JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT, CEO

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

October 3, 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: Advancing Care Coordination Through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model (CJR); Proposed Rule (CMS-5519-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 that would create three new Episode Payment Models (EPMs), establish the Cardiac Rehabilitation Incentive Payment Model, and change the Comprehensive Care for Joint Replacement (CJR) model, published in the *Federal Register* on August 2, 2016 (81 Fed. Reg. 50793).

In general, we appreciate CMS' efforts to develop EPMs that qualify as Advanced Alternative Payment Models (APMs) so that more physicians will have the option to participate in an Advanced APM and receive an incentive payment under the Quality Payment Program (QPP).

The AMA believes that physician leadership is a key factor in improving care delivery. We urge CMS to develop EPMs that can be undertaken jointly by teams of different providers, including hospitals, physicians, and post-acute care facilities. As we have emphasized previously, we feel it is important for CMS to recognize that it is not the payment model that will improve care, it is the physician and other health professionals.

The AMA is concerned that CMS did not solicit feedback from the medical specialty societies whose members will be participating in these EPMs prior to the release of this proposed rule. We urge CMS to give serious consideration to their comments on this proposed rule and, going forward, to work with physician organizations that want to develop and participate in episode payment models and bundled payments, and can share lessons learned from their work to date on APMs with CMS.

In order for these new EPMs to be successful, we recommend a number of changes be made to the proposals. The major changes include:

- Incorporate input from the AMA and specialty societies whose members will participate in new payment models into the final model design and plans for implementation;
- Recognize that physician leadership is essential for successful implementation of any payment model intended to support a comprehensive approach to care for Medicare patients;
- Allow flexibility for physicians, hospitals, and post-acute care providers to organize themselves into different arrangements than the hospital-led governance model CMS has proposed;
- Align quality and Certified Electronic Health Record Technology (CEHRT) requirements with Advanced APM requirements under the QPP;
- Allow voluntary participation in the acute myocardial infarction (AMI), coronary artery bypass graft (CABG), and surgical hip/femur fracture treatment excluding lower extremity joint replacement (SHFFT) EPMs;
- Reduce the nominal risk requirement to allow more providers to participate in the QPP as Advanced APMs;
- Improve the risk adjustment methodology by collaborating with the clinical community and relevant medical specialty societies that have experience with the different risks facing patients who will be treated within these episode models;
- Ensure payment is predictable and limits physicians' accountability to costs that are within their control;
- Expand access to evidence-based telehealth services;
- Develop a fair and transparent process for providers to appeal reconciliation report data; and
- Ensure new EPMs will qualify as Advanced APMs.

We also provide detailed recommendations on how CMS can improve the proposed EPMs and comments on potential future condition-specific and event-based EPMs in the subsequent sections of this letter. In addition, we suggest that CMS review the AMA's comments on the Comprehensive Care for Joint Replacement Payment Model proposed rule, which we submitted on September 1, 2015 (see https://www.regulations.gov/document?D=CMS-2015-0082-0058). This comment letter contains additional detailed information on how we believe the Center for Medicare and Medicaid Innovation (CMMI) should approach the development of new payment models and bundles.

EPM Design

CMS proposes three new EPMs targeting care for Medicare fee-for-service beneficiaries receiving services to treat acute myocardial infarction (AMI), coronary artery bypass graft (CABG), and SHFFT.

While we support the additional opportunities these EPMs create for physicians to participate in Advanced APMs, we have some concerns, outlined below, regarding the design of the new EPMs.

Physicians Play Crucial Role in Reducing Cost and Improving Care

Incorporate Physician Input

The AMA has repeatedly heard from physicians regarding how they could improve care for patients in ways that will also lower the costs of care; however, they often indicate that they cannot pursue these opportunities due to barriers created by the way current Medicare payment systems are designed. Physicians have expressed strong interest in participating in APMs that would remove these barriers and give them the flexibility to redesign care in ways that will improve quality for their patients and reduce costs for Medicare and other payers. Greater benefits and fewer unintended consequences will occur if new payment models are specifically designed with input at the front end from specialty societies whose members provide the services included in the new EPMs.

