors. A primary care practice receiving the Core Primary Care Services Payment would commit to deliver high-quality care to patients as cost-effectively as possible, and the payment amount would be increased or decreased based on the practice's performance on quality and resource use measures. A PCPC Practice would be paid additional fees beyond the Core Primary Care Services Payment and patients would provide some cost-sharing for office visits for acute issues, tests and procedures performed in the office, and office visits for non-enrolled patients.

A third primary care model was recently presented at the Aspen Ideas Festival and has been developed by Iora Health. Under this model, primary care practices receive a per-patient payment for comprehensive primary care and do not take any fee-for-service payment. Participants in the Iora model indicate that it has allowed them to transition to a true population health approach to patient care in which physicians can focus on improving their patients' health and keeping them "out of trouble." Moreover, they have the flexibility to provide the most appropriate care (preventive, acute, chronic) in the most appropriate setting (office, home, hospital) via the most appropriate means (in-person, telephone, email) without having to worry about whether they will get a payment for each service they provide. A model like this would allow physicians to focus on important services which are not currently payable under the Medicare physician fee schedule, such as population health management, patient self-management support, care coordination and compacts with specialists, and quality improvement efforts.

Focus on Costs that Physicians Can Influence or Control

If CMS proposes expansion of the CPC initiative, it should not tie payments to savings the practices achieve. Primary care practices that are managing their patients' care effectively have already achieved "savings" for Medicare and should not be forced to choose between denying services to patients in order to achieve additional savings and losing the revenues they need to support their practices. Moreover, practices should be accountable for the costs associated only with their own patients, and they should not have their payments based on the performance of primary care practices in other parts of a region or state. Evaluation of the CPC model should show CMS where the practices have been successful in controlling

Andrew M. Slavitt September 8, 2015 Page 38

costs, such as avoiding ambulatory care sensitive hospital admissions and controlling spending on patients with certain conditions like diabetes, asthma, or urinary tract infections. CMS can then require that payments to practices under an expanded CPC initiative focus on achieving and maintaining feasible levels of avoidable admissions and complications for the patients cared for by the CPC practices, instead of expecting primary care physicians to take accountability for the total cost of care for their patients or the patients in an entire region or state.

Developing more targeted means of measuring CPC participant efforts to control Medicare spending would allow CPC expansion to occur on a voluntary basis throughout the country. Availability of models like the CPC initiative will be important for the Secretary's goals for alternative payment models and the goals of the MACRA legislation to be realized. Patient-centered medical home models and episode bundled payment models should be able to coexist within an accountable care organization (ACO). There is no need for different models to be exclusively available in a community, a state, or even a practice. For example, patients in an ACO should be able to benefit both from better quality and lower per-episode costs due to a bundled payment program for joint replacement as well as from better non-surgical management of hip and knee osteoarthritis provided through a CPC practice.

Other Issues

Reports from physicians participating in the CPC model indicate that data sharing with practices needs to be significantly improved. In order to meet performance goals on quality and costs, physicians need timely, accurate and actionable data. The quarterly feedback reports provided through the CPC web application are time-consuming, burdensome, and difficult to understand.

Finally, the AMA recommends that CMS provide flexibility to allow appropriate physicians in specialties other than primary care to participate in this and other relevant alternative payment models. For example, payment models similar to the CPC could be effectively used by practices that manage particular conditions or patient populations who are not in a primary care specialty.

G. Medicare Shared Savings Program

The AMA was recently a signatory to the comprehensive comment letter regarding the proposed rule for the Medicare Shared Savings Program (MSSP) that was submitted on February 6, 2015 letter on behalf of seventeen entities representing physicians, hospitals, medical group practices, and nearly all existing MSSP ACOs. For purposes of this Proposed Rule, we offer our comments regarding the appropriateness and timing of including the following quality measures in the MSSP program.

Percent of PCPs who Successfully Meet Meaningful Use Requirements (ACO-11)

A quality measure that simply measures participation in the MU program is not a reliable or appropriate indicator of success given the significant program costs, lack of interoperability between vendors, and dwindling user satisfaction. MU and health IT should be viewed as one component in the set of tools that physicians can use to diagnose, treat, and coordinate patient care. There is neither clear evidence nor well established metrics to measure whether MU participation, in and of itself, actually translates to improved patient outcomes. Furthermore, there are growing concerns that aggressive federal program timelines—particularly the stages and standards requirements for MU—are causing patient harm proportionally to the expediency with which many health IT systems are deployed. Increasing the footprint of EHR adoption across the various physicians and other providers who participate in ACOs does not guarantee the capture

of better data. Nor will forcing a critical mass of health IT products across the nation bolster the interoperable exchange of data. In fact, further tying advanced payment models to certified EHRs and MU could stall any momentum gained thus far. We are concerned that lessons learned by poor MU participation are not being taken into account in the development of this measure.

Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (ACO-42)

The AMA has concerns with CMS adding the following measure to the MSSP program as CMS in the middle of the three-year contract cycle. If CMS moves forward with adding the measure, it should only be used for pay-for-reporting, not for assessing performance. In order for an ACO to assess or improve its performance on a particular measure, it must collect its own data relevant to that measure. Adding new measures midstream prevents ACOs from preparing for this crucial preparation and self-assessment. In addition, changes in measures require ACOs to shift focus to different aspects of clinical care, change data collection and analysis systems, etc. Frequent changes in quality measures are a recipe for failure of this vital Medicare program. As we have stated in past comments, instead of CMS continuously moving the goal posts, CMS should be working to provide more stability for Medicare ACOs. CMS should set quality standards for the entire three-year agreement period. These should not be changed during the contract period unless CMS first consults with the ACOs and receives agreement from a majority of the ACOs, that the change is necessary and helpful.

H. Value-Based Payment Modifier and Physician Feedback Program

In the MACRA, Congress directed CMS to give quality metrics more weight than resource use in the initial years of a new MIPS program that will replace the current payment incentive programs. In addition, lawmakers called for the development of new care episodes and codes to address current weaknesses in the methodology surrounding resource use measurement. The directives are a tacit acknowledgement that there are problems with the way Medicare currently calculates the cost part of the VM. The AMA concurs with this conclusion and appreciates that in this proposed rule CMS has decided to "stabilize" the VM program rather than increasing penalties and moving ahead at the pace we have seen in the last few years. Ultimately, we believe that significant modifications will be needed under the resource section of MIPS and we urge CMS to help inform those modifications by conducting more indepth analysis and evaluation of the value modifier and its underlying physician feedback reports.

