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October 3, 2016

Andrew Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-5519-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

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)

Dear Acting Administrator Slavitt:

On behalf of the Advanced Medical Technology Association (AdvaMed), I am pleased to offer comments on the proposed rule, Advancing Care Coordination through Episode Payment Models (EPMs), published in the *Federal Register* August 2, 2016. This proposed rule would establish three new episode payment models targeting care for Medicare beneficiaries receiving services during acute myocardial infarction (AMI), coronary artery bypass graft (CABG), and surgical hip/femur fracture treatment (SHFFT) episodes. The rule would also establish a Cardiac Rehabilitation incentive payment model. The proposed rule would also make modifications to the Comprehensive Care for Joint Replacement Model (CJR) implemented April 1, 2016. AdvaMed has been a strong supporter of delivery reform models, including bundled or episode payment programs, since their inception in the Affordable Care Act. We recognize the importance of the goals of these programs as they seek to improve both the efficiency and quality of health care in this country and we support CMS and the Center for Medicare & Medicaid Innovation (CMMI) initiatives that aim to achieve these goals.

Our member companies can play a critical role in helping providers meet the goals set out for delivery reform programs. They do so through improvements in medical technologies, diagnostics, and other advanced medical technologies, which, among other things, allow health care services to be provided remotely to patients. These products and services improve patient care quality and outcomes and many improve efficiency by reducing the lengths of stay of patients in health care facilities, enhancing perioperative productivity and reducing costs,

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allowing procedures to be performed in less intensive and less costly settings, providing early detection of disease and infections, and improving the ability of providers to monitor care, among other benefits.

In this letter, we offer comments on a number of issues and questions raised in the proposed rule:

EPM Collaborators [Comments related to Section III.I.2-3]

In its discussion about EPM financial arrangements for sharing risk and a subsequent discussion about EPM collaborators, CMS notes that EPM participants may want to engage with organizations that are neither providers nor suppliers to assist with matters such as episode data analysis, local provider and supplier engagement, care redesign planning and implementation, beneficiary care coordination and management, and other related activities. AdvaMed recommends that the final rule expand the list of designated collaborators beyond ACOs, hospitals, and CAHs to include manufacturers of medical devices and diagnostics. AdvaMed's member companies have in-depth knowledge of the patient care protocols, best practices, and treatments that lead to improved patient outcomes, and are ideally suited to provide value within the episode of care. In fact, some are already engaged with delivery reform model participants in several of the ways mentioned in the proposed rule, but only to a limited extent. We believe that our companies could make even greater contributions to patient outcomes if they are designated by the final rule as permitted collaborators.

More specifically manufacturers of medical technologies could collaborate with EPM participants by integrating data analytics infrastructure and services to optimize care to achieve quality goals, by providing services that streamline the supply chain to reduce cost, or by sharing risk for the performance of innovative technologies used by EPMs to meet their savings and/or efficiencies goals in care delivery. We recognize that some of these arrangements might require changes in regulatory policies and guidance concerning safe harbors in fraud and abuse laws. Therefore, we request that CMS clarify the specific circumstances under which manufacturers could act as collaborators under the EPM final rule and the CJR. Further, as discussed below, AdvaMed recommends that CMS provide Anti-Kickback Statute waivers for bona fide value-based arrangements, as needed, between EPM participants and collaborator medical technology and diagnostic companies.

Compliance with Fraud and Abuse Laws [Comments related to Section III.I.10]

As CMS and OIG consider the need for and scope of any waivers, AdvaMed believes that it would be beneficial to incorporate an Anti-Kickback Statute waiver that would provide protection for bona fide value-based arrangements between EPM participants and medical technology company collaborators. Currently, value-based arrangements between medical technology manufacturers and providers are structured by cobbling together constructs within the discounts, warranties, and personal services safe harbors. However, this analysis necessitates committing significant resources, both in terms of time and legal costs, and because of current regulatory limitations, these costs may be incurred by all stakeholders without ultimately moving

forward with a value-based collaboration, given the possibility of CMS/OIG applying historic fee-for-service reimbursement principles as a framework for enforcement actions.

In short, regulatory uncertainty concerning the application of the criminal Anti-Kickback Statute to EPM participants and medical technology companies would chill innovative collaborations. Further, the Anti-Kickback Statute safe harbors are narrowly constructed. While there are ways to construct these engagements currently, they do not offer the fluidity that would be possible with a waiver. The freedom and efficiencies afforded by a waiver would permit greater investments in value-based solutions.