Support Physician Leadership in Redesigning Care Delivery

Physician leadership is essential for successful implementation of any payment model intended to support a comprehensive approach to care for Medicare patients. Only physicians can make the determination as to what types of care could effectively address patients' needs and in which settings those care services can be delivered safely and successfully. Patients rely on physicians to help them decide which choices to make when alternative types of care and alternative facilities are available.

These proposed EPMs fail to recognize the central and essential role of physician leadership in care redesign. CMS proposes to designate the hospital as the accountable entity for all services the Medicare beneficiary receives, including services delivered by physicians and post-acute care providers. A bundled payment should instead be developed so physicians have leadership roles in designing the care delivery process and ensuring that it achieves good patient outcomes without unnecessary costs. The physicians, hospital, and other providers involved in the episode can then decide together what role the hospital should play in the coordination and financing of the care, rather than this being dictated by CMS in regulations.

Provide Flexibility to Support Different Organizational Arrangements

CMS proposes to design the three new EPMs to primarily hold hospitals responsible for managing quality and cost of each episode. The AMA believes that, instead, CMS should develop episodes that allow physicians, hospitals, and post-acute care providers to organize themselves into different arrangements in which they would jointly take accountability for the episodes of care.

CMS proposes to design the new EPMs to only offer a retrospective model for paying participants that would reconcile quality scores and payments two months after the end of each performance year. This limits the flexibility of providers and payment models. Instead, the new EPMs should allow providers two options: 1) providers could organize themselves in the manner most efficient to accept a prospective bundled payment from Medicare, and allocate it among the participating providers; or 2) alternatively, other providers may find it easier to continue billing under current payment systems and then retrospectively reconcile those payments against a prospectively defined budget. The payment model

under the new EPMs, as well as the existing CJR program, should have the flexibility to support both arrangements.

As we have stated in previous comment letters, one of the most important accomplishments CMS has made through the CMMI is making multiple payment models available in the Bundled Payments for Care Improvement (BPCI) program for the same procedure or conditions. It would be a step backwards to only use a retrospective payment model in the new EPMs when many physicians and other providers may be willing to implement a simpler and more flexible prospective payment model if properly designed. Jointly-governed teams should have the flexibility to determine which organizational approach and retrospective or prospectively-determined payment model best works for their particular circumstances.

Align Quality Requirements with Advanced APMs under the QPP

CMS should adopt a meaningful and flexible approach to measuring quality in the AMI, CABG, and SHFFT models. Specialty societies whose members perform these episodes have experience regarding how best to evaluate the quality of these services and extensive experience with use of registry data to improve quality of care. CMS should build on this expertise and engage the relevant specialty societies in developing the most effective way to measure quality for each model.

In response to the QPP proposed rule, the AMA strongly supported CMS' proposal to allow Advanced APMs to choose their own approach to measuring quality. CMS proposed to provide Advanced APMs with flexibility by allowing each APM to choose one quality measure from various categories of Merit-Based Incentive Payment System-comparable quality measures listed in the rule. We also supported CMS' proposal that Advanced APMs require 50 percent of participating physicians to use CEHRT to document or communicate clinical care to their patients or other health care providers. We believe these proposals provide an appropriate non-prescriptive approach that allows each Advanced APM to choose how to most appropriately use quality measurement and CEHRT.

In this rule, CMS proposes a set of different required quality measures for each EPM to determine a discount factor for each EPM participant, and financially reward higher quality in an EPM episode.

We urge CMS to consider comments on its approach to quality metrics in the new EPMs, such as those offered by the Society of Thoracic Surgeons (STS) on the CABG model, using the STS CABG Composite Score to measure quality. This composite score is a single number that summarizes all available information about the quality of care delivered by an individual provider. The CABG Composite Score is comprehensive, mitigates sample size concerns, is National Quality Forum endorsed, and is already used and voluntarily reported by the majority of thoracic surgeons.