Summary of AMA-Supported Provisions

The AMA supports CMS's proposals to:

- Maintain, rather than increase, the current potential VM penalties of 2 percent for physician groups with fewer than 10 practitioners and 4 percent for those with 10 or more.
- Determine application of practice-size-related VM policies based on either what is reported in the Provider Enrollment, Chain & Ownership System (PECOS) or determined from claims analysis, whichever is lowest.
- Exempt innovative payment models run by the Center for Medicare & Medicaid Innovation (CMMI) from VM and to slow the VM phase in for non-physician practitioners.
- Examine stratification of cost benchmarks by patient risk scores.
- Allow practices that signed up but failed to successfully report PQRS measures as a group to avoid a VM penalty if at least 50 percent of their individual practitioners successfully reported.
- Not count Medicare Spending Per Beneficiary (MSPB) around a hospital visit in VM cost measures unless a practice has at least 100 applicable cases.

 Continued use of all applicable PQRS measures in the VM and creation of separate benchmarks for electronically reported and other PQRS measures.

Summary of AMA Concerns

We oppose or are concerned by:

- Continuation of mandatory participation in the quality-tiering program—especially for small groups and solo physicians.
- Extension of VM to Medicare Shared Savings Plans (MSSPs).
- Continued use of low-bar standards for testing reliability of VM's cost and quality measures and
 the inclusion of measures such as MSPB and hospital readmissions that were created for hospitals
 and have never been tested in physician offices.
- CMS's failure to address weaknesses in its methods of adjusting for differences in physician specialty and patient risk.
- Inadequate outreach to make physicians aware of the VM and how it works.
- Failure to conduct and/or share comprehensive and timely evaluation of contractor analysis of experience with the VM and physician feedback reports.

Greater Flexibility for Small Practices

A key reason for the widespread physician support of MACRA was its provisions calling for flexibility in the application of MIPS components to different sizes and types of physician practices. As mentioned above, the law also recognized the need for better tools for attributing costs and applying payment incentives based on services that physicians actually had some control over. In recognition of the shortcomings of current VM methodologies, it also called for the resource portion of MIPS to be weighted at only 10 percent of the total initially compared to 50 percent for the quality section. We believe CMS should heed these signals of Congressional concern by taking additional steps to protect small practices and high risk patients from unintended consequences.

The AMA recognizes that until MIPS takes effect in 2019, CMS must comply with the ACA which calls for application of the VM to all physicians by 2017. That does not mean that all practices must be treated exactly the same for the remaining life of the VM—a point that CMS itself has recognized by imposing lower penalties for small practices (-2 percent) than for large ones (-4 percent). In fact, this proposed rule would extend this variation by limiting penalties for any-sized non-MD practices to 2 percent. As we have noted in commenting on prior proposals, there are other steps that could and should be taken in advance of MACRA's implementation to avoid unintended consequences of the VM. These include elimination of mandatory tiering entirely, exempting practices with fewer than 10 practitioners or continuing the current provision disallowing any tiering-related penalties for these practices.

Protection of High Risk Patients and Their Physicians

There are a number of signs that as currently designed, the VM does not include adequate protections for physicians in practices with a large percentage of patients who are likely to have high health care costs. An evaluation of the 2012 QRUR report found that among groups with 25 or more practitioners, those with patient risk scores in the highest quartiles were three times more likely than average to have low quality scores and four times more likely than average to have high cost scores. In a similar vein, information published in the 2014 proposed rule found that even after CMS's adjustment for specialty mix, physician specialties, such as oncologists and geriatricians, that typically treat patients with multiple

Andrew M. Slavitt September 8, 2015 Page 41

and/or very serious conditions were more likely than other physicians to be seen as having very high aggregate costs per patient.

Experience in 2015 offers corroborating evidence. According to a CMS report, groups with the highest patient risk scores were more than four times as likely to get a VM penalty as those with the lowest patient risk scores. None of those with the highest risk patients got a bonus compared to 22 percent of those with the lowest risk. Percentages of patients with chronic diseases that are highlighted in VM cost measurement (diabetes, congestive obstructive pulmonary disease, coronary artery disease, and heart failure) were anywhere from 10 percent to 80 percent greater in the groups with the highest risk scores than in those with lowest risk scores.

In the proposed rule, CMS reiterates its belief that its current method of adjusting for patient risk is sufficient but then asks for comments on a plan to address possible inadequacies in the risk adjuster by stratifying cost measure benchmarks so physician practices are compared to others treating beneficiaries with similar risk scores. The AMA supports exploration of risk stratified comparisons but reserves final judgment until an evaluation of the impact of this approach is made public. Whatever it shows, we continue to believe that CMS must address other weaknesses in its methodology. These include the failure to distinguish between specialists and sub-specialists in the same field or between physicians with similar training but very different practice profiles such as primary care physicians who are office-based versus those that are largely providing care in a hospital, skilled nursing facility or patient's home.

Redesigning VM Cost and Outcome Measures

In the proposed rule, CMS signals that it will no longer apply its Medicare Spending Per Beneficiary (MSPB) cost measure—which includes costs from 3 days prior to 30 days after a hospitalization—to practices with fewer than 100 hospitalizations. Previously the minimum had been 20 hospitalizations but after a year of experience, CMS has discovered that at that threshold, the measure fails to meet even a modest 0.4 percent reliability standard. This follows a similar situation that occurred last year when the minimum threshold for the readmissions outcome measure was increased from 20 cases to 200. Neither of the measures were designed or tested as measures of physician performance. In both cases, the change was not made retroactive and therefore some practices potentially did poorly on the VM due simply to measures that were poorly chosen and executed.

The AMA supports increasing the minimum threshold for both these measures but believes that a better option would be to eliminate them entirely. In addition, even though CMS's contractor defines 0.4 percent as a "moderate reliability," in prior years, CMS often cited reliability of 0.7 or more for its proposed policies. In the future, the AMA believes CMS should conduct office-based tests of the validity and reliability of any measures it proposes to use in that setting before introducing them in the VM or the resource section of MIPS in physician practices. Any that cannot meet a reliability standard of at least 0.7 should be rejected.