Safe harbor protection is afforded only to those arrangements that meet all of the conditions set forth in the safe harbor regulations. Unfortunately, the safe harbor constructs are narrowly fashioned around fee-for-service payment models and this serves to inhibit using delivery reform models that have the potential for improving both quality and efficiency of care delivery. For example, the Discount Safe Harbor includes the limitation that the bundled good or service be reimbursed by the Federal health care program using the same methodology and be earned based on purchases of that same good or service within a single fiscal year. The “same methodology” limitation can materially restrict the range of possible devices and services that may be integrated to deliver the best value because of the uncertainty around what items or services would be considered to fall under the “same methodology.” Furthermore, one episode of care may span two fiscal years.

Integral to developing and executing value-based arrangements between delivery reform participants and medical technology company collaborators is the need for manufacturers to be able to communicate with providers, payers and other stakeholders about clinical goals, efficiency measures, and economic performance terms. Starting points for these goals, measures, and terms may originate from economic and clinical data (with varying levels of support) that may not be specified in the approved or cleared label of the device. However, this scientific and health care economic information will be needed to both establish and optimize the clinical and economic goals of the value-based collaboration.

In light of the challenges noted above, we believe it would be beneficial to:

- Create a waiver that will maintain protections for patients and Federal health care programs while allowing for greater involvement and investment in EPMS, by allowing:
 - *Risk-sharing between EPM participants and medical technology company collaborators* that incentivize and reward improvements in clinical outcomes and/or reductions in cost. This waiver should allow for sharing value-based rewards and the shifting of risk over the course of an arrangement so long as such risks and rewards are set in advance.
 - *Bundling medical technologies with services to collect and monitor data, analytics, monitoring equipment, and IT infrastructure.*
 - *Outcome warranties* that specifically address warranting an outcome instead of a product failure and protect payments for bundled products and services provided when an outcome is not met. For example, this would provide a targeted approach to

addressing scenarios where a medical device company agrees to reimburse a hospital not only its aggregate purchase price for the implant device acquisition costs, but also unreimbursed products and services if a patient is readmitted to the hospital within 90 days following the surgical procedure because the surgical site is infected or a revision surgery is needed. Currently when this occurs, there is arguably protection under the safe harbor warranty for only the device cost when the device fails.

- Issue guidance that clarifies that communications on efficiency (e.g., performance/throughput claims), population outcomes/cost, and economics that are not specifically part of the product labelling are necessary and permissible to develop and operationalize as value-based arrangements in EPMs and that varying levels of supportive data are acceptable (e.g., case study, big-data analytics).

Billing and Payment for Telehealth Services [Comments related to Section III.J.5]

As it has done in BPCI Models 2 and 3, the CJR, MSSP ACOs and Next Generation ACOs, CMS would provide waivers of the telehealth originating site and geographic site requirements and allow in-home telehealth visits for all three proposed EPMs and permit services to be covered in all rural and urban areas included among the mandated MSAs. AdvaMed strongly supports these waivers and agrees with CMS that the waivers will support care coordination and timely access to high quality care for all EPM beneficiaries.

However, we do not believe that the waivers go far enough in testing the efficiencies and quality of care improvement potential of telehealth technologies. For example, the proposed rule makes clear that only those telehealth services on the Medicare approved list of covered telehealth services can be covered under the proposed EPMs. In addition, only services meeting the requirement of being furnished via an interactive telecommunications system would be covered. The proposed rule also clarifies that no additional payment would be made to cover set-up costs, technology purchases, training and education, or related costs. We believe that CMS and its Innovation Center are missing an opportunity, through their existing waiver authorities, to use delivery reform models for creatively testing situations where additional flexibility in the provision of telehealth services would increase overall care efficiency and improve care quality.

AdvaMed encourages CMS and its Innovation Center to undertake demonstrations, through its delivery reform models, to determine whether and under what circumstances expanded coverage of telehealth can be cost effective and improve quality of care for Medicare beneficiaries. The demonstrations could focus on covering expanded telehealth services, beyond those on the Medicare approved list, and targeted at specific population groups, for example, persons with multiple chronic conditions. These services could be provided through a broader array of technologies than the interactive telecommunications systems allowed under current law, such as store and forward technologies, remote monitoring technologies, and point-of-care testing. The demonstrations could also test alternative methods for paying for telehealth beyond fee-for-service, and include, for instance, capitation that would pay a delivery reform model participant a

specified amount per month for telehealth services. If necessary, the demonstrations could be limited to models with two-sided risk.

