AMA
AMERICAN MEDICAL ASSOCIATION

JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT, CEO

ama-assn.org
t (312) 464-5000

September 6, 2016

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 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Proposed Rule (CMS-1654-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) on the proposed rule for calendar year (CY) 2017 to revise the Medicare Physician Fee Schedule and Part B, published in the *Federal Register* on July 15, 2016 (81 Fed. Reg. 46,162).

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 3*)

- The AMA opposes CMS' proposed **policy to collect data on the post-operative visits and resources used in furnishing global services**, and urges CMS not to finalize this proposal, but to work with stakeholders, including the AMA and the RUC, to develop a reasonable solution. (*Page* 4)

- The AMA continues to urge CMS to **explore the use of commercial rent data** instead of residential rent data in the practice expense Geographic Practice Cost Indexes (GPCIs). *(Page 10*)

- The AMA **supports the addition of new telehealth codes** and urges CMS to finalize the rule to expand coverage of telehealth as proposed. We also urge CMS to develop a far more expansive set of strategic proposals that are cohesive and forwarding-looking in order to expand coverage and access to telehealth services for Medicare beneficiaries. (*Page 11*)

- The AMA supports CMS' proposals to **improve payment accuracy for primary care, care management, and patient-centered service**s. Specifically, we support a separate payment for non-face-to-face prolonged Evaluation and Management (E/M) services, separate payments for services furnished using the Psychiatric Collaborative Care Model (CoCM), the implementation of other codes in the Current Procedural Terminology® (CPT®) family of Chronic Care Management (CCM) services, and a separate payment to recognize the work of a physician in assessing and creating a care plan for beneficiaries with cognitive impairment. We also applaud CMS' proposals to simplify CCM codes for physicians. (*Page 15*)

- The AMA opposes CMS' plan to eliminate the 2017 physician payment increase Congress provided in the Medicare Access and CHIP Reauthorization Act (MACRA) in order to fund an **add-on payment for services provided to patients with mobility-related disabilities**. (*Page 17*)

- The AMA **strongly supports CMS' proposal to expand the duration and scope of the Diabetes Prevention Program (DPP) model** with the establishment of the Medicare DPP. (*Page 20*)

- The AMA appreciates the opportunity to provide feedback to CMS regarding the Open Payments program. We are pleased CMS is considering a requirement for applicable manufacturers and applicable group purchasing organizations (GPOs) to **pre-vet payment information with physicians and other covered recipients**. The AMA also continues to urge CMS to simplify reporting requirements and exclude educational material from the Open Payments System. (*Page 23*)

- The AMA believes **full scale Appropriate Use Criteria (AUC) implementation should be delayed until January 1, 2019, and should be phased in over time,** starting with a list of conditions that could be specialty tailored. (*Page 24*)

- The AMA appreciates CMS' attempt to allow an alternative reporting period for the 2017 Physician Quality Reporting System (PQRS) payment adjustment for individual physicians or group practices that billed under an Accountable Care Organization (ACO), and where the ACO fails to report on their behalf. We urge CMS, however, to **provide a waiver for physicians under this scenario as the preferred solution**. (*Page 27*)

- The AMA supports CMS' proposed modification to the Value-Based Modifier (VM) to **protect practices by designating both "low" quality and "high" cost scores as average when there are widespread issues with PQRS or claims data,** or when an informal review receives a miscalculation. (*Page 29*)

- The AMA has serious concerns with **CMS' proposed changes to the quality measures used to assess ACO performance.** (*Page 31*)

- The AMA urges CMS to ensure the Medicare Shared Savings Program (MSSP) is aligned with the Quality Payment Program (QPP) by **allowing ACOs to utilize health information technology in ways that most effectively meet the needs of their patient population**. (*Page 34*)

- The AMA strongly supports CMS' proposal to incorporate a voluntary patient choice process into the **ACO assignment methodology**. (*Page 35*)

- The AMA supports CMS' proposal to **provide greater transparency to the Medicare Advantage (MA) and Medicare Part D prescription drug benefit** by releasing MA bid pricing data and Part C and Part D Medical Loss Ratio (MLR) data. (*Page 36*)

- The AMA urges CMS to review and **revise its policies on Medicare Advantage seamless conversions** to ensure that plans cannot abuse them and that appropriate patient protections are in place. (*Page 36*)

II. PROVISIONS OF THE PROPOSED RULE FOR THE 2017 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.

A. Physician Payment Update and Misvalued Codes Target

Congress provided in MACRA annual physician fee schedule (PFS) updates of 0.5 percent from July 2015 through 2019. The Protecting Access to Medicare Act of 2014 (PAMA) set an annual target for reductions in the PFS from adjustments to relative values of misvalued codes. The Achieving a Better Life Experience Act of 2014 accelerated those targets, setting the target at 0.5 percent for 2017 and 2018. CMS estimates the 2017 net reduction in expenditures from proposed adjustments to relative values of misvalued codes to be 0.51 percent. Since this exceeds the 0.5 percent target, there is no additional reduction. However, CMS estimates that the 2017 conversion factor will be reduced to 35.7751 (2016 conversion factor was 35.8043), based on the budget neutrality adjustment and the 0.5 percent update factor.

This budget neutrality adjustment is primarily computed to capture the increased Medicare costs due to a new add-on payment to office visits for patients with mobility impairments. Following years of threats of significant payment reductions under the Sustainable Growth Rate (SGR) formula, physicians had expected to receive a 0.5 percent update in 2017, as Congress provided in MACRA. The AMA is concerned that this proposal, which would wipe out the PFS update with no input or validation from patient or physician stakeholders, will erode support for the QPP prior to its full implementation. Please see Section F below for our detailed comments on the proposed add-on code for patients with mobility-related disabilities.

B. 10- and 90-Day Global Services Reporting Requirements

The AMA joins the RUC in urging CMS not to adopt the proposal for 010- and 090-day global services reporting requirements. We disagree with CMS' proposed policy to collect data on the post-operative visits and resources used in rendering surgical global services. While we agree that physician services valued in the Resource-Based Relative Value Scale (RBRVS) should be accurate and relative, the proposed plan goes beyond the scope of the legislative mandate to collect data in the surgical global period. Furthermore, the complexity of the plan, as proposed, will create undue burden on physicians during a period of significant Medicare payment system changes as MACRA is implemented, with relatively little benefit to actual payment accuracy. The proposal is inconsistent with the Acting Administrator's goal to reduce the administrative burden on physicians.

Background

In the 2015 Medicare Physician Fee Schedule Final Rule, CMS finalized a plan to transition all 010- and 090-day codes to 0-day global codes. In support for its plan, CMS referenced challenges it has experienced in obtaining available data to verify the number, level, and relative costs of post-operative visits included in global packages. CMS also expressed concern that 010- and 090-day global packages may, in some cases, no longer accurately reflect the post-operative care provided to the typical patient. The AMA opposed this proposal to eradicate surgical global periods, arguing that the level of granularity sought by CMS was unnecessary given the system of relativity in the RBRVS.

In January 2015, after significant advocacy from AMA and other physician groups, Congress passed MACRA, prohibiting the implementation of the above stated CMS policy. In place of the transition, the statute requires CMS to "develop and implement a process to gather, from a representative sample of physicians, beginning not later than January 1, 2017, information needed to value surgical services." In addition, the statute notes that "such information shall include the number and level of medical visits furnished during the global period."

CMS' Data Collection Proposal

CMS proposes a three-pronged approach to collect data on the frequency of and inputs involved in rendering global services, including the procedure, pre-operative visits, and post-operative visits. CMS' proposal includes:

- Comprehensive claims-based reporting about the number and level of pre- and post-operative visits furnished for 10- and 90-day global services.
- A survey of a representative sample of physicians about the activities involved in and resources used in providing a number of pre- and post-operative visits during a specified, recent period of time, such as two weeks.
- A more in-depth study, including direct observation of the pre- and post-operative care delivered in a small number of sites including some ACOs.

CMS proposes to collect the pre- and post-operative visits included in the global surgical bundle through newly created Healthcare Common Procedure Coding System level II G-codes from all physicians reporting procedural services in Medicare. CMS proposes a new series of eight G-codes which are intended to collect the pre- and post-operative activities based on place of service, complexity of patient,

and completion time by 10 minute increments as listed below. The AMA has numerous concerns regarding this expansive collection of data.

Inpatient	GXXX1	Inpatient visit, typical, per 10 minutes, included in surgical package
	GXXX2	Inpatient visit, complex, per 10 minutes, included in surgical package
	GXXX3	Inpatient visit, critical illness, per 10 minutes, included in surgical package
Office or Other Outpatient	GXXX4	Office or other outpatient visit, clinical staff, per 10 minutes, included in surgical package
	GXXX5	Office or other outpatient visit, typical, per 10 minutes, included in surgical package
	GXXX6	Office or other outpatient visit, complex, per 10 minutes, included in surgical package
Via Phone or Internet	GXXX7	Patient interactions via electronic means by physician/NPP, per 10 minutes, included in surgical package
	GXXX8	Patient interactions via electronic means by clinical staff, per 10 minutes, included in surgical package

Problems with CMS' Data Collection Proposal

Number of Codes Surveyed is Illogical

The AMA notes that there are currently 4,239 CPT codes with surgical global packages in the Medicare payment schedule. According to 2015 Medicare utilization data, however, there are only 110 010-day and 149 090-day global codes that are performed more than 10,000 times. With so few surgical codes widely performed, CMS' proposal to mandate reporting from all codes is unlikely to be effective.

Level of Visits is not an Issue

The AMA understands that the statute asks the Secretary to develop a process to gather information needed to value surgical services, including the number and level of medical visits furnished by a physician during the global period. However, we do not believe that there is an issue regarding the level of service being provided in the global period by physicians, as illustrated below. Therefore, the AMA asks CMS to collect data on the level of service provided in the least burdensome way to physicians.

The median established office visit in a global surgical package is a 99212, whereas the median level for separately-reported visits is a 99213. Only one percent of all established patient office visits in 010- and 090-day global surgery packages have a visit level above a 99213, whereas nearly 47 percent of all separately-reported E/M visits are reported as a 99214 or 99215.

In addition, the median hospital visit in a global surgical package is a 99231, whereas the median level for separately-reported hospital visits is a 99232. Fifty-seven percent of hospital visits in a global package have a hospital visit level of 99231, whereas only 11 percent of all separately-reported hospital visits are reported as a 99231.

Therefore, the AMA does not believe it is necessary to distinguish the level of service in a claims collection process, as there is no identified problem to solve regarding the level of E/M services bundled into the surgical global period.

Collection of Time per Patient is not Feasible

CMS proposes that physicians will bill the new G-codes in 10 minute increments for every task that physicians and their clinical staff perform throughout the day. Physicians will be required to both learn the reporting requirements of these new codes and begin monitoring their time in 10 minute increments. The AMA believes that CMS may not understand the significant negative impact this proposal will have on physicians. The RUC reviewed specialty data on hours worked per week from the large, multi-specialty Physician Practice Information survey conducted in 2008. Below are four of the top specialties who perform commonly billed, high cost surgical services, and the amount of time they typically spend in the operating room each week.

Specialty	Average Hours in OR (per week)	Average Patient Care Hours (per week)	Percent NOT in OR (per week)
Orthopedic Surgery	17.1	59.3	71%
General Surgery	20.5	66.3	69%
Vascular Surgery	23.8	68.0	65%
Neurosurgery	21.2	63.7	67%

As illustrated by the chart above, most surgical specialists spend the majority of their time outside the operating room and with their patients or patient families. CMS is asking physicians and their clinical staff to catalogue every minute of this time.