We also want to go on record as supporting a movement from the current cost measures to the episode approach that is envisioned in MACRA. As the AMA has repeatedly pointed out, the current cost and claims-based outcome measures use attribution methods that hold some physicians responsible for costs they could not possibly have controlled and leave others without any attributed costs that can be used to calculate a VM score. In addition, the measures are largely duplicative so that a physician treating a patient with multiple chronic conditions could be punished repeatedly as that patient triggered services that would be included in the readmission outcome measure and VM cost measures for Medicare

spending per beneficiary, aggregate total costs and aggregate costs for each of the four chronic conditions cited above. It is our hope that CMS will work closely with the AMA and other physician organizations to develop appropriate episode-based cost measures to replace its current measures.

Application of the VM to Alternative Payment Models

Over the past two years, CMS's policies with regard to alternative/innovative payment models have fluctuated, creating unnecessary confusion and complexity around the VM, which is already poorly understood by most physicians. The AMA agrees with the current proposal to waive the VM requirement for a number of new payment models run out of the Center for Medicare and Medicaid Innovation. We see no real difference between these programs and the ACOs created under the MSSP section of the law. All include other incentives for increased efficiency and quality and none should be subject to the VM. The ACA authorized the use of waivers for MSSP participants and MACRA re-enforced Congressional intent on the subject by exempting ACOs from MIPS. It is unnecessary to create a whole new set of complications about what happens if a physician participates in more than one ACO, or switches ACOs, or meets PQRS standards in one but not the other.

I. Physician Self-Referral Updates

The AMA recognizes and appreciates CMS' efforts to amend the physician self-referral regulations in order to promote increased access to care while simultaneously protecting against potential program abuse. The proposed new exception for assistance to physicians to employ non-physician practitioners can help further this goal, while facilitating physician-led team-based care to meet patient needs. The AMA believes that expanding the scope of this proposed exception to include additional categories of medical services and non-physician practitioners could help meet the health care needs of remote and underserved areas.

According to a study prepared for the Association of American Medical Colleges earlier this year, the projected physician shortfall by 2025 will range from 46,100 to 90,400 physicians, with shortfalls in primary care ranging between 12,500 and 31,100 physicians and shortfalls in non-primary care ranging between 28,200 and 63,700 physicians. The study estimates that expanded medical coverage under the Affordable Care Act will increase physician demand by 2.0 percent, with the highest percentage increase for surgical specialties (3.2 percent), followed by primary care (2.0 percent), medical specialties (1.7 percent), and other specialties (1.5 percent).

As such, the proposed limitation on assistance to physicians in hiring non-physician practitioners to specified provider types furnishing "primary care services" may be overly restrictive in terms of CMS' stated goal of adapting the self-referral regulations to changes in the health care delivery and payment systems. Moreover, excluding independent contractor arrangements from the proposed exception may be similarly counterproductive. Given CMS' determination that arrangements for assistance to physicians to employ non-physician practitioners do not pose a risk of program or patient abuse, it is difficult to see how an independent contractor arrangement would substantially differ, particularly with appropriate conditions attached similar to § 411.357(d). This is especially so in light of the proposed safeguard that remuneration to the physician cannot exceed the actual amount paid to the non-physician practitioner. So long as the physician's reimbursement is limited to the non-physician's practitioner's compensation, the

⁴ Association of American Medical Colleges, *The Complexities of Physician Supply and Demand: Projections from 2013 to 2025*; final report. March 2015. https://www.aamc.org/download/426242/data/ihsreportdownload.pdf.

risk of program or patient abuse should not be heightened based upon the nature of the arrangement under which the non-physician practitioner is providing services.

The AMA also appreciates the opportunity to offer comments regarding the impact of the self-referral regulations on health care delivery and payment reform. As CMS noted in its proposed rulemaking, significant changes in health care delivery and payment have occurred since the enactment of the self-referral law, including numerous initiatives to align payment under Medicare, Medicaid, and non-federal programs with the quality of care delivered. Physician leadership in these new efforts is instrumental to optimizing care, improving population health, and reducing costs.

However, outside of models for which the Department of Health and Human Services Office of Inspector General (OIG) has explicitly established waivers of the federal program integrity laws, physicians may be wary of pursuing participation in innovative delivery and payment models due to real or perceived prohibitions under the compensation standards of the self-referral regulations. In particular, the "fair market value," "volume or value," and "other business generated" standards can make it exceedingly difficult to structure incentive payments tied to quality improvement criteria. Indeed, the GAO has found that stakeholders' concerns about the legal framework for program integrity "may hinder implementation of financial incentive programs to improve quality and efficiency on a broad scale." ⁵

In the same vein, the OIG has permitted some waivers for physicians who participate in ACOs under the MSSP to facilitate physician leadership and participation in the MSSP and mitigate confusion for program participants. Yet these waivers are limited to the MSSP and may still not be sufficient to encourage physician participation. The AMA believes that CMS should consider expanding these exemptions to encourage other forms of innovative delivery and payment models. Specifically, we encourage CMS to publish guidance regarding the waiver of federal program integrity laws for those physicians participating in programs developed by the CMMI. Programs run by the CMMI pose little risk of fraud and abuse because they have built-in safeguards, including careful monitoring by CMS. For CMMI's programs to succeed, physicians and other participants need to fully assess how care can and cannot be provided to patients under these new models. Without bright line guidance, program integrity provisions can deter the adoption of payment and delivery reforms, including bundled payments, medical homes, and other initiatives. Currently, CMMI has addressed the applicability of fraud and abuse laws through the contract process on a case-by-case basis. Program applicants therefore do not have up-front guidance regarding the challenges and restrictions that will apply.

Moreover, current broad prohibitions under the fraud and abuse laws discourage physicians from using innovative incentive plans and other arrangements to improve care quality and reduce costs. To facilitate potentially beneficial arrangements, we urge CMS to issue waivers of the prohibitions of the self-referral law and other program integrity laws that incorporate the following safeguards:

- Specific, identifiable, transparent, and verifiable cost savings;
- Arrangements of fixed duration;
- Provisions for participating physicians to make a patient-by-patient determination of necessary care and other patient-care safeguards;
- Disclosures to patients about the hospital and physician participation in cost-saving efforts;

⁵ Government Accountability Office, *Medicare: Implementation of Financial Incentive Programs under Federal Fraud and Abuse Laws.* Report 12-355 (March 2012). http://www.gao.gov/products/GAO-12-355
⁶ 76 Fed. Reg. 67,992 to 68,010 (November 2, 2011).