With this new proposed rule, CMS clearly signals that it believes that delivery reform models should be expanded to improve efficiency and quality of care delivery for Medicare beneficiaries. As this rule and preceding ones note, these goals can only be achieved with providers committed to care redesign and infrastructure changes necessary to support greater coordination and care management during a defined episode. Telehealth services can be, and, from our point of view should be, central in any plan for redesigning care for payment across an episode of care. Waivers of the originating site and geographic site requirements that apply to telehealth services are a step in the right direction. But they are insufficient for allowing providers to maximize the potential of the various telehealth technologies to reduce the cost of care and improve health care outcomes. CMS's delivery reform models offer the ideal scenario for testing and defining how these services can be cost effective and AdvaMed urges CMS to actively pursue using delivery reform models, including the EPMs of the proposed rule, for such purposes.

Special Policies for Hospital Transfers of Beneficiaries [Comments related to Section III.C.4.a(5)]

The proposed rule notes that the asymmetric distribution of cardiac care across hospitals makes transfer, either from an inpatient admission or from the emergency department without inpatient admission of one hospital to another, a common consideration in the treatment course for beneficiaries and an important consideration for the AMI and CABG models.

CMS proposes an overarching policy in which every AMI or CABG episode would begin at the first AMI or CABG model participant to which the beneficiary is admitted. That participant would be the hospital with financial responsibility for managing the costs of the 90-day episode of care, even though it may not be the hospital where the beneficiary is treated and ultimately discharged from acute care.

AdvaMed recommends that the hospital actually performing the procedure assume the risk for managing the costs of the episode. The proposed rule cites data showing that about half the average AMI model historical episode spending has been for the initial hospitalization, with the majority of spending following discharge from the initial hospitalization due to hospital readmissions and relatively less spending on SNF services, Part B professional services, and hospital outpatient services. In CABG model historical episodes, about three-quarters of episode spending has been for the initial hospitalization, with the remaining episode spending relatively evenly divided between Part B professional services and hospital readmissions, and a lesser percentage on SNF services. Under CMS's proposal, this means that the hospital where the patient was first seen but did not receive treatment must assume responsibility for both the costs and outcomes of care received at another hospital, but also for care that consequentially flows from the treatment received at the treating hospital. This places an unfair burden on the transferring hospital. In addition, while it may be possible in the future for the hospital with

limited cardiac care resources to enter into collaborative arrangements with other hospitals to which a patient may be transferred, the bulk of spending, according to CMS's own data, will still be attributed to the hospital providing the treatment and will be determined by the care received during that inpatient stay. For these reasons, AdvaMed argues that the treating hospital should assume responsibility for the costs of the episode, and if the referring hospital can play a role in post-acute care, its spending would then be among those costs managed by the treating hospital post discharge.

Financial Arrangements under the EPM and Patient Access to Care [Comments related to Section III.I]

Whether through the traditional Medicare fee-for-service program or a delivery reform model, a beneficiary's access to the full range of treatment options appropriate for a given medical condition is critical for positive health care outcomes to be achieved. While AdvaMed supports bundled payment programs and other delivery reform models, we are concerned that the financial incentives in these programs – to reduce short-term costs and reward providers for cost savings through gainsharing programs – have the potential to compromise patient access to the full range of appropriate treatment options for a given medical condition, especially those that are more expensive than others, including innovative treatments that are more expensive than the current standard of care, even when they produce better outcomes for patients. We refer to this dynamic as stinting on care.

AdvaMed is particularly concerned that stinting in the proposed EPMs can take the form of avoiding complex, high cost cases by delaying treatment, not admitting patients at all, or by transferring patients to nearby facilities or referral centers that would be outside of the model. Monitoring for stinting is especially critical, since beneficiaries, as noted in the rule, would not be able to opt out of an EPM episode of care provided by an EPM participant in the model.