The RUC conducted an analysis of the number of claims this proposal would create, and estimates the number of codes that would need to be billed in 10 minute increments related to pre- and post-operative work in global services is more than 234 million. In addition, a rough estimation of clinical staff time that would be billed is more than 271 million codes. Combined, this proposal will mandate the reporting of at least 451 million new codes. If each claim allows up to six codes to be entered, over 75 million new claims will need to be processed. Previous analysis of Medicare contractors and the non-profit Council for Affordable Quality Healthcare suggests the cost of processing a straightforward claim to be between $1.36 and $1.50. Therefore, the cost of processing the additional claims alone will amount to over $100 million. This does not include the additional staff needed to redesign IT infrastructure and assist physicians in time motion accounting.

Asking physicians and their staff to use 10 minute timed increments to document all their non-operating room patient care activities is by itself an incredible burden, and especially so at a time that system-wide changes in Medicare reporting requirements are being implemented under MACRA. In addition, using 10 minute timed increments is not consistent with the Acting Administrator's goal to reduce physicians' administrative burden.

Inability to Match G-codes with E/M Services

The AMA believes a significant weakness with these proposed G-codes is the inability to match them with the E/M services assumed to be bundled into the current global surgical package. It is unclear how

CMS intends to take the raw data collected by the G-codes and translate them to existing E/M services. By redefining the parameters of these post-operative visits, CMS has created a scenario which makes the actual task of ensuring surgical services are accurately valued extremely difficult and nontransparent.

Failure to Survey Representative Sample

CMS proposes that any physician that provides a procedure that is a 010- or 090-day global service must report the pre- and post-operative services furnished on a claim using the new G-codes. CMS cites numerous reasons as to why they proposed this method of data collection, including the inability to collect a sufficient volume of data, lack of knowledge regarding factors that drive variation in pre- and post-operative care, and the inability to identify a representative sample.

The AMA believes CMS' proposal to collect data from all physicians is counter to the legislative intent of Congress, instructing the Secretary to collect data from a representative sample of physicians. The definition of a sample is a subset of an entire population. Therefore, under no circumstance, can CMS' proposal to require the entire physician population to report these data properly align with Congress' stated intent that a representative sample must be used.

Furthermore, even if collecting data on all physicians was within the scope of the statute, it would still be ill-advised. Requiring every physician to report new G-codes will be extremely complex and burdensome for physicians, particularly for smaller practices that may not have the technology systems or staff in place to adequately report these codes.

AMA Recommendations

The AMA believes that CMS must find a simplistic and transparent method to collect data from a representative sample of physicians on the number of pre- and post-operative services provided in 10- and 90-day global codes. We support the RUC's alternative proposals, summarized below. We believe these data collection methods are within the scope of the statute and would result in a significantly easier data collection process for both CMS and physicians.

Creation of a Representative Sample

As discussed previously, there are only 110 010-day and 149 090-day global codes performed more than 10,000 times. The AMA agrees with the RUC's recommendation that the data collection process should not include all services, as many surgical global codes are low volume which would make it difficult to find a meaningful sample. The RUC reviewed publicly available 2014 data and identified a set of criteria which focuses the collection process on a wide range of relatively high volume surgical services which are commonly performed by physicians across the nation. The criteria are as follows:

- Medicare volume of at least 10,000.
- And/or $10 million in allowed charges.
- At least 100 separate physicians perform the procedure.

These criteria identified 235 CPT codes primarily performed by 20 specialties when reviewing the 2014 Medicare data. To ensure this list is representative, the RUC confirmed that the post-operative breakout of this sample matches the total pool of surgical global services.

- 97 percent of office/outpatient visits are either a 99212 or 99213.
- 82 percent of hospital visits are either a 99231 or 99232.

These 235 services represent 73 percent of all Medicare allowed charges for 010- and 090-day services, and 71 percent of all visits incorporated into surgical global periods**. This list of codes should be the universe of codes from which to select a targeted sample of both CPT codes and physicians, as it provides a suitable representation of all 010- and 090-day codes.** In considering the sample collection, CMS should ensure that no single specialty is unduly burdened.

In addition, CMS must survey a representative sample of physicians in order to comply with the statute. We urge CMS to create a representative sample of physicians based off the pool of services defined above. CMS has adequate claims data to identify specific physicians or practices that perform these services. Using geographical data, CMS should identify a representative sample that includes medium and small practices, not just large, hospital-based practices that often represent practice patterns that differ from the majority of physicians. We urge CMS to work with the RUC to determine the best way to obtain a representative sample of physicians that includes a wide variety of specialties, practice sizes, and locations.

In a CMS Town Hall meeting regarding this proposal, CMS indicated it had concerns that when two surgical global services are reported on the same day, it would be extremely difficult to parse out the post-operative visits for each respective code. First, a review of the 2014 Medicare five percent sample file shows that only 18 percent of the time two surgical codes are performed on the same date of service, by the same physician. Second, this concern would apply to any proposal that uses large scale claims reporting. The use of CMS' G-codes would not alleviate this relatively small subset of instances. These appear to be relatively rare instances, and should not deter CMS from implementing these recommendations. We note that CMS may have to eliminate these data from analyses as it will be difficult to attribute a particular visit to a surgery done concurrent with another surgery. We assume that CMS would review the claims from codes reported alone, reflecting 82 percent of all claims for 010- and 090-day services.

<u>Collection of Data via CPT Code 99024</u>

The AMA supports the RUC's recommendation to use CPT code 99024 *Postoperative follow-up visit normally included in the surgical package, to indicate that an E/M service was performed during a postoperative period for a reason unrelated to the original procedure* to identify the number of post-operative visits associated with a surgical procedure. This service is currently status "B" (bundled) in the Medicare physician payment schedule, and therefore is not paid. In addition, this code is already being reported by several large, hospital-based physician group practices that use the code internally to report each bundled post-operative visit.

The AMA agrees with the RUC that it is not appropriate to delineate incremental time from post-operative visits. The cost of requiring physicians to report their activities in 10 minute increments far outweighs the benefits. The CPT code 99024 should simply be reported once for each visit, to track the number of visits, and CMS should institute a separate process to track the level of each visit.

As we argued previously, there is relatively little to gain by tracking the level of each visit; however, we understand that the statute asks CMS to collect data on the level of visits in global codes. We agree with

the RUC that CMS should collect the level of visit data as part of its broad survey of physicians, that CMS describes as stage two of its data collection process. Additionally, CMS could create a separate, secure portal specifically to collect post-operative visit data. CMS could create a reporting pathway, separate from the survey process that would allow the data to be easily integrated among multiple reporting sites.

These processes would allow CMS to focus limited resources on high volume services, while also providing valuable data on the reliability of surgical package valuation. Using 99024 would also collect post-operative visits using the current E/M coding structure, ensuring continuity when determining if current global package bundles are valued properly.

The AMA supports the RUC's recommendations and urges CMS to adopt a data collection method that is limited in scope and utilizes a representative sample to better understand the necessary post-operative visits.

Implementation

The AMA believes if CMS changes the order in which it implements its three proposals, it would allow CMS time to work with the AMA and the RUC to develop a more feasible solution to collect information regarding the number and level of pre- and post-operative visits furnished in global services.

CMS could begin, as the statute instructs, gathering information from a representative sample of physicians on January 1, 2017, if it starts the information collection process with the third step—an in-depth study, including direct observation of the pre- and post-operative care delivered in a small number of sites, including ACOs.

CMS could then move to the second stage of information gathering they propose in the rule, which consists of surveying a representative sample of practitioners about the activities involved in and resources used in providing a number of pre- and post-operative visits during a specified recent period of time such as two weeks.

The AMA believes if CMS begins its data collection process with the in-depth study and survey of resources that it proposes in the rule, it would allow CMS time to work with the AMA and the RUC to develop an effective way to survey a random sample of physicians regarding the number of visits furnished in global services. In addition, we believe that the information gathered in the in-depth study and the survey regarding resources may help inform the development of the survey of physicians regarding the number of pre- and post-operative visits in global services.

Funding

The AMA believes if CMS plans to spend funding made available under the PAMA, it should conduct an updated survey on practice expense data. In 2007 and 2008, the AMA conducted the Physician Practice Information survey, along with 72 medical specialty societies and other health care professional organizations. The survey collected physician practice expense data that was used by CMS to confirm the accuracy of practice expense data in the Medicare Physician Fee Schedule. We believe that it would be beneficial for CMS to conduct a similar survey a decade later to confirm the accuracy of practice expense

data, given the many changes that have occurred since that time (e.g., the widespread adoption of certified electronic health record technology with its associated maintenance and staffing costs).

C. Geographic Practice Cost Indexes Update

CMS is required to update the Medicare Geographic Practice Cost Indexes (GPCIs) at least every three years, and has proposed changes to this element of the RBRVS in the eighth GPCI update. The key data sources to be used are the same as in the previous GPCI update, although CMS would be using more recent data. In particular, CMS is proposing to use Bureau of Labor Statistics wage data for 2011-2014 in calculating the physician work and practice expense GPCIs in place of 2009-2011 wage data. They are proposing to use residential rent data for 2009-2013 to calculate the office rent portion of the practice expense GPCI in place of 2006-2008 rent data. And, they are proposing to use 2014-2015 professional liability insurance (PLI) premium data to calculate the PLI GPCI in place of 2011-2012 premium data.

The methodology for calculating the revised GPCIs would remain the same under CMS' proposal, with a few notable changes. First, CMS is proposing to set the GPCIs for Puerto Rico at the national average of 1.0 in place of the current policy of using wage, rent and PLI premium data from the commonwealth to determine Puerto Rico's GPCIs. This would result in a substantial increase in Medicare physician payment schedule amounts in Puerto Rico, which has consistently been at the bottom of all Medicare localities in terms of physician pay. Second, CMS is proposing to implement a provision of the PAMA that would restructure the physician payment schedule localities in California based on metropolitan statistical areas. This would increase the number of payment localities in the state from nine to 27, with payment changes in some areas subject to a six year transition. Counties within some localities would have different GPCIs (and thus different payment amounts) during the transition. Finally, CMS is proposing a technical change to the methodology for dealing with missing PLI premium data that they state will reduce potential bias in calculating the PLI GPCI.

In the seventh GPCI update CMS sought comment on whether it should use a proprietary source it had identified for commercial rent data, instead of continuing to use residential rent data in the practice expense GPCI. The AMA has long objected to the use of residential rents as a proxy for physician office space costs, and encouraged CMS to explore the opportunity to improve the accuracy of the GPCIs. **We continue to urge CMS to explore the collection or use of commercial rent data, either as the basis for measuring geographic differences in physician office rents, or if this is not feasible, to validate the use of residential rents as a proxy.**

D. Expanding Access to Care Through Digital Health

The broad array of digital medicine tools and services has begun a fundamental transformation of health care delivery. The AMA is strongly committed to accelerating the adoption and integration of telehealth services into everyday practice in order to promote improved patient health outcomes, support care coordination, and improve communication. Our efforts to accelerate digital health uptake over the past five years have not been incremental, but strategic and focused. The AMA has modernized previously longstanding policy to account for rapid technological advances coupled with broad public access to new technologies that enable patient and physician interactions that were not possible in the past, launched federal and state advocacy efforts to update regulatory oversight and expand private and public payer coverage, invested in medical education initiatives to support physician fluency in this new ecosystem,

forged key collaborations with innovators, and begun rolling out tools to help physicians utilize these new technologies.