For the AMI model, it may not be appropriate to weight the MORT-30-AMI measure (NQF #0230) at 50 percent. CMS should engage with the relevant specialty societies to find other quality measures that could be included to lower the weighting of this measure and provide a more balanced quality score.

Maintain CEHRT Flexibility

The AMA strongly supports the flexibility CMS proposes for how the new EPMs are required to use CEHRT. CMS notes that it is necessary for an APM to require the use of CEHRT in order to be considered an Advanced APM. Therefore, CMS proposes to require participant hospitals to use CEHRT

to document and communicate clinical care with patients and other health care professionals to participate in Track 1 of the EPM and CJR models. We commend CMS for allowing these EPMs to determine how to best use CEHRT in their workflows, and support the proposal that allows EPMs flexibility in their CEHRT use.

Allow Voluntary Participation in the AMI, CABG, and SHFFT EPMs

Any Medicare payment change that could help improve patient care should be available in all parts of the country. Participation in the new EPMs, as well as the CJR model, should be voluntary, not mandatory. If these new payment models can benefit patients—and we believe they can, if designed correctly—then those benefits should be made available to all patients in all parts of the country, not just those living in selected metropolitan statistical areas. The combination of widespread access to new EPMs and voluntary participation has the potential to foster a learning health care system in which both the benefits and unintended consequences of the new payment models are identified, while acknowledging that organizations and locales vary in their readiness to participate in such models.

If a team of physicians and other providers believe they can use the flexibility and resources available in a bundled payment program to improve patient care, then they will have a strong incentive to voluntarily participate in a new model. If they do not believe they can improve care by participating in the model, and particularly if they believe that these payment models would compromise their ability to deliver high quality care, CMS should not force them to participate.

The large and diverse population that has entered into agreements to participate in the BCPI is evidence of the interest and willingness of physicians and other health care providers to voluntarily implement properly designed new payment models.

Reduce Advanced APM Risk Requirement

The AMA has repeatedly expressed its concerns with the definition of more than nominal financial risk for Advanced APMs that CMS proposed in the QPP proposed rule. As we stated in our comment letter, the AMA recommends that CMS base the risk requirements that count toward nominal risk on physician practice or APM organization revenues instead of Medicare expenditures. We also urged CMS to reduce the amount of losses that would need to be at risk in order to be "more than a nominal amount."

In this proposed rule, CMS points out that the rural hospitals, sole community hospitals (SCHs), Medicare Dependent Hospitals (MDHs), and Rural Referral Centers (RRCs) will have a stop loss limit of three percent in performance in year two. Because this percent is less than the proposed threshold of at least four percent of expected expenditures for Advanced APMs in the QPP, these hospitals would not meet the nominal risk standard for Advanced APMs and would have to be in Track 2.

This illustrates how shortsighted CMS' proposed definition of nominal risk is in practice. CMS proposes lower risk levels for rural hospitals, SCHs, MDHs, and RRCs because it recognizes that these hospitals will have a more difficult time taking on higher risk. CMS notes that these hospitals have unique challenges that do not exist for most other hospitals, including being the only source of health care services for beneficiaries living in rural areas, or being located in areas with fewer providers.

Setting the nominal risk level at four percent of expected expenditures is arbitrary and leaves out numerous physicians who contribute to managing these episodes of care for patients at these types of hospitals. This is an important illustration of why CMS must be flexible in its definition of nominal risk, and how nominal will not mean the same thing for every provider. The AMA supports all organizations having opportunities to participate.

Improve Risk Adjustment Methodology

The AMA acknowledges that it is difficult to risk adjust when patients have multiple chronic conditions that interact with one another, and continues to urge CMS to work with physician organizations to improve its risk adjustment methodologies.

One way CMS could improve risk adjustment in the new EPMs is to work with the clinician community to establish as much clinical homogeneity as possible among beneficiaries. For example, in the AMI model, CMS should only include beneficiaries that have AMI as their primary diagnosis. Limiting inclusion to the most clinically similar subset of patients, in this case those with a principal diagnosis of AMI, allows for meaningful comparison among patients and provides CMS the opportunity to clearly evaluate the impact of EPMs on patient care and outcomes.