- · Equal distribution of cost savings among all participating physicians; and
- Maintenance of quality monitoring that has been mutually agreed upon, or developed, by
 participating physicians and the hospital to ensure that the quality of, and patient access to, health
 care services is not negatively affected.

These factors ensure that patients are aware of compensation mechanisms, that physicians retain the right to use the most appropriate items and services for their patients, and that the programs are effective by achieving cost savings. Using these factors, we believe that CMS could provide more explicit guidance on when an arrangement will or will not prompt action under the self-referral and other fraud and abuse laws, thereby safeguarding against patient or program abuse while facilitating desired delivery system reform.

J. Private Contracting/Opt-Out

With strong support from the AMA, the private contracting/opt out law was amended by MACRA. Prior to MACRA, the law specified that physicians may opt out for a minimum of two years. CMS established regulations requiring individuals that wished to continue their opt-out status at the end of a two-year period to file new affidavits with their MACs every two years. Effective on or after June 16, 2015, physicians' opt-out affidavits are automatically renewed every two years without having to be resubmitted. CMS has proposed to revise the regulations governing the requirements and procedures for private contracts to conform with these statutory changes. The AMA strongly supports the proposed revisions.

IV. Requests for Comments on Additional Issues

A. Defining the Low-Volume Threshold for Participation and Clinical Practice Improvement (CPI) Activities for the MIPS Program

The AMA plans to address issues regarding the MIPS program, including definitions of the low-volume threshold and CPI activities, as we begin discussing these issues in greater detail among state and national specialty societies, and particularly in the context of next year's proposed rule.

B. Defining Physician-Led Alternative Payment Models (APMs) under the MACRA

With strong support from the AMA, MACRA promotes the development of APMs and provides incentive payments for physicians who participate in APMs. As an initial step in the MACRA rulemaking process, CMS intends to publish specific questions related to the MACRA APM provisions in a forthcoming Request for Information (RFI). The AMA offers its perspective on key questions that CMS should ask in this RFI.

Definition of Financial Risk

The issue of how "more than nominal financial risk" will be defined is a key question in the development of APM regulations. As discussed in this letter with regard to potential expansion of the CPC initiative, the AMA has serious concerns about requiring physicians to assume accountability for the total cost of care for a patient population as part of APMs. Physicians participating in APMs should only be expected to accept accountability for those aspects of costs that they can control or influence, such as the costs associated with the services they deliver or order and the complications associated with the specific health

conditions that they manage. In addition, it is important for CMS to recognize that physicians incur many costs to participate in any payment model that are not reflected in the payments Medicare makes for services; this includes administrative costs, services that are not explicitly billable, and losses of revenues from reducing or changing the types of services delivered. Examples of costs and losses that should be considered as financial risk under MACRA but that are not recognized as risk under most of the APMs that CMS has developed to date include:

- Incurring one-time initial costs to form an Alternative Payment Entity, to purchase equipment, engage in training, etc. in order to participate in a payment model that does not directly reimburse for these expenses;
- Incurring ongoing operating costs in order to deliver services to patients that are not directly reimbursable under the APM (such as hiring care managers);
- Incurring losses in revenues or reductions in profit margins by avoiding the use of billable services, preventing the need for billable services, using alternative services that generate lower margins, or accepting a discounted payment, or by devoting time to implementing the APM that reduces billable time on other activities;
- Obtaining loans or issuing bonds in order to form an Alternative Payment Entity or deliver services under an APM that would require repayment regardless of the success of the Alternative Payment Entity; and
- Contributing equity capital in order to form an Alternative Payment Entity or to support the costs
 of delivering services under an APM that would be lost if the Alternative Payment Entity were
 not successful.

The RFI should therefore ask about both (a) the types of costs physicians are likely to incur in order to participate in an APM and (b) the types of costs that physicians can and cannot control for the types of patients and health conditions that would be covered by an APM.

Eligible Alternative Payment Entities

MACRA requires that an "Eligible Alternative Payment Entity" must be at financial risk, not the individual physician. This is a positive feature of the law because the Eligible Alternative Payment Entity could:

- Pool the patient panels of multiple physician practices, thereby making it easier for small
 physician practices to participate in payment models and also for physicians to participate with
 respect to subsets of their patients who have particular medical conditions or for whom they
 perform specific procedures;
- Accept the risk of participating in the APM without directly jeopardizing the assets of the
 participating physicians or their practices; and
- Engage or employ individuals with expertise in administration of APMs without requiring individual physicians or their practice administrators to develop that expertise.

At the same time, it will be important for CMS to establish standards for organizations to function as Eligible Alternative Payment Entities. The AMA recommends that the RFI ask the following questions:

 What are good and bad examples of how entities have played an intermediary role in existing CMS programs and demonstrations such as the MSSP and the Bundled Payments for Care Improvement demonstrations?

- What restrictions in existing CMS programs and demonstrations regarding organizations playing intermediary roles should be preserved or changed in regulations regarding Eligible Alternative Payment Entities?
- What information about the structure or operations of Eligible Alternative Payment Entities should be available to patients, family members, or the general public so they can evaluate the nature of financial incentives for providers and the proportion of resources being devoted to patient care?

Participation Thresholds

Several questions should be asked in the RFI to help clarify how compliance with the numerical thresholds for physician participation in APMs should be measured, particularly for group practices. For example, the RFI should ask for advice about how to measure the proportion of <u>payments</u> for physician services that are attributable to APMs in the following circumstances:

- When multiple physicians share the care of patients;
- When patients receive services from non-physician staff in a physician practice;
- When patients receive services from a physician that are not documented using procedure codes because they are not billable.

The RFI should also ask for advice on how to measure the proportion of a physician's <u>patients</u> participating in APMs, and whether this alternative to the criterion based on proportion of revenues should be used in all or only some circumstances.