As we move forward there are many opportunities and challenges that will require focused efforts by CMS, physicians, policymakers, and other health care stakeholders. The AMA has gained significant experience in the area of digital medicine and has embraced policy priorities that CMS should consider as it finalizes the Rule. Namely, telehealth must be validated, evidence-based, actionable, and connected while preserving important patient protections that are time-tested and relevant today. **And, payers, including Medicare, must provide viable payment and reimbursement models.** For digital health to improve clinical practice in fundamental and new ways, digital medicine must bring patients and physicians closer together for the common purpose of improving health outcomes.

The AMA's range of telehealth and related digital health initiatives and efforts have covered the breadth of AMA focus areas and components. For example, the AMA has leveraged its role as a convener and hosted regular meetings with the national medical specialty societies to encourage the development of objectives and initiatives to support digital medicine adoption, including the use of telemedicine and mobile health apps. In addition, the AMA's focus on Accelerating Change in Medical Education initiative and grant funding includes participating medical schools promoting e-learning and innovations that encourage increased literacy and fluency in the digital medicine space. In another key focus area, the AMA offers an online tool kit, STEPS*forward*™, which is a medical practice transformation series comprised of a collection of interactive, educational modules developed by the AMA to help physicians address common practice challenges, including a module on Adopting Telemedicine in Practice. Each module addresses a specific challenge by offering real-world solutions, steps to implementation, practical examples, case studies, and downloadable tools and resources. Physicians and their practice staff can use these modules to help improve practice efficiency and ultimately enhance patient care, physician satisfaction, and practice sustainability. The telemedicine STEPS*forward*™, module highlights important considerations for physicians including applicable federal and state laws. In addition to the above areas of focus, the AMA has forged a broad number of partnerships with leading health care organizations and joined key collaborations with those also interested in telehealth technologies that work better for patients and physicians. The AMA continues to develop partnerships and collaborations that support the AMA's strategic focus area activities with outside innovators including:

- Ongoing monitoring and interaction with digital health companies connected to our focus areas.
- Collaboration established with a leading digital diabetes prevention company to scale physician referral into these programs.
- Efforts to build and disseminate principles and guidelines for digital health tools and applications.

Medicare Telehealth Services

The AMA applauds CMS' efforts to increase the number of covered telehealth services and supports the addition of new telehealth services/codes. However, the AMA urges CMS to maximize existing authorities and discretion to expand coverage of telehealth services that Medicare has determined have an established evidence base, but which only a limited number of beneficiaries are eligible to receive. We are at a pivotal juncture where the telehealth evidence base is well-established in some areas and rapidly growing in others. Significant technological advances continue, and practice transformation accelerated by digital health tools is needed in order to succeed in new payment and delivery models that are centered on improved patient health outcomes. While the AMA strongly supports CMS' proposed expansions of

telehealth, we are concerned that missed opportunities remain to significantly increase coverage to the benefit of Medicare beneficiaries.

We are aware that the Center for Medicare and Medicaid Innovation (CMMI) is engaged in telehealth activities through the Health Care Innovation Awards and the State Innovation Models initiative, with activities ranging from behavioral telehealth to telecardiology and teleneurology and other projects focused on chronic care management, remote patient monitoring, E-ICU services, and post-hospitalization care. However, we are concerned that the slow pace employed by CMS to expand coverage leaves Medicare beneficiaries and their physicians at a disadvantage in realizing improved outcomes and increased value. As noted in the recently released U.S. Department of Health and Human Services report to Congress, E-health and Telemedicine, Medicare spent less than $15 million on services delivered via telehealth in 2015, or less than 0.01 percent of total spending on health care services.

The AMA strongly urges CMS to finalize the rule to expand coverage of telehealth as proposed, and to develop a far more expansive set of strategic proposals that are cohesive and forward looking in order to expand coverage and access to telehealth services for Medicare beneficiaries in a meaningful manner and without creating barriers to delivery models and tools that improve medical care.

Proposed Addition of New Codes

The AMA strongly supports the addition of the following services for coverage under the telehealth benefit:

- CPT codes 90967 (End-stage renal disease [ESRD]) related services for dialysis less than a full month of service, per day; for patients younger than 2 years of age;
- 90968 (End-stage renal disease [ESRD] related services for dialysis less than a full month of service, per day; for patients 2–11 years of age;
- 90969 (End-stage renal disease [ESRD] related services for dialysis less than a full month of service, per day; for patients 12–19 years of age); and
- 90970 (End-stage renal disease [ESRD] related services for dialysis less than a full month of service, per day; for patients 20 years of age and older).

The AMA supports the qualification that the required clinical examination of the catheter access site must be furnished face-to-face "hands on" (without the use of an interactive telecommunications system). The AMA also supports the proposed addition of two advance care planning services to the telehealth list:

- CPT codes 99497 (advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health care professional; first 30 minutes, face-to-face with the patient, family member(s), or surrogate); and
- 99498 (advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health care professional; each additional 30 minutes (list separately in addition to code for primary procedure)).

In order to promote uniform and consistent coding across health care payers, clearinghouses, and providers, the AMA continues to strongly urge all health care stakeholders to utilize the CPT Editorial Panel process to seek the adoption of new codes to reflect new services or to seek code modification (where appropriate) including for telehealth. Nonetheless, at this time the AMA supports the proposal to make payment through new codes, initial and subsequent, used to describe critical care consultations furnished via telehealth (GTTT1 and GTTT2). CMS notes that this coding would provide Medicare a mechanism to report an intensive telehealth consultation service, initial or subsequent, for the critically ill patient under the circumstance when a qualified health care professional has in-person responsibility for the patient but the patient benefits from additional services from a distant-site consultant specially trained in providing critical care services. CMS proposes limiting these services to once per day per patient. The AMA appreciates the effort by CMS to identify telehealth services that may not otherwise be covered by existing CPT codes and we welcome an ongoing dialogue with CMS telehealth services staff to identify such services for consideration by the CPT Editorial Panel Telehealth Services Workgroup, and ultimately the Panel.

The CPT Editorial Panel organized its Telehealth Services Workgroup in September, 2015, with a charge to:

1. 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).
2. Address the accuracy of current code set in describing the services provided when telehealth data is reviewed and analyzed, including potential code set revisions and/or education for:
    a. Appropriate code use (e.g., E/M versus data analysis codes);
    b. Potential code development to report analysis of transmitted data;
    c. Definition of data types whose interpretation will require differentiation and consideration of separate reporting of current E/M services/codes; and
    d. Potential new E/M services codes based on emerging new patterns for sites of service.
3. Recommend whether any other telehealth service codes should be developed based upon services currently being provided.
4. Develop new introductory language or modify existing introductory language to guide coding of telehealth services. The Telehealth Services Workgroup also helps to facilitate discussions with key stakeholders who may wish to bring forward telehealth services applications for consideration.

Utilization of this process going forward would ensure that CMS has the full benefit of obtaining information from the physician community and a broad array of other stakeholders, including other payers, on whether the use of new coding would create a helpful distinction between telehealth consultations, for, example, critically ill patients relative to telehealth consultations for other hospital patients or how Medicare proposed services would be distinguished from existing critical care services and examples of different scenarios when each code would be appropriate.

Place of Service Telehealth Code

In addition, the AMA urges CMS to reconsider the proposed place of service code proposal as the AMA's CPT Editorial Panel has adopted a telehealth modifier for those medical services that are currently covered telehealth services by Medicare or other payers. The foregoing obviates the need for new place

of service codes. As Medicare and private payers expand coverage of medical services offered via telehealth modalities, the CPT Editorial Panel, as advised by its Telehealth Services Workgroup, will update the codes where it is appropriate to use the telehealth modifier.

DPP and Digital Health

On a related note, while encouraging and supporting innovation, the AMA is equally committed to ensuring digital medicine and prevention is implemented in a manner that protects patient safety and promotes improved patient health outcomes. The diversity of telecommunication technologies, clinical practice settings, and medical specialties, along with the rapid rate of innovation, are factors that should be carefully weighed. For that reason, the AMA applauds the CMS' proposals to expand the DPP option to include telehealth providers. Recently, the AMA announced collaboration with Intermountain and Omada, a CDC certified DPP. Omada became the first digital health company to publish peer-reviewed results demonstrating that program participants maintained reductions in body weight and average blood sugar levels—critical indicators of diabetes progression—two years after beginning the program. The AMA continues to encourage efforts to bolster the clinical evidence base in a targeted fashion to realize the beneficiary benefits.

E. Primary Care Payments

The AMA supports CMS' proposals to improve payment accuracy for primary care, care management, and patient-centered services. In response to CMS' CY 2016 PFS final rule, the RUC restructured its existing CPT/RUC workgroup on these issues and convened the relevant specialty societies to develop new CPT coding that would better address these services.

We welcome the ongoing CMS effort to work with the CPT Editorial Panel and the RUC to identify and expedite new ways to report and pay for high-value care collaboration and care management services. Specifically, two sets of new codes are scheduled to be included in the CY 2018 CPT code set in response to CMS' 2016 solicitation. One is a set of new codes describing services furnished under the Psychiatric CoCM and the other is a code for assessment and care planning services for patients with cognitive impairment. CMS cites the upcoming release of these codes, and states that some stakeholders urged CMS to facilitate Medicare payment for these and other new primary care management codes sooner than CY 2018 by proposing G-codes for CY 2017. We support CMS' efforts to develop interim G-codes until the full list of new CPT codes is released next year.

In addition, we support CMS' proposal to develop separate payment for non-face-to-face prolonged E/M codes. Strategies to enhance chronic care management are essential to improving patient health outcomes and bending the cost curve. As access to new technologies to facilitate effective and efficient communication between patients, their physicians and their medical team grows, CMS policies that promote such communications to facilitate care coordination and improved patient support are essential. We also support CMS' proposal to provide separate payment to recognize the work of physicians in assessing and creating a care plan for beneficiaries with cognitive impairment.

We provide detailed comments on each of CMS' individual proposals below. Please note we also provide separate comments regarding our concerns with CMS' proposal to create a new G-code for care of patients with mobility-related disabilities in Section G.

i. Non-Face-to-Face Prolonged Evaluation and Management (E/M) Services

The AMA strongly supports CMS' proposal to establish separate payment for non-face-to-face prolonged E/M codes instead of the current bundled status. Specifically, CMS is proposing separate payment for CPT codes for non-face-to-face prolonged E/M services by the physician (or other billing practitioner) that are currently bundled, and to unbundle CPT codes 99358 (Prolonged evaluation and management service before and/or after direct patient care, first hour) and 99359 (Prolonged evaluation and management service before and/or after direct patient care, each additional 30 minutes) for separate payment under the PFS. This proposal is critical to ensuring that many of the collaborative codes can be implemented for quality patient care that is supported by established and new tools. The proposal supports the provision of services that will address an area of substantial disease burden and cost to Medicare—chronic care. Increased flexibilities to provide chronic care management will ensure that patients and Medicare do not pay the tremendous cost associated with poor patient outcomes that inexorably drive higher costs and patient suffering.

ii. Separate Payment for Behavior Health Integration (BHI)

We support CMS' proposal to begin making separate payments for services furnished using the Psychiatric CoCM beginning January 1, 2017. We support the temporary use of G-codes (GPPP1, GPPP2, and GPPP3) for one year while the RUC develops valuation recommendations for CY 2018.

We also commend CMS' acknowledgement of the need for this model to be developed, while also supporting resource costs associated with furnishing behavioral health care management services to Medicare beneficiaries under related but different models of care. We support the creation of an additional code, GPPPX, to be used while more information is collected on how other behavioral health care models are being used and implemented.

iii. Increased Payment for Chronic Care Management (CCM) Services

The AMA supports CMS' proposal to begin implementation of other codes in the CPT family of CCM services including:

- 99487: Complex chronic care management services, with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation or functional decline; establishment or substantial revision of a comprehensive care plan; moderate or high complexity medical decision making; 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month; and
- 99489: Each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month.