AdvaMed is therefore pleased to learn in the proposed rule that CMS plans to monitor EPM participant claims data to compare each EPM participant's case mix relative to a pre-model historical baseline. The proposed rule provides examples of the analyses CMS plans to conduct: a comparison to determine whether complex patients are being systematically excluded, whether there is an unusual pattern of referral to regional hospitals located outside of the EPM's catchment area; or whether there exists a clinically unexplained increase or decrease in CABG rates or rates of other related surgical procedures not covered under the EPMs.

In addition to these claims data analyses, AdvaMed strongly recommends that CMS move conduct audits of a sample of patient medical records to determine whether the services actually received by beneficiaries in the proposed EPMs correspond to existing standards of care – and whether they also include innovative treatments and procedures appropriate for a beneficiary's medical condition. It is only at this more granular level of analysis that CMS will be able to see whether patients are receiving the care they require.

Transparency of Findings on Impact of EPMS [Comments related to Section III.I]

CMS states in the proposed rule that it intends to publish claims data comparisons of patterns of care delivery pre- and post-EPM participation as part of the EPMS' evaluations to promote transparency and an understanding of the EPMS' impact on patient care outcomes. Given the mandatory nature of the proposed demonstration, AdvaMed believes that these analyses must be published at least quarterly in order for patients and policymakers to identify significant changes in services to ensure that all parties may be informed about variations in quantity and quality of care provided at institutions in their areas that may have an impact on clinical outcomes. We note that the Bundled Payments for Care Improvement (BPCI) initiative Year One Evaluation was published February 2015 and the Year 2 Evaluation was not released until September 19, 2016. Given the critical nature of the medical conditions covered by the proposed EPMS, the public release schedule for BPCI evaluations is inadequate for patients and other stakeholders to understand what impact the models have on health care services and the care they would receive at specific institutions. We again note that patients cannot opt out of an EPM episode of care provided by an EPM participant in the model. AdvaMed recommends that the final rule for the proposed EPMS provide a commitment to quarterly public release of data analyses showing impact of the models on patient care.

Risk Adjustment [Comments related to Section III.D.4.b.(2)]

CMS continues to believe, as the agency initially stated with regard to CJR episodes, that no widely accepted standard risk adjustment approach exists for the proposed EPM episodes. Therefore CMS would not make risk adjustments based on beneficiary-specific demographic characteristics or clinical indicators. Nor does CMS believe that the CMS Hierarchical Condition Categories used to adjust for risk in the Medicare Advantage (MA) program are appropriate for risk-adjusting EPM episodes, since HCC categories are used to predict total Medicare expenditures in an upcoming year for MA plans and may not be appropriate for use in predicting expenditures for shorter episodes of care. Instead CMS proposes specific policies and payment adjustments, such as adjusting the AMI model episode benchmark prices for certain AMI model episodes involving a chained anchor hospitalization. AdvaMed agrees that such price adjustments to the benchmarks are appropriate at the present time in the absence of appropriate risk adjustment, but AdvaMed urges CMS to work with appropriate specialty societies to develop an adequate risk adjustment mechanism.

Blending Hospital-Specific and Regional Historical Data [Comments related to Section III.D.4.b.(7)]

The proposed rule would calculate EPM-episode benchmark prices using a blend of EPM-participant hospital-specific and regional historical average EPM-episode payments, including historical EPM-episode payments for all IPPS hospitals that are in the same U.S. Census division. Over the course of the 5 performance years that are part of the demonstration, the calculation of benchmark prices would transition primarily from hospital-specific to completely

regional pricing. CMS's stated goal with regional pricing is to improve efficiency of both historically-efficient and less efficient EPM participants in each of the nine U.S. Census divisions that would be used.

AdvaMed believes that U.S Census regions are too large and diverse to be used for the transition to regional benchmark pricing. These large regions will result in a new set of inefficiencies, not significantly different from benchmark pricing based on national averages. For example, hospitals that treat sicker patients on average might be penalized in regions that are too large and diverse. AdvaMed recommends using smaller and more cohesive regions such as those designated for Medicare's Administrative Contractor program or not base benchmark prices fully on a regional average. Alternatively, CMS could also take into account a hospital's MCC/CC mix of patients.

Excluding New Technology Payments from EPM Episodes [Comments related to Section III.C.b.]

CMS proposes to exclude IPPS new technology add-on payments and OPPS transitional pass-through payments for medical technologies from EPM episodes, excluding them from both the actual historical episode data used to set EPM-episode benchmark prices and from actual EPM payments that are reconciled to the quality-adjusted target prices. This would apply to both the anchor hospitalization and any related readmission during the EPM episodes. As we have noted in previous comment letters to CMS on other proposed rules, we support this proposal for EPM episodes.