Evaluating APMs and Communicating Information About APMs to Patients

Instead of focusing exclusively on "risk" and "savings" as the defining characteristics of alternative payment models, it would be desirable to classify payment models in terms of how well they encourage or require physicians, hospitals, and other providers to be "clinically and financially accountable" for both high quality and lower-cost care to patients. The RFI should ask how APMs can be evaluated and whether there are criteria that would measure benefits for physicians in terms of the ability to deliver higher-value services and the benefits and risks to patients. It should also ask commenters to identify specific changes that should be made in current CMS regulations or procedures in order to facilitate access to claims and clinical data that would help physicians to develop successful APMs, in the evaluation of the performance of physicians and other providers under APMs, and in the communication of quality and cost information to patients. Finally, the RFI should ask for suggestions on effective mechanisms for including patients or patient representatives in the planning process for APMs and the review of proposed APMs.

Application of MACRA Provisions on EHR Use

As noted above in our comments on measuring EHR adoption in ACOs, increasing the footprint of EHR adoption across physicians participating in APMs will not guarantee the capture of better data nor bolster the interoperable exchange of data. In fact, further tying APMs to certified EHRs and MU could stall progress to date. As MACRA requires that Eligible Alternative Payment Entities utilize a certified EHR, the RFI should ask commenters to describe their experiences with use of EHRs in APMs and how they think the Eligible Alternative Payment Entities can best apply this requirement. In particular, commenters should be asked to suggest the kinds of improvements that ought to be made in EHRs and the EHR

Andrew M. Slavitt September 8, 2015 Page 47

certification process in order make EHRs serve a positive function in the APMs to be developed under MACRA.

V. Conclusion

In conclusion, the AMA appreciates the opportunity to provide comments and thanks you for considering our views. If you should have any questions regarding this letter, please feel free to contact Margaret Garikes, AMA Vice President for Federal Affairs, at margaret.garikes@ama-assn.org, or 202-789-7409.

Sincerely,

James L. Madara, MD

Appendix A: AMA Comments on Table 22/Proposed Individual Quality Cross-Cutting Measures for PQRS to Be Available for Satisfactory Reporting via Claims, Registry & EHRs Beginning in 2016

NQF/ PQRS	CMS E- Measure ID	NQS Domain	Measure Title and Description	Measure Steward	AMA
2152/NA	N/A	Community/ Population Health	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling: Percentage of patients aged 18 years and older who were screened at least once within the last 24 months for unhealthy alcohol use using a systematic screening method AND who received brief counseling if identified as an unhealthy alcohol user. Rationale: This measure has been proposed as a cross-cutting measure for PQRS for CY 2016 as it represents a screening assessment for unhealthy alcohol use that most EPs may perform, assess, and document to ensure maintenance for this risk, and is applicable to most Medicare adult patients.	AMA- Physician Consortium for Performance Improvement (AMA-PCPI)	The AMA supports inclusion of these measures as cross-cutting measures in PQRS for 2016.
0151/154	N/A	Patient Safety	Falls: Risk Assessment: Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months. Rationale: This measure has been reportable through PQRS for 7 years and was finalized for reporting through claims and registry in PQRS in the CY 2013 PFS final rule. In the CY 2015 PFS final rule, this measure was finalized for the addition of measures group reporting. This measure has been proposed as a cross-cutting measure for PQRS for CY 2016 PFS as it is applicable to a variety of physician specialties and should be integrated into the standard of care for providers who serve patients with a history of falls.	National Committee for Quality Assurance (NCQA) / AMA-PCPI	The AMA supports inclusion of these measures as cross-cutting measures in PQRS for 2016.

NQF/ PQRS	CMS E- Measure ID	NQS Domain	Measure Title and Description	Measure Steward	AMA
0101/155	N/A	Communicati	Falls: Plan of Care: Percentage of patients aged 65 years and	NCQA /	The AMA
		Coordination	documented within 12 months.	AIMA-FUFI	supports inclusion of
			Rationale: This measure has been reportable through PQRS		these measures
			for 7 years and was finalized for reporting through claims and		as cross-
			registry in PQRS in the CY 2013 PFS final rule. In the CY 2015		cutting
			PFS final rule, this measure was finalized for the addition of		measures in
			measures group reporting. This measure has been proposed		PQRS for 2016.
			as a cross-cutting measure for PQRS for CY 2016 as it is		
			applicable to a variety of physician specialties and should be		
			integrated into the standard of care for providers who serve		
			patients with a history of falls.		

Appendix B: AMA Comments on Table 23 / New Individual Quality Measures & Those Included in Measures Groups for PQRS to Be Available for Satisfactory Reporting Beginning in 2016

NQF/PQRS	CMS E- Measure ID	NQS Domain	Measure Title and Description	Measure Steward	AMA Comments
N/A/ N/A	N/A	Patient and Caregiver- Centered Experience and Outcomes	Adult Kidney Disease: Referral to Hospice: Percentage of patients aged 18 years and older with a diagnosis of end-stage renal disease (ESRD) who Withdraws from hemodialysis peritoneal dialysis who are referred to hospice care.	Renal Physicians Association / AMA-PCPI	The AMA supports inclusion of this measure in PQRS, as the AMA-PCPI collaborated closely in its development.
N/A/ N/A	N/A	Effective Clinical Care	Appropriate Follow-Up Imaging for Incidental Abdominal Lesions: Percentage of final reports for abdominal imaging studies for asymptomatic patients aged 18 years and older with one or more of the following noted incidentally with follow-up imaging recommended: liver lesion < 0.5 cm; cystic kidney lesion < 1.0 cm; adrenal lesion < 1.0 cm.	American College of Radiology	The AMA supports inclusion of this measure in PQRS, as the AMA-PCPI collaborated closely in its development.
N/A/ N/A	N/A	Effective Clinical Care	Appropriate Follow-Up Imaging for Incidental Thyroid Nodules in Patients: Percentage of final reports for computed tomography (CT) or magnetic resonance imaging (MRI) studies of the chest or neck or ultrasound of the neck for patients aged 18 years and older with no known thyroid disease with a thyroid nodule < 1.0 cm noted incidentally with follow-up imaging recommended.	American College of Radiology	The AMA supports inclusion of this measure in PQRS, as the AMA-PCPI collaborated closely in its development.
N/A/ N/A	N/A	Patient Safety	Extravasation of Contrast Following Contrast-Enhanced CT: Percentage of final reports for patients aged 18 years and older who received intravenous iodinated contrast for a CT examination who had an extravasation of contrast.	American College of Radiology	The AMA supports inclusion of this measure in PQRS, as the AMA-PCPI collaborated closely in its development.