We support CMS' implementation of these codes beginning January 1, 2017, and its adoption of CPT provisions regarding appropriate reporting of these codes. CMS also proposes to add a G-code, GPPP7, to improve payment for visits that may qualify as initiating visits for CCM services. We urge CMS to work with the CPT Editorial Panel to transition the code to a CPT code.

We also commend CMS' proposals to simplify CCM codes for physicians by not requiring 24/7 access to electronic care plans, the use of any specific electronic technology in managing a beneficiaries transition, the documentation of redundant information, or a specific method for obtaining beneficiary consent. We provide specific feedback on these issues below.

Electronic Care Plan

The AMA strongly supports CMS' proposal to remove the requirement that individuals providing CCM after hours must have access to the electronic care plan. We agree with CMS' reasoning that while health information systems that include remote access to the care plan or the full EHR after hours, or a feedback loop that communicates back to the primary care physicians and others involved in the beneficiary's care regarding after-hours care or advice provided may be helpful, imposing EHR-related requirements at the service level as a condition of PFS payment could create disparities between the fee schedule and other federal health IT incentive programs. We also appreciate CMS' recognition that not all after-hours care warrants follow-up or a feedback loop with the physician managing the beneficiary's care overall, and that desired feedback can be achieved through oral, telephone, or fax methods.

Similarly, we support CMS' proposal to no longer require individuals providing the beneficiary with the required 24/7 access to care for urgent needs to have access to the care plan as a condition of CCM payment. We again agree with CMS' reasoning that remote access to the care plan is not always possible, and is not always necessary to address urgent patient needs after business hours, and again appreciate CMS' recognition that transmission of the care plan may occur via fax. As such, we ask CMS to finalize its proposal to change the CCM service element to require timely electronic sharing of care plan information within and outside of the billing practice, but not necessarily on a 24/7 basis, and to allow transmission of the care plan by fax.

Clinical Summaries

The AMA strongly supports CMS' proposal to no longer require the use of any specific electronic technology to manage a beneficiary's care transitions as a condition of payment for CCM services, but rather to simply require the billing practitioner to create and exchange continuity of care documents in a timely manner. The billing practitioner is best equipped to determine how to exchange a beneficiary's care transition documents, and we agree with CMS that the method of transmission should not be a condition of payment for CCM services.

Beneficiary Receipt of Care Plan

CMS is proposing to simplify the current requirement to provide the beneficiary with a written or electronic copy of the care plan, by instead adopting the CPT language specifying more simply that a copy of the care plan must be given to the patient or caregiver. CMS notes that a specific format of the care plan should not be a condition of payment for CCM services. It also reasons that there may be times in which the patient will be better served when his or her caregiver receives the care plan (consistent with applicable privacy and security rules), rather than the patient himself. The AMA supports CMS' proposal and underlying reasoning.

Beneficiary Consent

CMS is proposing two changes to the advance beneficiary consent process that is required to receive CCM services. First, noting that it believes the consent process should be left to the practitioner and the beneficiary to determine the best way to establish consent, CMS proposes to permit the practitioner to document the beneficiary's oral consent in the beneficiary's medical record rather than requiring the practitioner to obtain written consent. Second, CMS is proposing to remove the language requiring beneficiary authorization for the electronic communication of his or her medical information with other treating providers as a condition of payment for CCM services due to this requirement's intersection with HIPAA. The AMA supports both of these proposals, as well as CMS' underlying reasoning.

Documentation

CMS proposes to no longer require the use of a qualifying certified EHR to document communication to and from home- and community-based providers regarding the patient's psychosocial needs and functional deficits and to document beneficiary consent. The AMA supports this proposal, as well as CMS' statement that the requirement to document the information in a certified EHR is redundant due to the CCM billing rules requiring documentation of core clinical information in a certified EHR format.

Rural Health Clinics and Federally Qualified Health Clinics

The AMA supports CMS' proposed revisions that would keep CCM requirements for Rural Health Clinics (RHCs) and federally qualified health centers (FQHCs) consistent with, and not more burdensome than, the CCM requirements for practitioners billing under the PFS.

iv. Cognitive Impairment Care Assessment and Planning

The AMA appreciates CMS' proposal of a G-code that would provide separate payment to recognize the work of a physician in assessing and creating a care plan for beneficiaries with cognitive impairment. However, we echo the RUC's comments that CMS should use the CPT code and RVU and practice expense values and inputs that RUC has recommended and provided in their comment letter.

F. Payment for People with Mobility-Related Disabilities

The AMA opposes CMS' plan to eliminate the 2017 physician payment increase Congress provided in MACRA in order to fund an add-on payment for services provided to patients with mobility-related disabilities. While the AMA supports payment policies that improve access to care for patients with these and other impairments, there is no justification for funding these services with an overall cut in physician payment rates. Following years of threats of significant payment reductions under the SGR formula, physicians had expected to receive a 0.5 percent update in 2017, as provided in MACRA. Proposals such as this one, which wipe out physician fee schedule updates based on perceived issues and solutions that are derived with virtually no input or validation from patients and physicians, will erode physician support for the Quality Payment Program prior to its full implementation.

We also believe the proposal raises program integrity questions, creates unequal coverage for care of disabled patients, covers costs physicians have already been at least partially reimbursed for, and increases out-of-pocket costs for patients with disabilities.

Additional Information Needed

In the proposed rule, CMS states that treating patients with mobility-related disabilities can require more physician time and increased equipment costs. To validate this argument, CMS notes that Medicare beneficiaries under age 65 have more difficulty finding a doctor who accepts Medicare than beneficiaries over 65 and that people with disabilities report worse experiences than people without disabilities on many quality measures. The AMA agrees with CMS that these are issues that need to be evaluated further, and taken into consideration when making policy decisions. However, these statistics do not necessarily illustrate a need for higher physician reimbursement or justification of a specific payment add-on ($44) when treating patients with mobility-related disabilities. The AMA urges CMS to work with stakeholders to conduct additional studies that will provide information on why younger Medicare patients have more difficulty finding a physician, and why certain quality measure scores may be lower among patients with disabilities. Once further studies have been done to diagnose the root cause of these issues, the AMA, along with the CPT Editorial Panel and the RUC, would like to work with CMS to develop an appropriate solution.

Program Integrity Issues

The AMA has serious program integrity concerns related to CMS' proposal to create an add-on code for physicians treating patients with mobility-related disabilities. There are no clear guidelines laid out regarding when physicians could bill for this add-on code. Physicians will likely have numerous questions regarding when they can bill for this add-on code including:

- What counts as a sufficient mobility problem to justify the $44 rate?
- What kind of documentation will they have to provide if audited?
- What if the patient could have been examined in a wheelchair but the physician put them on a special examining chair in order to charge the add-on fee?
- What if the physician brings in mobile x-ray or ultrasound equipment rather than moving a patient?
- Who decides when a patient with a temporary mobility problem no longer warrants a special fee?
- Would surgical patients who have a temporary mobility issue following surgery that require the use of a power table in post-operative visits be included?
- Are patients who can walk but can't hold still during an examination included in the group perceived to have mobility problems?
- What about patients who have trouble navigating due to eye problems that do not require use of a special examining table but are accommodated with special equipment or facilities that address their particular kind of mobility problems?
- Would ophthalmologists or other specialists who routinely use chairs that move up and down be permitted to charge an add-on fee for all patients?

We believe this proposal will create significant confusion about when physicians can bill this add-on code and which patients qualify as having a mobility-related disability.

Inconsistent Assumptions

In this proposal, CMS has bypassed the normal process and standing rules for valuing services in

fee-for-service Medicare. Normally, the program bases payment on "typical" patients with no distinction between those who have characteristics that makes it unusually difficult to treat them and those who do not. If special equipment is required, it would be recognized in the practice expense portion of payments and included in the calculation of all patients who use the service, which in this case is a physician visit. For example, an examining table required by the Americans with Disabilities Act (ADA) would normally be used by physicians for all patients, not just those who are disabled, and its cost would be included in practice expense and therefore apportioned among all patients, not just those who are disabled.

The AMA also questions CMS' utilization assumptions. CMS estimates the cost of implementation of the new code by assuming that seven percent of all Medicare patients will be eligible. However, we know from previous experience that implementation of new codes, even when they are more broadly accepted CPT codes, have not been reported consistently with these eligibility assumptions. For example, the Chronic Care Management (CCM) code and the Transitional Care Management code estimated utilization was projected based on Medicare beneficiaries eligible to receive the service and physician practices equipped to perform and report the codes. In reality, less than one-third of the expected utilization has been reported.

CPT Code	Projected Annual Medicare Utilization	2013 Actual Medicare Utilization	2014 Actual Medicare Utilization	2015 Actual Medicare Utilization	Actual / Projected Utilization (Year 1)	Actual / Projected Utilization (2015)
99490 CCM	7.7 million	N/A	N/A	827,141	11%	11% (year 1)
99495 TCM	1.3 million	162,104	301,662	374,164	12%	29%
99496 TCM	870,000	136,160	259,447	330,372	15%	38%

We urge CMS to use this previous experience to modify its utilization assumption for mobility impairment to 25 percent of the eligible patients. We believe that this is a reasonable adjustment, particularly as physicians may be reluctant to report a code that will lead to additional copayments for this vulnerable population.

Tax Policies Address Increased Equipment Costs

Currently, the ADA offers a tax credit which physicians can use to cover increased equipment costs for treating disabled patients. The tax credit can be used for architectural adaptations or the purchase of adaptive equipment by any business that, for the previous tax year, had either revenues of $1,000,000 or less, or 30 or fewer full-time employees. The amount of the tax credit is equal to 50 percent of the eligible access expenditures in a year, up to a maximum expenditure of $10,250. We believe most small practices that incur significant costs associated with providing adaptive equipment for mobility-disabled patients will be able to take advantage of this tax credit.

If the tax credit is not sufficiently covering costs for physicians to purchase adaptive equipment, the remaining 50 percent of the cost of equipment should be recognized in practice expense. If CMS has data showing physicians are not able to purchase adaptive equipment, we ask them to share it with the AMA and other medical specialty groups, who are willing to assist CMS in developing an appropriate solution.

Increases Copayment for Disabled Patients

The AMA is concerned that this proposal will increase the cost of copayments for individuals with mobility-related disabilities. Based on the proposed $44 add-on payment for physicians, patients with mobility-related disabilities will have an additional $9 copayment each time special equipment is required during a physician visit. As we stated previously, if there is an access issue for disabled patients or a reimbursement issue for physicians that treat these patients, we urge CMS to work with the CPT Editorial Panel and the RUC to develop a better policy to address the issue that does not negatively impact patients with mobility-related disabilities.

III. OTHER PROVISIONS OF THE PROPOSED REGULATIONS

A. Expansion of the Diabetes Prevention Program (DPP) Model

The AMA strongly supports CMS' proposal to expand the duration and scope of the DPP model with the establishment of the Medicare DPP. The DPP is a preventive service with proven benefits in helping patients with prediabetes avoid progressing to type 2 diabetes.

More than 11 million seniors, or 26.9 percent of the Medicare population, have diabetes and 26 million, half of all seniors over age 65, have prediabetes. In addition, one in every three Medicare dollars is spent on diabetes and its complications, such as cardiovascular disease. Diabetes is the leading cause of kidney failure, accounting for more than 44 percent of new cases of end-stage renal disease in 2011. Spending on Medicare beneficiaries with prediabetes and diabetes is estimated to be more than $2 trillion over the next 10 years, including $1.7 trillion in federal spending.