In the CABG EPM model, CMS could improve risk adjustment by incorporating clinical data and the STS Risk Calculator into the risk adjustment methodology instead of relying solely on claims data. This tool is already being used by CMS in other settings and could provide a more accurate analysis of patient risk factors.

Also, as the Society of Cardiovascular Angiography and Interventions has noted, the EPMs could discourage treatment of the sickest patients, such as those in cardiogenic shock or those with multi-vessel disease. Improving the risk adjustment methodology could help to lessen the likelihood that this will occur.

Ensure Payment is Predictable and Within Physicians' Control

Physicians Need Predictable Payment Arrangements

CMS proposes to retrospectively reconcile an EPM participant's actual EPM-episode payments against the quality-adjusted target prices two months after the end of the performance year. If the EPM participant's actual EPM-episode payments are found to be higher than the quality-adjusted target prices during the reconciliation process, then the hospital would be responsible for repayment during quarter two of that calendar year.

We believe that retrospective repayment may make it difficult for providers to plan and budget for each year. Providers will not know what the EPM target price or their specific quality adjustment will be until the end of the performance period. Therefore, budgeting to adequately ensure repayment to Medicare for these EPM episodes would be difficult. It is impossible for physicians and other providers to make investments in facilities, equipment, training, and additional personnel if they cannot predict how much they will be paid for services.

As previously discussed, the AMA believes CMS should instead offer providers two options. Providers could organize themselves into a team that could effectively accept a prospective bundled payment from Medicare, and allocate it among participating providers. Alternatively, providers could choose to retrospectively reconcile their payments as CMS proposes. This would allow each team of providers to determine which payment model works best for their team.

In addition, the AMA supports CMS' proposal to provide physicians with a transition period without penalties as they gain experience with new EPMs. However, we note that while CMS states that penalties will not begin until the third quarter of performance year two when, in fact, these penalties will begin one year after the program begins, as performance year one lasts only six months, from July 1 through December 31, 2017.

Hold Providers Accountable for Costs within Their Control

The AMA continues to urge CMS to ensure new payment arrangements are designed to hold providers accountable only for costs within their control. Under the proposed EPMs, CMS would hold providers responsible for all of a patient's care within 90 days of discharge from the hospital. We believe providers need more control over where the patient goes after discharge. While we support patient choice, providers should not be held accountable if a patient picks a suboptimal post-discharge facility. In addition, this is another reason why CMS should allow hospitals, physicians, and post-acute care facilities to organize into provider teams that can better coordinate care for patients and improve adherence to treatment plans throughout the episode.

Expand Access to Evidence-Based Telehealth Services

While the AMA supports efforts to expand access to evidence-based telehealth services, we recommend that CMS modify its proposal to expand a policy contained in the final CJR rule where the practice expense for telehealth services is not paid by CMS. The AMA urges CMS to seek information from organizations representing the physicians who perform these services about the expenses involved in their delivery instead of basing payment rates on an assumption that the providers incur no practice expense. We want to ensure the development of these new EPMs does not create a financial disincentive that will reduce patient choice and convenience and may undermine adoption and integration of telehealth services into clinical practice.

Develop a Fair and Transparent Process for Providers to Appeal Reconciliation Report Information

Providers must be given adequate notice that their reconciliation reports are available, and provided sufficient time to review their data. In many cases the reconciliation reports may need to be reviewed by multiple providers at multiple locations, including hospitals and post-acute care facilities. To expect providers to access, review, and contest data in 45 days ignores the demands of patient care and competing priorities providers face on a daily basis. The AMA recommends extending the appeals process to no less than 90 days.

Develop EPMs that Qualify as Advanced APMs

The AMA strongly supports CMS' proposal to provide a Track for each of the new EPMs and the CJR that would allow these models to qualify as Advanced APMs. The AMA urges CMS to provide more physicians with the opportunity to participate in an Advanced APM and receive an incentive payment under the QPP.
We believe CMS should continue to develop pathways and provide assistance to organizations who wish to develop or become participants in Advanced APMs. As illustrated by our comments below, there is significant work currently underway by many specialty societies to develop APMs for a number of important patient conditions, such as cancer and diabetes that can be used to create episode payment models and episode bundles that qualify as Advanced APMs.