NQF/PQRS	CMS E- Measure ID	NQS Domain	Measure Title and Description	Measure Steward	AMA Comments
N/A/ N/A	N/A	Efficiency and Cost Reduction	Imaging in Adult Emergency Department (ED) Patients with Minor Head Injury: Percent of adult patients who presented within 24 hours of a non- penetrating head injury with a Glasgow coma score (GCS) ≤ 15 and underwent head CT for trauma in the ED who have a documented indication consistent with guidelines prior to imaging.	American College of Emergency Physicians	The AMA supports inclusion of this measure in PQRS, as the AMA-PCPI collaborated closely in its development.
N/A/ N/A	N/A	Efficiency and Cost Reduction	Imaging in Pediatric ED Patients Aged 2 through 17 years with Minor Head Injury: Percent of pediatric patients who presented within 24 hours of a non-penetrating head injury with a Glasgow coma score (GCS) of 14 or 15 and underwent head CT for trauma guidelines (PECARN) prior to imaging.	American College of Emergency Physicians	The AMA supports inclusion of this measure in PQRS, as the AMA-PCPI collaborated closely in its development.
0053/NA	N/A	Effective Clinical Care	Osteoporosis Management in Women Who Had a Fracture: The percentage of women age 50-85 who suffered a fracture and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis.	NCQA/AMA-PCPI	The AMA supports inclusion of this measure in PQRS, as the AMA-PCPI collaborated closely in its development.
N/A/ N/A	N/A	Patient Safety	Perioperative Temperature Management: Percentage of patients, regardless of age, who undergo surgical or therapeutic procedures under general or neuraxial anesthesia of 60 minutes duration or longer for whom at least one body temperature greater than or equal to 35.5 degrees Celsius (or 95.9 degrees Fahrenheit) was recorded within the 30 minutes immediately before or the 15 minutes immediately after anesthesia end time.	American Society of Anesthesiologists	The AMA supports inclusion of this measure in PQRS, as the AMA-PCPI collaborated closely in its development.

NQF/PQRS	CMS E- Measure ID	NQS Domain	Measure Title and Description	Measure Steward	AMA Comments
N/A/ N/A	N/A	Communication and Care Coordination	Post-Anesthetic Transfer of Care Measure: Procedure Room to a Post-Anesthesia Care Unit (PACU): Percentage of patients who are under the care of an anesthesia practitioner and are admitted to a PACU in which a post- anesthetic formal transfer of care protocol or checklist which includes the key transfer of care elements is utilized.	American Society of Anesthesiologists	The AMA supports inclusion of this measure in PQRS, as the AMA-PCPI collaborated closely in its development.
N/A/ N/A	N/A	Communication and Care Coordination	Post-Anesthetic Transfer of Care Measure: Use of Checklist or Protocol for Direct Transfer of Care from Procedure Room to Intensive Care Unit (ICU): Percentage of patients, regardless of age, who undergo a procedure under anesthesia and are admitted to an ICU directly from the anesthetizing location, who have a documented use of a checklist or protocol for the transfer of care from the responsible anesthesia practitioner to the responsible ICU team or team member.	American Society of Anesthesiologists	The AMA supports inclusion of this measure in PQRS, as the AMA-PCPI collaborated closely in its development.
N/A/ N/A	N/A	Patient Safety	Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination: Percentage of patients, aged 18 years and older, who undergo a procedure under an inhalational general anesthetic, AND who have three or more risk factors for PONV, who receive combination therapy consisting of at least two prophylactic pharmacologic antiemetic agents of different classes preoperatively or intra-operatively.	American Society of Anesthesiologists	The AMA supports inclusion of this measure in PQRS, as the AMA-PCPI collaborated closely in its development.

NQF/PQRS	NQF/PQRS CMS E- Measure ID	NQS Domain	Measure Title and Description	Measure Steward	AMA Comments
2152/N/A N/A	N/A	Community/ Population Health	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling: Percentage of patients aged 18 years and older who were screened at least once within the last 24 months for unhealthy alcohol use using a systematic screening method AND who received brief counseling if identified as an unhealthy alcohol user.	AMA-PCPI	The AMA supports inclusion of this measure in PQRS, as the AMA-PCPI collaborated closely in its development.
N/A/ N/A	N/A	Effective Clinical Care	Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques: Percentage of final reports for patients aged 18 years and older undergoing CT with documentation that one or more of the following dose reduction techniques were used: • Automated exposure control • Adjustment of the mA and/or kV according to patient size • Itse of iterative reconstruction technique	American College of Radiology/ AMA-PCPI/ NCQA	The AMA supports inclusion of this measure in PQRS, as the AMA-PCPI collaborated closely in its development.

Appendix C: AMA Comments on Table 24 / Proposed National Quality Strategy (NQS) Domain Changes for Individual Quality Measures & Those Included in Measures Groups for PQRS Beginning in 2016

Previously Finalized NQS Domain	Proposed New NQS Domain	Measure Title and Description	AMA Comments
Effective Clinical Care (PFS 2015 final rule)	Communication and Care Coordination	Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care: Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months. Rationale: This measure has been reportable through PQRS for 9 years and was finalized for reporting through claims, registry, and EHR in the PQRS in the CY 2013 PFS final rule. CMS is proposing to re-categorize this measure from the effective clinical care domain to the communication and care coordination domain in the CY 2016 PFS proposed rule in accordance with NQS priorities which follow the General Rules for Categorizing Measures. According to the HHS guidelines for categorizing measures, this measure constitutes the deliberate organization of patient care activities to facilitate appropriate delivery of health care services and outcomes that primarily reflect successful care coordination.	The AMA supports re-categorization of this measure to fall under the NQS Domain "Communication and Care Coordination." Communication of the findings of the macular or fundus exam greatly assists the physician performing the ongoing care of the patient to better manage the patient's diabetes. Based on the definitions of the proposed rule, we believe this is a more appropriate category for this measure.