Mounting evidence has found appropriate interventions like the DPP model are effective at preventing type 2 diabetes and cardiovascular disease. The US Preventive Services Task Force (USPSTF) acknowledged the strength of this evidence when it gave a "B" grade to two companion behavioral counseling recommendations. First, in 2014, the USPSTF gave a "B" grade to intensive behavioral counseling interventions for cardiovascular disease prevention after evidence showed reduced cardiovascular disease risk in overweight or obese adults. This was followed in 2015 by a "B" grade for behavioral counseling to prevent the development of type 2 diabetes mellitus after evidence showed a moderate benefit. The USPSTF used the same terminology to describe the behavioral counseling recommendations for the prevention of heart disease and for type 2 diabetes mellitus: refer patients to intensive behavioral counseling interventions to promote a healthful diet and physical activity.

The language used by USPSTF includes physicians' referral and follow-up services as well as intensive behavioral counseling interventions. Physicians need to screen and test patients before making a decision to refer for counseling. As a first step, patients must be screened to assess their risk for diabetes, including calculating their body mass index (BMI) and evaluating their blood glucose level. If a patient's data confirms a diagnosis of prediabetes or type 2 diabetes, the physician counsels the patient on treatment options. Persons with prediabetes who are willing to make lifestyle changes are often referred to a DPP for intensive behavioral counseling. The referring physician communicates with the DPP provider to monitor the patient's participation and progress, then follows-up to reevaluate the patient's status and determine if he or she has successfully lowered their risk for developing type 2 diabetes.

As part of its Improving Health Outcomes Initiative, the AMA was an early supporter of the DPP and has partnered with the YMCA of the USA to encourage physician referrals to its DPP, which received a CMS Health Care Innovation Award and was the basis for the certification by the CMS Actuary cited in this expansion proposal. DPP participants meet as a group in a classroom setting or virtually for 16 core sessions with a trained lifestyle coach. During the sessions they learn how to make healthier food choices, incorporate more physical activity into their daily routine, and manage a healthy weight. After the initial 16 core sessions, participants meet monthly for added support to help them maintain their progress. Evidence shows that DPP participants maintain healthier behaviors three years later.

Medicare DPP Payment Model

The proposed payment model for the Medicare DPP is highly dependent on patient adherence in attending the sessions and health outcomes as measured by weight loss. The AMA urges CMS to give serious consideration to comments on this payment model that may be submitted by organizations with experience delivering the DPP to diverse patient populations. Adoption of a single one-size-fits-all payment model with no risk stratification could potentially lead to DPP providers cherry-picking locations for service delivery based on the probability that the patient population will attend more sessions, be more adherent to the education and counseling they receive, and be more likely to lose weight, while avoiding Medicare-Medicaid patients and others who might find DPP attendance and adherence more challenging.

Medicare DPP Eligible Beneficiaries

The AMA strongly supports use of the hemoglobin A1c test result between 5.7 and 6.4 percent as one of the eligibility criteria for the Medicare DPP. Just as CMS covers tests that are needed to diagnose other conditions, CMS needs to clarify the Medicare coverage policy for screening hemoglobin A1c tests so that it is clear that physicians should screen their Medicare patients for prediabetes using an hemoglobin A1c test and, if appropriate, refer them to the DPP.

The AMA supports the CMS proposal to permit beneficiaries who meet the proposed eligibility criteria to obtain Medicare DPP services by self-referral, community-referral, or health care practitioner-referral.

The differences between the eligibility criteria to participate in a DPP using CDC recognition program guidelines compared to the proposed criteria for Medicare DPP eligibility may be a barrier to appropriate utilization of the Medicare DPP benefit. The proposed fasting plasma glucose testing threshold of 110-125 mg/dL is higher than the threshold of 100-125 mg/dL in clinical guidelines for managing prediabetes. In his certification letter, the CMS Actuary explains that the progression rate to diabetes for individuals with an Impaired Fasting Glucose of 100 to 109 mg/dL is very low based on empirical studies, so excluding this group would place a greater focus on those, who are in the Actuary's view, far more likely to become diabetic. The AMA recommends that CMS continue to study this eligibility issue as it expands the model, as we are concerned that having varying standards for eligibility could lead to confusion, result in a missed opportunity to help patients with prediabetes, and limit physicians' ability to provide patients with evidence-based preventive care.

Program Integrity

CMS seeks comments on development of policies to monitor and audit Medicare DPP entities. The AMA has worked with the CDC over the past two years to engage physicians nationwide in diabetes prevention. As part of this work, the AMA has reviewed the CDC's existing Diabetes Prevention Recognition Program (DPRP) standards at length and is familiar with the CDC's process for implementing DPRP standards. CDC's DPRP standards are sufficient for ensuring program fidelity to the published evidence and CMS should work to avoid duplication or overlap with the DPRP framework. In particular, as many medical practices plan to set up on-site diabetes prevention programs, the administrative burden of ensuring compliance with standards and policies issued by two separate federal agencies could pose a significant barrier to the spread of this important population health intervention.

Enrollment of New Medicare Suppliers

The AMA does not support CMS' proposal to require Medicare Diabetes Prevention Program (MDPP) coaches to obtain a National Provider Identification (NPI) number. We do, however, support CMS' alternative policy, which would require DPP organizations to obtain the NPI number, is a more appropriate approach. CMS should also not require individual coaches to enroll in Medicare. Instead, CMS should require each DPP organization to obtain an NPI number, and collect and submit information to Medicare on the coaches who would deliver the MDPP services. This information could include identifying information such as first and last name, Tax ID number, date of birth, education, and state license if applicable.

Site of Service

The AMA appreciates CMS' proposal to cover both in-person and virtual participation in the Medicare DPP and its plans to monitor claims for virtual services seem reasonable. Patients should have options for evidence-based interventions that will work for them regardless of site of service. Evidence on the comparability of virtual diabetes prevention programs to in-person versions continues to grow and the AMA believes that having the option of a virtual program will allow a larger number of at-risk people to benefit from this risk reducing intervention.

Quality Monitoring and Reporting

CMS asks for feedback on what, if any, quality metrics should be reported by MDPP suppliers in addition to the reporting elements required on Medicare claims submissions. The AMA believes that no additional public reporting on quality metrics is necessary or useful at this time. The MDPP is a new program that will be significantly expanded in 2018. We believe that CMS should launch the program, and review lessons learned from the first few years of the program, prior to implementing any additional reporting requirements.

In addition, reimbursement under the MDPP is already contingent on performance, as DPP organizations will only be reimbursed if patients meet certain weight loss requirements. Therefore, there is already a quality component built into the DPP program to evaluate performance of DPP coaches. We urge CMS to refrain from implementing any additional quality metrics until the MDPP program has been successfully expanded.

Timeframe

The AMA strongly recommends that CMS expand the Medicare DPP nationally in year one to allow all Medicare patients with prediabetes to benefit from it. Based on the evidence, due to their age group Medicare patients are at increased risk of progressing to type 2 diabetes from prediabetes and therefore stand to benefit the most from rapid scaling-up of the MDPP program. It remains unclear how CMS determines eligibility in phased implementation. Organizations have been delivering CDC-recognized programs for years, deeming a phased-in approach unnecessary.

B. Open Payments Program

CMS requests comments on possible changes to the Open Payments program in order to inform future rulemaking. The AMA appreciates CMS' effort to respond to stakeholder feedback in requesting these comments, and provides detailed feedback below.

Suggested Improvements to the Open Payments System

The AMA agrees that the Open Payments program was intended by Congress to create transparency around the nature and extent of relationships that exist between drug, device, biologicals and medical supply manufacturers, and physicians and teaching hospitals (covered recipients and physician owner or investors). At the same time, Congress provided that certain transfers should be exempt from reporting in order to avoid chilling the transfer of information that directly benefits patients, for instance, and it is safe to say that Congress supported transparency of accurately reported data.

We are pleased that CMS is considering a requirement for applicable manufacturers and applicable group GPOs to pre-vet payment information with physicians and other covered recipients. The vast majority of the Open Payments program data has not been validated beyond the manufacturers and GPOs as most physicians have faced significant barriers accessing the Open Payments dispute resolution online portal offered by CMS and, as a result, physicians have been effectively unable to dispute inaccurate reports without expending substantial time and resources.

The AMA has repeatedly urged manufacturers to provide physicians with an opportunity to review physician data before it is transmitted to CMS. A growing number of manufacturers have incorporated this important feature in their Open Payments compliance efforts in order to ensure accurate data is reported to CMS in the first instance. We look forward to CMS' identification of effective methods and models that have been successfully implemented. This would help to prevent the transmission of erroneous data to CMS.

CMS also requested suggestions on ways to streamline or make the Open Payments process more efficient. The AMA has long standing concerns with CMS' decision to expand the scope of the reporting requirements to include journal reprints, medical textbooks, and other educational materials that directly benefit patients or are intended for patient use. The inclusion of these materials in the Open Payments system is not consistent with congressional intent and has added significantly to the reporting burden. Predictably, it also has served as a deterrent for physicians to agree to accept these educational materials. The AMA urges CMS to simplify the reporting requirements and to support medical innovations that directly benefit patients by following congressional intent and excluding educational material from the Open Payments System.

C. AUC for Advanced Diagnostic Imaging Services

As part of the PAMA, Congress directed CMS to develop a program that would require physicians as of January 1, 2017 to consult AUC prior to ordering advanced diagnostic imaging services. In the 2016 payment rule, CMS laid out the requirements that organizations must meet to become "provider-led entities" (PLEs) eligible to develop the appropriateness criteria physicians could consult to meet the requirement. CMS also said that it would develop a list of priority clinical areas for use in meeting PAMA's precertification requirement for outlier ordering physicians and acknowledged that implementation would be delayed beyond the statutory deadline. A list of 11 organizations that have qualified as provider-led entities was published in June.

In the proposed 2017 rule, CMS has taken the next step by laying out rules that clinical decision support mechanisms (CDSMs) incorporating approved AUC sets must meet in order to be deemed to meet PAMA's consultation requirement. These include a requirement that at a minimum, the CDSM must cover eight priority clinical areas and about 70 diagnosis codes that were chosen because they generate a large percentage of advanced diagnostic imaging services. A list of qualified CDSMs would be published in June 2017. In addition, CMS must offer one free tool, which is expected to be a web-based product or products developed by one or more PLEs. Based on this timing, CMS thinks it is possible that required AUC consultation might start on January 1, 2018.

The AMA agrees that the January 1, 2017 implementation date set in PAMA was unrealistic and we are pleased that CMS is proceeding at a more deliberate pace. In fact, because these changes will come at a time when physicians are also grappling with hundreds of pages of new MACRA-related rules and regulations and because we believe more time will be needed to work out key details in the process, we think **full-scale implementation should be delayed to January 1, 2019, rather than 2018.** It is also our view that AUC implementation should be phased in over time starting with a list of priority conditions that could be specialty-tailored. **Earlier implementation or testing of more robust systems could be considered for large healthcare systems that have already adopted system-wide criteria,** including several of the 11 qualified provider-led entities. We have concerns that at least one of the approved PLEs appears to be a radiology benefits manager in disguise, which, if true, would undermine physician support for AUC and subvert the program's intent.

<u>Priority Clinical Areas</u>

The AMA agrees that identification of outlier physicians should be based on advanced imaging orders within priority clinical areas and that initially, AUC should focus on these areas. We have several reservations about the approach that is proposed in the rule, however. One potential problem centers on the use of diagnosis codes to define priority conditions since diagnosis codes often are not known until the test is completed. Another involves CMS' decision to use volume and utilization as the only determinant of priority areas.