Potential Future Condition-Specific Episode Payment Models

CMS invites comments on potential future EPMs for managing specific patient conditions, stating that such models may have the potential to be Advanced APMs that emphasize outpatient care and are physician-led rather than hospital-led. The AMA welcomes the opportunity to comment on this topic.

There are many national medical specialty societies working to design APMs to improve management of different conditions. Generally, the specialties start by identifying from among the conditions that they manage in their patients those that have the biggest opportunities for improvement in care delivery and patient health outcomes. Each specialty can identify particular patient populations who have too many emergency department visits and hospital admissions, undergo too many expensive tests with questionable appropriateness, experience very fragmented care, or receive the wrong medications or other treatments. There may also be opportunities to prevent diseases or conditions from progressing to a more serious stage or to reverse a condition.

Generally, these gaps in the current care for the condition can be traced to barriers in the current payment system which an APM could help solve. For example, if patients frequently experience seizures, headaches, asthma attacks, chest pain, dehydration from chemotherapy, or opioid overdoses, there may be specific services and strategies that would help reduce these exacerbations so that the conditions are better controlled, but they are often not supported by current fee schedules. For example, payers generally do not pay for responding to patient phone calls about new symptoms or drug side effects, physician-to-physician calls to coordinate treatment plans, or nurse educators to help patients with medication adherence and better self-management, even though these services can reduce the need for much more expensive services.

A key difference between the condition-based models that specialty societies have been developing and those that CMS has developed is that they begin with diagnosis of the condition and aim to prevent the need for hospitalizations, instead of beginning with a patient's hospital admission. Several examples of APMs under development that could support the improvements in care if barriers in current payment system are overcome are described below:

- Headaches: Opportunities to improve care and reduce costs include: reducing misdiagnosis, unnecessary tests, emergency department visits for headaches and complications such as dehydration from nausea, avoidable hospital admissions, and inappropriate medications; and by achieving better headache control, preventing progression from episodic to chronic migraine, and

reducing dependence on opioid analgesics. Barriers are: inadequate payment for diagnosis, treatment planning, patient education and counseling, telephone support to patients, open slots to treat exacerbations, and communications between primary care physicians and neurologists. An APM could provide payment for a comprehensive diagnostic work-up, testing, development of a treatment plan and the first few months of treatment. Then, a headache care team could get monthly payments instead of separate visit payments for patients who continue to have frequent, severe or disabling headaches, with payment amounts stratified based on specific headache diagnosis, frequency and severity of headaches, and comorbidities like depression, anxiety, and coronary artery disease. Once the headaches are well-controlled, if patients had occasional low-severity headaches, the team could be paid for phone calls and face-to-face visits to rapidly respond to problems so they do not get worse, with ongoing management shifting to the patient's primary care physician. The headache team would take accountability for the cost and quality of headache-related care for their patients by reducing avoidable emergency department visits, tests and admissions.

- Epilepsy: An APM for epilepsy would help improve the accuracy of diagnosis for patients and make sure they are getting the best possible medication. This can in turn help reduce the frequency and severity of seizures, medication side effects, and injuries from seizures, all of which often lead to emergency visits and hospitalizations. The APM could support complete diagnostic work-ups to reduce misdiagnosis of non-epileptic seizures, multiple referrals for diagnosis, and unnecessary diagnostic tests. There would be a period of initial treatment that includes determining what medications and other treatments are most effective, managing treatments over time and improving adherence, improving decisions and coordination if surgery needed, and changing treatment regimens when indicated.