Appendix D: AMA Comments on Table 25 / Measures Proposed for Removal from the Existing PQRS Measure Set Beginning in 2016

NQF/PQRS	NQS Domain	Measure Title and Description	Measure Steward	AMA Comments
AQA Endorsed/ 173	Community/ Population Health	Preventive Care and Screening: Unhealthy Alcohol Use – Screening: Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use at least once within 24 months using a systematic screening method. Rationale: This measure has been reportable through PQRS for 7 years and was finalized for reporting through claims, registry, EHR, and the Preventive Care Measures Group in PQRS in the CY 2013 PFS final rule. In the CY 2014 PFS final rule, this measure was finalized for removal of claims and EHR reporting methods. CMS proposes removal of this measure and replacing it with NQF 2152: Preventive Care and Screening: Unhealthy Alcohol Use: Screening and Brief Counseling. NQF 2152 includes counseling in addition to screening.	AMA-PCPI	The AMA supports removal of this measure, given the recommended inclusion of a more comprehensive measure (Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling) that includes a counseling component in addition to screening.
0386/194	Effective Clinical Care	Oncology: Cancer Stage Documented: Percentage of patients, regardless of age, with a diagnosis of cancer who are seen in the ambulatory setting who have a baseline American Joint Committee on Cancer (AJCC) cancer stage or documentation that the cancer is metastatic in the medical record at least once during the 12 month reporting period. **Rationale:** This measure has been reportable through PQRS for 6 years and was finalized for reporting through claims, registry, and measure groups in the PQRS in the CY 2013 PFS final rule (77 FR 69238). In the CY 2015 PFS final rule, this measure was finalized for a removal of claims and measures group reporting methods. CMS proposes removal due to this measure representing a clinical concept that does not add clinical value to PQRS because documenting cancer stage is a basic standard of care for oncology. Cancer stage is standard of care that is documented early in the patient's care before treatment options are discussed.	AMA-PCPI / American Society of Clinical Oncology	The AMA does not support removal of this measure from the registry reporting option for PQRS. Documentation of cancer stage is critical to guide the course of treatment and discussion of treatment options with patients. While PQRS performance may be high for this measure, we do not feel it is nationally representative due to the voluntary nature of the program up to this point. In fact, data from the Quality Oncology Practice Initiative (QOPI), which is

ure AMA Comments	also a voluntary program whose participants are likely to be high performers, indicate average performance of approximately 85% with scores ranging from 31% to 100% in 2014. Based on this evidence of a continued gap in care, we feel this measure continues to add clinical value to the PQRS program and should be retained.	Inclusion of this measure, given its importance the delivery of high quality maternity care, provided that a steward can be identified.	The AMA supports inclusion of this measure, given its importance the delivery of high quality maternity care, provided that a steward can be identified.
Measure Steward		AMA-PCPI	AMA-PCPI
Measure Title and Description		Maternity Care: Elective Delivery or Early Induction Without Medical Indication at ≥ 37 and < 39 Weeks: Percentage of patients, regardless of age, who gave birth during a 12-month period who delivered a live singleton at ≥ 37 and < 39 weeks of gestation completed who had elective deliveries or early inductions without medical indication. Rationale: This measure has been reportable through PQRS for 2 years and was finalized for reporting through registry in the PQRS in the CY 2014 PFS final rule. CMS proposes removal due to the measure steward indicating they will no longer maintain this measure.	Maternity Care: Post-Partum Follow-Up and Care Coordination: Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for post-partum care within 8 weeks of giving birth who received a breast feeding evaluation and education, post-partum depression screening, post-partum glucose screening for gestational diabetes patients, and family and contraceptive planning. Rationale: This measure has been reportable through PQRS
NQS Domain		Patient Safety	Communicati on and Care Coordination
NQF/PQRS		N/A/335	N/A/336

NQF/PQRS	NQS Domain	Measure Title and Description	Measure Steward	AMA Comments
-		for 2 years and was finalized for reporting through registry in the PQRS in the CY 2014 PFS final rule. CMS proposes removal due to the measure steward indicating they will no longer maintain this measure.		
N/A/193	Patient	Perioperative Temperature Management: Percentage of patients, regardless of age, undergoing surgical or therapeutic procedures under general or neuraxial anesthesia of 60 minutes duration or longer, except patients undergoing cardiopulmonary bypass, for whom either active warming was used intra-operatively for the purpose of maintaining normothermia, OR at least one body temperature equal to or greater than 36 degrees Centigrade (or 96.8 degrees Fahrenheit) was recorded within the 30 minutes immediately before or the 15 minutes immediately after anesthesia end time. Rationale: This measure has been reportable through PQRS for 6 years and was finalized for reporting through claims and registry in PQRS in the CY 2013 PFS final rule. CMS proposes removal in the CY 2016 PFS proposed rule due to this measure representing a clinical concept that does not add clinical value to PQRS. Literature indicates the adverse outcomes result in prolonged hospital stays and increased health care costs. CMS also states that EPs are consistently meeting performance on this measure with performance rates close to 100%, suggesting	American Society of Anesthesiologists	The AMA supports removal of this measure, given the recommended inclusion of an updated, more comprehensive measure (Perioperative Temperature Management).
		there is no gap in care.		

Appendix E: AMA Comments on Table 26 / Existing Individual Quality Measures & Those Included in Measures Groups for PQRS for Which Measure Reporting Updates Will Be Effective Beginning in 2016

NQF/PQRS	CMS E- Measure ID	Measure Title and Description	Measure Steward	AMA Comments
0088/18	167v3	Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy: Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular of fundus exam performed which included documentation of the level of severity of retinopathy and the presence or absence of macular edema during one or more office visits within 12 months. Rationale: This measure has been reportable through PQRS for 9 years and was finalized for reporting through claims, registry, and EHR in the PQRS in the CY 2013 PFS final rule. In the CY 2015 PFS final rule, this measure was finalized for removal of claims and registry reporting methods. CMS proposes to add this measure to the Diabetes Retinopathy Measures Group in the CY 2016 PFS proposed rule. Several level 1 RCT studies demonstrate the ability of timely treatment to reduce the rate and severity of vision loss from diabets (Diabetic Retinopathy Study – DRS, Early Treatment Diabetic Retinopathy Study – ETDRS). Necessary examination prerequisites to applying the study results are that the presence and severity of both peripheral diabetic retinopathy and macular edema be accurately documented. In the RAND chronic disease quality project, while administrative data indicated that roughly half of the patients had an eye exam in the recommended time period, chart review data indicated that only 19% had documented evidence of a dilated examination. (McGlynn, 2003). Thus, ensuring timely treatment that could prevent 95% of the blindness due to diabetes requires the performance and documentation of key examination parameters. The documented level of severity of retinopathy and the documented pereon persence or absence of macular edema assists with the on-going plan of care for the patient with diabetic retinopathy. This measure is the only	AMA-PCPI / NCQA	The AMA supports adding the Measures Group reporting modality to this measure, in addition to it already being reportable via EHR.
		measure in this proposed measures group that evaluates such documentation.		