As an alternative to diagnosis-based conditions, CMS could explore a list of priority areas based on CPT codes and anatomical region. With regard to how priorities should be identified, we note that CMS itself appears to have some doubts about the use of volume as the sole determinant. We share that doubt and urge CMS to pursue an approach that also considers variation in treatment and quality of the evidence in determining priority areas sooner rather than later. CMS raises the possibility of considering these factors in the future but unless changes are made before CDSMs are identified and begin operations, we fear that

changes would not be possible until reapplications are required five years later. **A better solution would be to delay implementation until 2019 so that CMS could develop a more relevant and productive priority list before a far less promising list is baked into the CDSMs for five years.**

AUC Consultation Mechanisms and Process

The AMA appreciates CMS' recognition that this is a new program that should provide CDSMs with flexibility in the way they design their products so that physicians have an array of products and can select the one that best meets their needs. We therefore concur that although CDSMs should be held to some standards regarding the number and type of criteria they incorporate, they should not be required to include criteria for every possible advanced image a physician might order. The question then becomes what should that minimum set of criteria look like and should it be the same for all physicians. CMS' answer is to require all CDSMs to incorporate and all physicians to consult appropriateness criteria for each of the clinical priority areas. The AMA believes a slower phase-in of the required consultations would be more realistic.

While primary care physicians are likely to deliver care in all of the priority areas, they will also be subject to very significant administrative burdens associated with MACRA implementation. It also is not clear that these physicians will have enough cases in all of the priority areas to accurately judge their performance when the "outlier" policy kicks in several years from now. It is possible that a more targeted list of priority areas that considers additional features discussed above will produce a smaller and more manageable number of priority areas. If it does not, **CMS should examine ways to reduce the burden of reporting for primary care physicians, including a more limited clinical priority list.**

The AMA also believes that for most specialists, requiring consultation for services outside their area of expertise will serve only to increase growing frustration with Medicare paperwork. **In our view, it likely would be more productive to give specialist physicians the option to purchase and consult specialty-specific CDSMs that include several sets of criteria for services normally ordered or performed by that specialty**. The option might be less expensive than what CMS is proposing and could be especially useful on complex cases where consultation of multiple criteria might make the ordering physician aware of a wider array of alternatives and/or issues to be considered. If claims data showed that some physicians within the specialty were frequently ordering advanced imaging outside their specialty's normal services, additional steps could be taken, including potentially requiring physicians with more than some specified number of such claims for services not normally provided by this specialty to consult a product that included all the priority areas.

The AMA also has questions regarding CMS' expectations for consultation on imaging decisions that are not covered in a physician's CDSM. Although this is not clearly stated, the rule appears to say that physicians must consult their CDSM even for services they know it does not cover and the system must then generate a note that says the criteria were "not applicable." In a CDSM that is embedded in an electronic record that automatically consults criteria for each order, this may not be a significant issue. However, we expect that the free product(s) will be web-based and that consequently a significant number of physicians will be using a web-based CDSM, which will require the physicians or their staffs to spend considerable time keying information into the web even when they know it will not provide any useful information. **We therefore believe that consultation of criteria that are not included in a physician's CDSM should be optional.**

CDSM Qualifications and Requirements

While CDSMs have the potential to provide value to physicians, their success will be dependent on technology's ability to support the collection of data and how information is provided back to the physician. Many physicians continue to encounter health IT integration issues in their clinical environment. The use of these tools, while required by CMS to comply with various reporting programs, often does not meet physician needs and does not always provide value back to the physician. (In previous comments, the AMA has provided examples of health IT products designed to meet federal reporting or certification requirements that provide little to support patient care.)

The AMA therefore was pleased that CMS did not propose to require the CDS mechanism to be Office of the National Coordinator for Health Information Technology (ONC)-certified or identify a technology standard. We believe this is necessary in order to facilitate and accommodate significant innovation that is expected to occur over the next few years. However, we are concerned with specific aspects of CMS' proposal that fail to recognize that the **ultimate goal of a CDMS should be supporting physicians' clinical decision making, not accommodating federal reporting requirements.**

CDSM and Health IT Alignment

While the AMA supports CMS' decision not to require CDSM certification, we foresee a possible disconnect between the proposed CDSM qualification timeline and EHR certification. It is crucial that, for there to be any degree of interoperability between qualified CDSMs and EHRs, there are shared common standards to enable the exchange of clinical information. It is likely that EHRs certified by ONC will undergo recertification as standards needed for interoperability evolve. Given the history of ONC's Health IT Certification Program we expect this cycle to repeat at least twice within the next five years alone. The AMA is concerned that a five-year application and approval cycle for qualified CDSMs will limit the opportunity to align EHR security and interoperability standards with those of CDSMs. **The AMA cautions CMS to consider the impact of changes to the EHR certification requirements on integrated qualified CDSMs and recommends that CMS consider future alignment between the two programs to ensure system functionality and maintain clinician productivity.**

Interoperability and Usability of CDSMs

The proposed rule discusses how, ideally, physicians would interact directly and "seamlessly" with the CDSM through their primary EHR user interface—thus minimizing interruption to the clinical workflow. CMS further observes that adhering to common interoperability standards, CDSMs could both ensure integration of patient-specific data from EHRs and allow clinicians to optimize the time spent using the tool. While we agree that would be ideal, it is unrealistic at this time, and we remain skeptical that CMS can effectively mandate or describe an ideal clinical workflow through regulations since practice transformation evolves faster than regulations can change.

Providing a free CDSM to physicians, as required under PAMA, is also laudable. However, a standalone CDSM introduces additional issues. As noted above, without tight clinical workflow integration, many physicians and staff will need to remove themselves from patient care in order to transcribe information from the EHR into a separate third-party application or website. This will drastically increase the data entry burden—further increasing physician dissatisfaction with their health IT tools, adding human error, or ultimately delaying patient care.

The AMA has therefore identified two major concerns. First, given the data-entry burden associated with a free web-based tool, we expect that most physicians will request their CDSM to be integrated within their EHRs. This will require additional functionality from their EHR vendors; however, forcing physicians to pay their EHR vendors and the CDSM vendor for what undoubtedly will become a "custom" interface. We expect this to trigger a new wave of health IT costs just as physicians are also facing significant costs related to the upcoming MACRA requirements.

Second, CMS proposes a number of new items that must be included on the claim form in order for the furnishing professional to be paid. In any case where consultation of the AUC is followed by an order, the furnishing professional must supply the ordering physician's AUC-use information to CMS. In many instances, the ordering physician and furnishing professional will not share the same office space, EHR, or technology platform. This will demand new or additional health IT interoperability between the ordering physician's EHR and the imaging center's systems. As many diagnostic imaging professionals are not utilizing EHRs, the exchange of this information could potentially become resource and time intensive for both groups. It is not clear if CMS has taken this issue into account or factored this into the proposed timeline.

While technology will eventually advance to resolve these issues, the AMA is concerned that CMS is proposing to once again take a "build it and they will come" approach—that is, by creating a multitude of programmatic requirements, CMS believes health IT vendors will develop highly-useable and low-cost products physicians will need for participation in reporting programs. As AMA has repeatedly pointed out, this approach is unlikely to work and has created a multitude of ongoing problems and downstream issues related to the Meaningful Use Program.

Given the number of technical and workflow challenges identified above, the AMA urges CMS to: **1) postpone the CDSM and AUC implementation data to no earlier than January, 2019; and 2) develop an automatic hardship exemption for any physician who does not have access to low-cost integrated CDSMs.** Emerging technologies—like SMART or FHIR—will enable a user-focused health IT ecosystem and, at this time, we urge CMS to take a measured approach with CDSM policy.

Privacy and Security

As evidenced by a number of recent health IT data breaches, the need for strong privacy and security measures is critical in protecting patient health information. While it is notable that CMS' proposal requires CDSMs to meet privacy and security standards under applicable provisions of law, each health IT component introduced into the flow of medical data increases the opportunity for unauthorized access to protected health information. Additionally, CDSMs that are not integrated with an EHR, or are hosted online, can be expected to have an even greater need to be secured against the growing frequency, scope, and sophistication of cyberattacks. **The AMA urges CMS to reevaluate its privacy and security requirements for qualified CDSMs and incorporate recommendations from the National Institute of Standards and Technology (NIST) voluntary framework for reducing cyber risks to critical infrastructure.**

CDSM Disqualification

CMS proposes removing CDSMs from the qualified list at any time if they fail to meet specific criteria. While the AMA concurs that there is a need to maintain an accurate and curated list of qualified CDSMs,

we are concerned that CMS has not proposed sufficient protections for those physicians who, through no fault of their own, may end up utilizing CDSMs that are subsequently disqualified. The AMA has provided similar comments to CMS and ONC relating to EHR decertification. **In both instances, we urge CMS to develop a hardship exemption to protect physicians for no less than two years after a health IT tool is disqualified or decertified.** This time is necessary for physicians to research, purchase, implement, and train themselves and their staff on new health IT products and tools.

Furthermore, CMS' proposal to "at any time" remove a CDSM from the qualified list may inadvertently disrupt diagnostic image ordering. Without a probationary period, some CDSM systems might immediately discontinue their service. Deactivating a CDSM may lead to downstream repercussions and could cause a breakdown in diagnostic workflows. **The AMA requests that CMS implement a process to temporarily suspend CDSM qualification before a CDSM is disqualified.** Qualification suspension will also provide CDSM vendors time to resolve any identified issues. **The AMA also requests that all CMS CDSM qualification reviews be conducted in a transparent manner and be made available to the public.**

Timing and Related Considerations

This proposed rule envisions a complex system that would track consultation and response any time a physician consulted AUC criteria whether or not a service was actually ordered. The AMA acknowledges that in order to identify "outlier" physicians, it will be necessary to evaluate how the services they ordered compared to the relevant AUC. We also agree that knowing about consultations for services that were not ordered can provide important information for individual physicians and for AUC developers. However, we have serious reservations about the feasibility of incorporating and transmitting the required information immediately. As noted earlier, we foresee problems in transmitting data between the ordering and furnishing physicians. It is also not clear that the required information can be incorporated on the current claims form without significant modifications. **We therefore urge CMS to reconsider inclusion of AUC-related data on all imaging claims until more experience is gained with the requirement, physicians and vendors have had time to modify and test new systems, and potential modifications in the claims form have been considered and moved through the existing process.**

As currently proposed, furnishing providers would be required to include: (a) which qualified CDSM was consulted before ordering the imaging service; (b) whether or not the ordering adheres to the AUC; and (c) the NPI of the ordering physician. There is already a place for the ordering physician NPI on the claim, so no new data element would be needed for this information; however, items (a) and (b) represent new data on the claim. Reporting this additional information on every imaging claim would be extremely burdensome to providers in multiple respects. Beyond the obvious additional work associated with entering more data elements on claims, this information, as noted earlier, would somehow need to be communicated between ordering and furnishing providers, as the physician ordering the imaging service in most cases will be different than the physician performing the imaging. We are also concerned that inclusion of these additional data elements on the claim could lead to adjudication errors and disruption of claims processing and payment.

There could also be challenges in adding these new data elements to claims by January 1, 2018. First, the implementation guides for the next version of transactions (7030) from X12 (the claims standards development organization) are currently being finalized, so these data elements could not be formally added to the claim for a number of years. (We expect 7030 to be implemented in approximately 2021 or

2022, and these new elements would be added in the subsequent version of the claim.) CMS could work with X12 to add the data to the claim more quickly through the K3 segment of the electronic claim, which is reserved for new data required under legislation and regulation. However, this is in principle a free text segment – which makes it harder to program and process and CMS would need to move quickly to go through the X12 process and give physicians and vendors time to prepare for the change.