- Asthma: An asthma APM could provide more flexibility for physicians to focus on getting an accurate diagnosis for asthma-like symptoms and identifying the most effective medications to manage the patient's symptoms and avoid exacerbations that can lead to emergency visits. Opportunities to improve care are more accurate diagnosis of asthma-like symptoms, helping patients identify and avoid triggers for exacerbations, reducing emergency visits and hospitalizations due to exacerbations and inappropriate medications, and achieving better asthma control. Barriers in the current payment system are inadequate payment for: accurate diagnosis of asthma-like symptoms, treatment planning, patient education, telephone support to patients, leaving open slots to treat exacerbations, communications between primary care physicians and allergists, as well as restrictions on needed medications such as prior authorization.

- Opioid Use Disorder: An APM for management of opioid use disorder could allow addiction specialists to focus on getting more patients into medication-assisted treatment with methadone and buprenorphine, making sure comprehensive services like counseling are provided that can enable long term recovery and support, and providing better support to primary care physicians who can take over from the addiction specialist once patients are stabilized, knowing they will have rapid access to specialty care for phone or online consultations or to see the patients if there is a relapse or another problem.

- Cancer: In addition to the CMS Oncology Care Model, several of the national medical specialty societies whose members treat cancer have been working on APMs to improve management of this disease, including organizations representing medical, radiation, and surgical oncologists.

There are significant opportunities to improve patient's health outcomes, reduce repeat operations and readmissions, emergency visits and unplanned hospitalizations, and improve the appropriateness of tests and medications through development of joint treatment plans, symptom management clinics to prevent and manage complications of chemotherapy and radiation therapy, patient and family education and counseling about their disease and treatment options, and coordination of survivorship and monitoring for recurrence.

- Diabetes: A diabetes APM could include a bundled payment to an endocrinologist or diabetes team for diabetic education, checking blood sugars, phone calls to change therapy, arranging consultations, communicating with primary care and other physicians, and office visits. The bundled payments would be adjusted for complexity based on patients' A1C scores, kidney and pain complications, obesity and cardiovascular issues.

As these examples illustrate, discussions by diverse specialties about APMs for an array of conditions have identified similar opportunities to improve care, similar barriers in the current system, and similar payment models. This work could provide a foundation to develop similar frameworks for specialty medical homes, outpatient bundled payments, and specialist-primary care collaboration that could apply to different specialists managing different conditions. In each case, the specialist would get more flexible bundled payments that can support provision of high-value services that can help patients achieve better control and slow disease progression, while also reducing avoidable emergency visits, hospital admissions, and inappropriate use of expensive tests and drugs.

In the case of a serious condition that requires ongoing management by a specialist, such as Crohn's disease, cancer, diabetes, heart disease, or epilepsy, the model could be described as a specialty medical home. For other conditions, the initial diagnostic, treatment planning, and first few months of treatment necessary to get the condition under control could be an outpatient bundled payment. Once the condition is well-controlled, a transition could take place to a collaborative care model in which the specialist serves on an as-needed basis and the primary care physician assumes ongoing management responsibility.

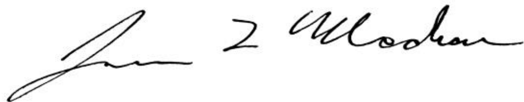
Potential components of such a model would be:

- Payment for complete diagnostic workup and treatment planning over the period of time typically required to ensure accurate diagnosis and effective treatment (i.e., 1-3 months);
- Monthly payments to a specialist or team for continued management of patients with difficult-to-control condition or complex comorbidities;
- Monthly payment to a primary care physician for continued management of those patients with well-controlled condition plus rapid access to phone consults with the specialist by the primary care physician if a well-controlled patient's condition deteriorates;
- Proactive outreach to avoid exacerbations or address patient problems early;
- Coordination with pharmacists, therapists, emergency services, clinical laboratories, imaging and all other providers involved in diagnosis and treatment for the condition;
- Financial accountability for avoidable utilization and spending related to the condition, such that payments under the model are reduced if utilization and cost standards are not met;
- Quality accountability for following relevant care pathways and providing high quality care, moving patients from their condition being poorly controlled to being well-controlled, and adherence to the treatment plan; and
- Minimum standards for structure and processes to be eligible to participate in model.

The AMA would welcome the opportunity to work with the specialty societies and CMS to further develop this framework.

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