AMA Comments	The AMA supports adding the Measures Group reporting modality to this measure, in addition to it already being reportable via claims, registry, and EHR.
Measure Steward	AMA-PCPI / NCQA
Measure Title and Description	Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care: Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months Rationale: This measure has been reportable through PQRS for 9 years and was finalized for reporting through claims, registry, and EHR in the PQRS in the CY 2013 PFS final rule. CMS proposes to add this measure to the Diabetes Retinopathy Measures Group. The physician who manages ongoing care of the patient with diabetes should be aware of the patient's dilated eye examination and severity of retinopathy. Such communication is important in assisting the physician to better manage the diabetes. Several studies have shown that better management of diabetes is directly related to lower rates of development of diabetic eye disease (Diabetes Control and Complications Trial – DCCT, UK Prospective Diabetes Study – UKPDS).
CMS E- Measure ID	142v3
NQF/PQRS	008919

Appendix F: AMA Comments on Table 27 / Cardiovascular Prevention Measures Group for 2016 & Beyond (Millions Hearts)

NQF/PQRS	Measure Title and Description	Measure Developer	AMA Comments
0028/226	Preventive Care and Screening: Tobacco use: Screening and Cessation	AMA-PCPI	The AMA supports
	Intervention: Percentage of patients aged 18 years and older who were		inclusion of this
	screened for tobacco use one or more times within 24 months AND who		measure in the
	received cessation counseling intervention if identified as a tobacco user.		Cardiovascular
			Prevention Measures
			Group.

Appendix G: AMA Comments on Table 28 / Diabetic Retinopathy Measures Group for 2016 & Beyond

NQF/PQRS	Measure Title and Description	Measure Developer	AMA Comments
0088/018	Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy: Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed which included documentation of the level of severity of retinopathy and the presence or absence of macular edema during one or more office visits within 12 months.	AMA-PCPI / NCQA	The AMA supports inclusion of this measure in the Diabetic Retinopathy Measures Group.
0089/019	Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care: Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months.	AMA-PCPI / NCQA	The AMA supports inclusion of this measure in the Diabetic Retinopathy Measures Group.
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	AMA-PCPI	The AMA supports inclusion of this measure in the Diabetic Retinopathy Measures Group.

Appendix H: AMA Comments on Table 29 / Multiple Chronic Conditions Measures Group for 2016 & Beyond

NQF/PQRS	Measure Title and Description	Measure Developer	AMA Comments
0326/047	Care Plan: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	NCQA / AMA- PCPI	The AMA supports inclusion of this measure in the Multiple Chronic Conditions Measures Group.
0041/110	Preventive Care and Screening: Influenza Immunization: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	AMA-PCPI	The AMA supports inclusion of this measure in the Multiple Chronic Conditions Measures Group.
0101/154	Falls: Risk Assessment: Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months.	NCQA / AMA- PCPI	The AMA supports inclusion of this measure in the Multiple Chronic Conditions Measures Group.
0101/155	Falls: Plan of Care: Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	NCQA / AMA- PCPI	The AMA supports inclusion of this measure in the Multiple Chronic Conditions Measures Group.

Appendix I: AMA Comments on Table 29B / Dementia Measures Group for 2016 & Beyond

NQF/PQRS	Measure Title and Description	Measure	AMA Comments
0326/047	Care Plan: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan	NCQA / AMA-PCPI	The Measure Developer for this measure should be the NCQA/AMA-PCPI. We do not agree with inclusion of PQRS #47 in the Dementia Measures Group. The more appropriate measure for this measures group is the measure "Palliative Care Counseling and Advance Care Planning" that specifically addresses palliative care and advance care planning for dementia patients; was developed as part of the Dementia Measurement Set by the AMA-PCPI; also addresses end of life decision making; and was previously submitted during a Call for Measures.
0418/134	Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan: Percentage of patients aged 12 years and older screened for clinical depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	CMS / Quality Insights of Pennsylvania	Although the AMA generally supports broadly-applicable measures in the interest of measure parity and harmonization, we do not support the removal of #285 as it addresses the unique considerations of screening patients with dementia for depression such as emphasis on caregiver report of symptoms.

Appendix J: AMA Comments on Table 29C / Diabetes Measures Group for 2016 & Beyond

NQF/PQRS	Measure Title and Description	Measure	AMA Comments
0041/110	Preventive Care and Screening: Influenza Immunization: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	AMA-PCPI	The AMA supports inclusion of this measure in the Diabetes Measures Group.
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	AMA-PCPI	The AMA supports inclusion of this measure in the Diabetes Measures Group.

Appendix K: AMA Comments on Table 29D / Preventive Care Measures Group for 2016 & Beyond

NQF/PQRS	Measure Title and Description	Measure Developer	AMA Comments
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients 18 years and older who were screened for tobacco use one or more	AMA-PCPI	The AMA supports inclusion of this measure in the Preventive Care Measures Group.
	times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.		
2152/N/A	Preventive Care and Screening: Unhealthy Alcohol Use:	AMA-PCPI	The AMA agrees with CMS' proposal to
	Screening & Brief Counseling: Percentage of patients aged 18		replace PQRS #173: Preventive Care and
	years and older who were screened at least once within the last		Screening: Unhealthy Alcohol Use -
	24 months for unhealthy alcohol use using a systematic		Screening with the newly proposed
	screening method AND who received brief counseling if		measure, Preventive Care and Screening:
	identified as an unhealthy alcohol user. This is a new measure		Unhealthy Alcohol Use: Screening & Brief
	described in Table 23 above.		Counseling, as it is a more comprehensive
			measure.