Alternatively, the CDSM data could be reported using modifiers or G codes. However, there are a number of MACRA-related provisions (including codes for physician-patient relationships, patient condition and episode groups) that must also be captured on claims forms in the near future and it is highly unlikely that all of these elements can be built into the current claims form. **Consequently, it is our recommendation that CMS create an agency-wide task force to work with the claims standards organization to simultaneously address all the demands that are about to be placed on the claims form**. In the interim, especially if CMS does not accept our advice that implementation be delayed for a year, we suggest **that CMS could ask physicians to annually attest, subject to audit, that they are consulting a CDSM prior to ordering relevant advanced imaging services.** If CMS is determined to proceed with a 2018 implementation date, CMS should assume for the purposes of measuring compliance that physicians who have demonstrated consultation of the criteria on the services they do order are also consulting criteria for services they do not order.

Exceptions

The AMA supports all the exceptions called for in the proposed rule along with the aforementioned additional exception related to disqualification of a physician's CDSM. We also are concerned that the actual regulatory language of the rule is not consistent with the preamble discussion indicating that physicians would not need to do an AUC consultation for a patient with an emergency medical condition even if the condition later is determined not to have been an emergency. **In view of the fact that it will be impossible to draw statistically valid conclusions about imaging patterns of physicians who rarely order images, we suggest that CMS also create a low volume exception.**

D. ACO Participants Who Report Physician Quality Reporting System (PQRS) Quality Measures Separately

The AMA appreciates CMS' proposal of an alternative reporting period for the 2017 PQRS payment adjustment for individual EPs or group practices that bill under the TIN of an ACO participant, but where ACO failed to report on their behalf during the previously established reporting period for the 2017 PQRS payment adjustment. We have heard from practices that tried to join an ACO during the 2015 PQRS reporting period, but for logistical reasons the ACO seized operations mid-reporting period and the practice could not submit alternative quality data for the purpose of satisfying PQRS and VM requirements. We believe the secondary reporting period proposal for the 2017 PQRS payment adjustment (January 1, 2016 through December 31, 2016) is an attempt to resolve this issue and allow physicians an opportunity to avoid the 2017 PQRS and VM adjustments.

Recommended Modifications

The AMA would prefer a waiver for physicians that fell under the scenario highlighted above since the physician and/or practice made the good faith effort to move towards adopting an alternative payment model—a priority for the Administration. Under CMS' proposal, a physician must be concerned, without

advance warning and toward the end of the reporting period, with ensuring their 2016 data is perfect since it will count towards two program years.

In addition, as part of the proposal, CMS highlights that it will only accept clinical data registry, qualified clinical data registry (QCDR) or EHR data and not allow claims or web-interface data to qualify under the secondary reporting period. CMS provides no reasoning or justification for the restrictive policy. Claims based reporting is still the most popular individual reporting option under PQRS and web-interface is the most successful and most popular reporting option for group practices. Physicians and group practices are in the middle of reporting for 2016 and were unaware of this caveat at the beginning of the 2016 reporting period. Potentially, many physicians will still be subject to a 2017 PQRS payment adjustment if CMS moves forward with its proposal to not accept claims or web-interface data. CMS has essentially provided no warning or notice to physicians about this proposal and it is unrealistic to expect practices to switch reporting mechanisms more than half way through the reporting period. Many EHR and registry vendors stop accepting new clients or data in the Fall, and in many cases transitioning to electronic sources of reporting requires significant system upgrades. **Therefore, to ensure fairness and the best opportunity for success under PQRS and VM, we urge CMS to accept all reporting options for the secondary reporting period.**

We are also concerned with the timeline related to the roll-out of the payment adjustment reversals given physicians and practices must first be subject to an adjustment in 2017 before CMS potentially reverses the penalty. More specifically, we are concerned with the impact of the PQRS adjustment. It will potentially take six to nine months before the penalty is reversed, which will create a dilemma for "non-participating" physicians who accept lower (95 percent) Medicare payment rates in return for being allowed to bill patients up to 115 percent of that lower allowance. Because PQRS adjustments apply to the Medicare allowed amount rather than the Medicare paid amount, these practices presumably will be forced to reduce what they bill their patients to reflect the PQRS penalty. Once Medicare removes the 2 percent penalty, it could go back and collect an additional amount from patients but this could be a huge administrative burden that we are not sure CMS has considered. One alternative would be to simply hold claims until CMS makes the correction and another would be to bill the lower amount and forego the additional money they could have collected once the PQRS penalty was removed. For many practices, either of these alternatives could have serious financial repercussions just as they are facing the need to make large investments in practice and system upgrades in preparation for MACRA changes. Alternatively, a practice could bill the lower amount and then go back and try to collect the correct amount from their patients, but this would be a serious administrative burden and would be difficult to explain to patients.

E. Value-Based Payment Modifier (VM) and Physician Feedback Program

As noted in the proposed rule, CMS encountered substantial flaws in 2014 PQRS data that created errors in the calculations of 2016 PQRS and VM payment adjustments. Although CMS had intended to address such situations through the informal review process, it concluded that the errors were too numerous and too diverse to address this way. Instead, it attempted to hold the affected practices "harmless" from any errors in the data by designating those with "low" quality scores as "average." The problem with this approach, as pointed out by the AMA at the time, was that it did not provide adequate protection in the case of practices which had "high" cost scores and therefore still experienced a VM penalty even though had it not been for the data errors, they might have had a high quality score that would have offset the high cost score and enabled them to avoid the VM penalty.

In a modification that the AMA very much appreciates, CMS is now proposing that in the future it will also protect practices in these situations from negative consequences on the cost side as well as the quality side. That is: in those cases where there are widespread issues with PQRS or claims data or when an informal review reveals a miscalculation, CMS will now designate both "low" quality and "high" cost scores as average. We believe that this new policy will improve equity in the program and alleviate physician cynicism regarding value-based payment. It is somewhat disheartening to learn from the discussion that CMS can "foresee that several of the issues that impacted the CY2016 VM …may continue."

F. Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs)

The AMA has significant concerns regarding CMS' proposals to change the quality measures that ACOs report. We also continue to urge CMS to improve its risk-adjustment model to ensure that MSSP participants who treat socio-disadvantaged patients are not unfairly penalized.

In addition, we urge CMS to recognize that ACOs should be able to utilize health information technology in ways that best and most effectively meet the needs of their patient population, as opposed to being required to comply with prescriptive regulations. More flexible health information technology requirements will help ensure the MSSP is aligned with the QPP.

Finally, we commend CMS' proposal to incorporate a process for patient choice into the ACO assignment methodology. The AMA has advocated that allowing patients the opportunity to choose their principal physician, and have ACO assignment based on that patient choice, will significantly improve the ACO assignment process.

Changes to Quality Measures

The AMA has serious concerns with CMS' proposals related to ACO quality reporting including the proposed changes to the quality measures used to assess ACO performance and the risk adjustment model used by CMS for these measures. We offer extensive comments related to quality measures that fall under the Care Coordination / Patient Safety domain below.

ACO-8, Risk-Standardized, All Condition Readmission:

The AMA is concerned that the All Condition Readmission measure is inherently flawed, does not provide a comprehensive picture of care, and can be viewed as a misrepresentation of quality of care that patients receive.

The All Condition Readmission measure, along with the other admission measures in the measure set, are currently undergoing National Quality Forum (NQF) review. As a result, we are concerned with conflicting information that may result from the review and potentially result in changes, including loss of its NQF endorsement status. As specified the measure does not account for any reduction in the denominator as rates in admissions decline. As a result, it does not provide a comprehensive picture and could be viewed as a misrepresentation of the quality of care that patients receive. Therefore, **we do not support the inclusion of the measure in the measure set.**

The AMA also remains concerned that the risk adjustment model in this measure does not adequately address the ongoing concerns around socioeconomic factors (SES). The traditional approach of risk adjusting at the patient level is appropriate for those measures with a discrete point in time measurement such as in-patient mortality rates, as those measures are less likely to be influenced by external factors. For measures where the measurement period includes care that is outside of the control of the hospital, and a 30-day post-acute phase where the availability of community supports and other resources will directly impact a patient's care, it is critical that CMS incorporate a risk adjustment methodology that looks at those factors at varying levels. We believe that there may be community-level variables that could impact the risk model of this measure that are not addressed. This omission is very likely due to the lack of available data and the fact that the current NQF measure evaluation criteria explicitly limits the risk adjustment methodology to patient factors. Measures that extend beyond the hospital stay or are outside the locus of control of the measured entity should continue to have SES adjustment addressed and new factors analyzed at different levels (e.g., patient, hospital, and community). **CMS should continue to explore new variables that are directly related to the community in which a patient resides, and work with NQF to revise its criteria to be more broadly inclusive of the levels at which adjustment should be examined.**

<u>ACO-36, All-Cause Unplanned Admissions for Patients with Diabetes; ACO-37, All-Cause Unplanned Admission for Patients with Heart Failure; ACO-38, All Cause Unplanned Admissions for Patients with Multiple Chronic Conditions:</u>

As highlighted earlier, these three measures, along with the all-cause readmission measure are currently undergoing NQF measure maintenance review. The AMA remains concerned that the risk adjustment model does not adequately address the ongoing concerns around socioeconomic factors (SES). As noted by the NQF All-Cause Admission and Readmission Committee and the developer (Yale/CMS), the analyses demonstrated that Accountable Care Organizations (ACOs) with higher numbers of low-SES patients performed worse than the national rate. These shifts in performance scores based on SES adjustment indicate that there may be other variables influencing admission rates that are outside of the ACO's control such as community-level factors. This omission is very likely due to the lack of available data and the fact that the current NQF measure evaluation criteria explicitly limits the risk adjustment methodology to patient factors. Measures that include factors that are difficult for ACOs to influence such as community supports should continue to have SDS adjustment addressed and new factors analyzed at different levels (e.g., patient, ACO, and community). The developer should continue to explore new factors that are directly related and at the community level. We urge CMS to work with NQF to revise its criteria to be more broadly inclusive of the levels at which adjustment should be examined.

<u>ACO-43, Ambulatory Sensitive Condition-Acute Composite:</u>

This is an Agency for Healthcare Research and Quality (AHRQ) composite measure, currently used in the physician VM program, which includes reporting on admissions related to dehydration, bacterial pneumonia, and urinary tract infections. Other ambulatory sensitive condition measures (heart failure and COPD) are currently in the measure set but are proposed to be removed and we support the removal. We appreciate that CMS has given consideration to using the same measures in the Value-Modifier/Merit-Based Incentive Payment System so that clinicians and ACOs have aligned quality goals; however, **we do not believe these measures add value to the measure set and continue to oppose inclusion of the measures.** We also continue to maintain our position that we do not support the acute composite for use in the MIPS program.

Generally, we have concerns about including additional utilization measures as the measure set already assesses unplanned admissions for heart failure (ACO-39) and multiple chronic conditions (ACO-38). Additionally the incentive to drive towards fewer admissions is imbedded in MSSP with strong spending targets. Where CMS should include utilization metrics as a quality measure are areas in which it is concerned there will be underutilization. Focusing in this way will help CMS arrive at a parsimonious measure set that is truly meaningful to clinicians and beneficiaries, and can monitor for unintended consequences of the program. In addition, the composite was intended to be implemented and reported at the metropolitan area or county level (per 100,000) and has been endorsed as such by the NQF. **Given the changes that are needed for implementation in this program, such as removing the per 100,000 calculation, we believe that the reliability and validity of this measure is not known and should be vetted by NQF and the public with the opportunity to comment prior to implementation in a payment program.**

CMS notes that this measure will be risk-adjusted for demographic variables and comorbidities. We, however, have concerns with this general statement as CMS has not provided any specific information in terms of the methodology it plans on utilizing, including variables. The AHRQ testing submitted to NQF on the PQIs demonstrated that risk adjustment is needed, particularly around SDS factors. AHRQ's testing and risk models endorsed by NQF included poverty level and **we urge CMS to incorporate and transparently publish the results using the same methodology, as well as incorporate community level factors.**

ACO-12, Medication Reconciliation Post- Discharge:

CMS proposes to replace the Documentation of Current Medications in the Medical Record measure (ACO-39) with Medication Reconciliation Post-Discharge (ACO-12, NQF #0097). This measure was previously replace by ACO-39 but is being proposed because it was recommended by the Core Quality Measure Collaborative. **We support replacing ACO-39 with Medication Reconciliation Post-Discharge and ask that CMS work closely with the measure developer to ensure the Group Practice Reporting Option web interface specifications and guidance are accurate and align with the intent of the measure.**

ACO-44, Use of Imaging Studies for Low Back Pain:

This measure, which looks at the percentage of patients with a primary diagnosis of low back pain who did not have an imaging study (plain x-ray, MRI, CT scan) within 28 days of the diagnosis, is proposed to address a gap in measures related to resource utilization, and align with the ACO measures recommended by the Core Quality Measures Collaborative core measure set. This measure, if finalized, would be calculated using Medicare claims data. **While we appreciate CMS' efforts to align measures across the public and private sectors, this measure is not appropriate for the Medicare population as ACOs will have few cases to report since the measure assesses care for individuals ages 18-50.** Given the possible small case sizes, CMS seeks comment on if this measure should be phased in to pay for performance or whether it should remain pay for reporting for all three performance years. We do not believe this measure adds value to the measure set for Medicare ACOs. **At a minimum, CMS must maintain the measure as a pay for reporting measure**; however, we note that all ACOs would be successful reporters since the measure is calculated by CMS using claims data. We agree that overuse of imaging is an important area to address and ask CMS to consider simply calculating the measure and providing information to ACOs through confidential feedback reports rather than adding the measure to

the program. Moreover, CMS is gradually implementing policies to require clinicians to consult with appropriate use criteria prior to ordering imaging services. We believe CMS should focus efforts on implementing the appropriate use criteria policies and developing measures of imaging overuse that are appropriate for the Medicare population. **We do not support including Use of Imaging Studies for Low Back Pain in the program measure set.**

Alignment with the Quality Payment Program (QPP)

The AMA urges CMS to avoid overly prescriptive regulations for ACOs' use of health information technology. Instead, CMS should continue to recognize that ACOs are best equipped to improve the health of their patients when they are able to utilize health information technology in ways that best and most effectively meet the needs of the ACO's patient population.

CMS states in the proposed rule that its goal is to align the MSSP with QPP proposals and proposes to do so by expanding the scope of clinicians measured by ACO Measure #11 (ACO #11), which assesses the degree of CEHRT use by primary care physicians participating in the ACO. CMS proposes to change the specifications of the measure to assess the ACO on the degree of CEHRT use by all eligible clinicians under the QPP proposed rule that are participating in the ACO. This measure would be phased into pay-for-performance after two years as a pay-for-reporting measure. CMS also proposes an alternative reporting requirement for this measure, allowing for pay-for-reporting in all performance years, exempting the measure from the minimum attainment level rules, and making these modifications apply only to MSSP tracks that meet the requirements to become Advanced Alternative Payment Models (APMs).

The AMA agrees with CMS' statement that there exist "established Shared Savings Program rules and incentives that directly tie the level of CEHRT use to the ACO's financial reward which in turn has the effect of directly incentivizing ever-increasing levels of CEHRT use among EPs."[1] CMS renewed its support of this principle in the MACRA NPRM when it refrained from requiring Advanced APMs to use CEHRT in specific and prescriptive ways. The AMA urges CMS to avoid overly prescriptive regulations for ACOs' use of health information technology. Instead, CMS should continue to recognize that ACOs are best equipped to improve the health of their patients when they are able to utilize health information technology in ways that best and most effectively meet the needs of the ACO's patient population.

The AMA also opposes CMS' proposal to expand ACO #11 to all eligible clinicians instead of limiting it to primary care physicians. ACO patient attribution is based on primary care services, so it is appropriate to continue to limit ACO #11 to primary care services. ACO #11 as it currently exists is sufficient to meet the criteria for an APM to be considered an Advanced APM under the recent MACRA NPRM. ACOs need stability in the measure set, particularly as they transition to new requirements under the Advancing Care Information (ACI) performance standards included in the MACRA NPRM proposals. The AMA also recommends that CMS keep the measure pay-for-reporting in all years, in part because these changes will take substantial time and effort to operationalize. Physicians participating in an ACO who are not qualifying APM participants under MACRA will already have their ACI performance scored as part of the Merit-based Incentive Payment System; they should not have their performance judged twice by having the revised ACO #11 be pay-for-performance. Should CMS finalize the proposal to modify the measure specification to assess the ACO on all clinicians' performance under Advancing Care

[1] MFS NPRM at 46429.

Information requirements, those clinicians who are excluded from the Advancing Care Information requirements under MIPS should also be excluded from ACO #11.

Incorporating Beneficiary Preference into ACO Assignment

The AMA strongly supports the CMS proposal to incorporate a voluntary patient choice process into the ACO assignment methodology. Allowing patients the opportunity to choose their principal physician and have their ACO assignment based on that choice will also help ACOs achieve more stability in their patient populations.

CMS proposes to modify the Medicare ACO assignment method to allow patients to designate a physician participating in an ACO as the physician as responsible for their overall care, and in so doing to be assigned to that ACO. This voluntary alignment with the ACO would take precedence over potential assignment to a different ACO based on claims data analysis of the plurality of primary care services provided to the patient. CMS proposes to use an "automated" approach to determine which physician patients believe is responsible for coordinating their overall care (i.e., their "main doctor") using information collected from patients through a CMS system such as MyMedicare.gov, 1-800-Medicare or the Physician Compare website.

CMS would notify patients of the opportunity to designate their "main doctor" through outreach efforts, and ACOs would be permitted to encourage these choices as well. Should CMS finalize the proposed automated approach, it proposes to do so for the 2018 performance year for ACOs in all tracks. CMS proposes Track 1 and 2 ACOs would have information from voluntary alignment updated on a quarterly basis and for Track 3 ACOs, this information would be updated on an annual basis. CMS further proposes that if a patient voluntarily aligns with a physician who is not participating in an ACO, then the patient would not be eligible for assignment to any ACO, even if they would have been assigned to an ACO under a claims-based approach.

After years of advocating for CMS to incorporate a voluntary patient attestation process into the ACO assignment methodology, we are very pleased to see this proposal. Allowing patients to align voluntarily with a physician who is an ACO participant can help balance patients' freedom to choose their physicians with ACOs' interest in reducing patient turnover or "churn," so that they will have more stability in their patient populations. This stability will in turn allow ACOs to work with their participating physicians to better target efforts to coordinate and improve care. In addition, allowing patients to attest to the physician they want to manage their care is likely to increase patients' engagement in their care.

G. Medicare Advantage (MA)

The AMA supports CMS' proposal to release MA bid pricing data and Part C and Part D Medical Loss Ratio (MLR) to the public. We believe the release of this data will promote accountability in the MA and Part D programs and facilitate additional research. The AMA also takes this opportunity to ask CMS to review and revise its policies on MA seamless conversions to ensure that plans cannot abuse them and that appropriate patient protections are in place.

Release of Part C Medicare Advantage Bid Pricing Data and Part C and Part D MLR Data

The AMA supports CMS' proposal to provide greater transparency to the public generally on various aspects of the Medicare program and welcomes the proposal to extend this to Medicare Advantage and the Medicare Part D Prescription drug benefit programs. As part of the annual bidding process required under the Social Security Act, Medicare Advantage organizations (MAOs) submit bids for each plan they wish to offer in the upcoming contract year (calendar year). In addition, MAOs and Part D sponsors are required annually to provide CMS data supporting their medical loss ratios (MLR). CMS has proposed to release to the public MA bid pricing data and Part C and Part D MLR data on a specific schedule and subject to specified exclusions. CMS also proposes to add contract terms and expand the basis and scope of regulations on MA bidding and Part C and Part D MLR submission to authorize disclosure.

The AMA agrees with CMS that the release of such information will improve the public health by facilitating research on the utilization, safety, effectiveness, quality and efficiency of health care services. The AMA strongly agrees that this proposal would promote accountability in the MA and Part D programs, by making MLR information publicly available for use by beneficiaries who are making enrollment choices and by allowing the public to see whether and how privately-operated MA and Part D plans administer Medicare—and supplemental—benefits in an effective and efficient manner. Furthermore, the AMA encourages the release of this information and all additional information that may be necessary to enable researchers, patients and interested health care stakeholders to assess the adequacy of the networks offered by MAOs.

Medicare Advantage Seamless Conversions

The AMA urges CMS to review and revise its policies on Medicare Advantage seamless conversions to ensure that plans cannot abuse them and that appropriate patient protections are in place.

Recent press reports about so-called "seamless conversions" into MA plans have heightened physician concerns about this practice. It is our understanding that MA plans may submit proposals to CMS which are then reviewed at the CMS Regional Office level to automatically enroll patients who are in commercial, exchange, or Medicaid insurance plans operated by the organizations into the MA plans offered by these same organizations once the patients become eligible for Medicare based on their disability or age. Patients in the non-Medicare plans receive a letter indicating that they will be automatically enrolled once they are Medicare eligible. If they do not want to participate in the organization's MA plan, they must take action to opt out of the "seamless conversion."

It has become clear that "seamless conversions" are not always seamless and that there are unintended consequences. Problems arise when patients either are not adequately informed about their choices or do not understand how to avoid the conversion. Problems also arise when the physician networks for the MA plan are narrower than those for the pre-Medicare health insurance. Clearly, when a patient's non-Medicare insurance has been covering their care from a particular physician(s) and this physician(s) is not in the MA plan's network, the result is far from seamless. In light of the documented widespread deficiencies in health plan provider network directories, it may not even be possible for patients or CMS officials to accurately compare the physician networks for the different plans.

The AMA urges CMS to review and revise its policies on MA seamless conversions to ensure that plans cannot abuse them and that appropriate patient protections are in place. The process of becoming eligible

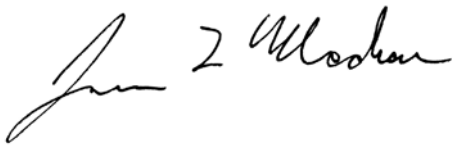
for Medicare can be confusing for patients. They face an array of Medicare Advantage options, prescription drug coverage options, and supplemental coverage options. It is certainly easy to see how one letter could be overlooked or misunderstood when patients are facing this barrage of options. It is also easy to understand how they might neglect to take the needed step to avoid auto-enrollment or might allow the auto-enrollment to proceed but later regret it. Outreach strategies should be required to include more than a single letter.

Physicians also need better information about these policies. Information about which plans are auto-enrolling patients should be publicly available. Whenever patients are in an open enrollment situation, they should be encouraged to check with their physician(s) to find out if they are participating in the network of whatever plan the patient is contemplating.

IV. CONCLUSION

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

Sincerely,



James L. Madara, MD