CMS explains that it proposes this policy so that it does not diminish beneficiaries' access to new technologies or to burden hospitals which choose to use these new technologies with concern about these payments counting toward EPM participants' actual EPM episode payment. The proposed rule also notes that use of these technologies varies unpredictably over time in their application to specific clinical conditions and beneficiaries should not have their access to these technologies compromised by their cost.

AdvaMed believes that additional innovative technologies, beyond NTAPs, should qualify for a similar adjustment as that being made for NTAPs and OPPS transitional pass-throughs, and that the justifications cited for the proposed policy are just as applicable to these other technologies.

AdvaMed recommends that CMS establish a review process for these technologies to determine whether their cost should be removed from benchmark price and actual spending totals for delivery reform models implemented by CMS and CMMI. CMS could test this process through a CMMI initiative specifically for those EPM participants mandated to participate in the demonstration for AMI and CABG conditions, for example. In brief, this process would allow manufacturers or developers to identify higher cost breakthrough technologies/treatments that offer clinical improvements for all or certain types of patients or offer significant therapeutic advances for new populations or conditions.

AdvaMed recommends that the review process for these technologies/treatments would be similar to the one now used by CMS for NTAPs, but without regard to the statutory and regulatory policies that apply to NTAP approvals. Manufacturers and developers would provide CMMI the estimated incremental increase in spending that would result from each use of an approved treatment. They would also provide CMS the data and methodology for such estimates as part of the application process to assist CMS in determining whether a treatment or technology warrants special accommodation and what adjustments would be made. If approved by CMMI, the adjustments would apply to use of the technology across all EPM participants, and other relevant delivery reform models. But we also recommend that CMMI allow individual EPM participants to request an adjustment if they were to adopt breakthrough/high cost treatments in advance of other hospitals. In this case, the adjustment would be applied to the individual participant and also to all participants using the technology/treatment.

Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey (NQF #0166) (III.E.4.d.(1))

In the proposed rule, CMS intends to use the HCAHPS Hospital Survey (NQF #0166) as one of a fairly limited set of quality metrics that will affect payment in each of the three Episode Payment Models (EPMs) for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) and surgical hip/femur fracture treatment (SHFFT). This is a national, standardized and publicly reported survey of patients' experience with hospital care. Although AdvaMed understands the important value of patient experience data and supports the adoption of CAHPS for use in these EPMS, the questions included in the proposed hospital version of the CAHPS survey is non-specific for the intended populations addressed here. CMS should consider whether it should include the clinician and group practice version of CAHPS or potentially the surgical version of CAHPS as an alternative metric. Additionally, CMS could consider filtering the HCAHPS results by DRG or ICD diagnosis and provide a separate report on those to the EPM participant hospital. **AdvaMed also recommends that the CAHPS measures that apply to these EPMS evolve quickly to include patient surveys that also query on access to specialists and assess whether or not patients thought that they were provided sufficient and timely access to medical innovation and technology in their care.**

Potential Future Measures for EPMS (III.E.4.d.4)

1. Coronary Artery Bypass Graft (CABG) / Acute Myocardial Infarction (AMI)

AdvaMed supports the use of the proposed measure for the CABG model, *Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2558) (MORT-30-CABG)*, as a critical quality measure for CABG. In addition, AdvaMed recommends that CMS consider the inclusion of the consensus-based morbidity measures that the vast majority of hospitals performing CABG are already reporting

on through the STS' Adult Cardiac Database.¹ Such measures include, the STS' risk-adjusted CABG Composite Score (NQF #0696), which is comprised of 30-day mortality, the five most serious complications of CABG, and key process measures that support high quality care.²

Importantly, this measure captures wound complications following this high-volume cardiac surgery. This is significant because of the variable incidence of post-operative sternotomy wound surgical site infections. Post-operative wound complications can significantly contribute to unnecessary poor outcomes including readmission rates due to wound infections, dehiscence and other complications, including death. There are several supporting studies that demonstrate how certain protocols and treatments can significantly lower the risk of wound complications following CABG.^{3,4,5} Including a quality measure that captures the type and incidence of subsequent wound complications post- CABG would help to address a major set of post-operative complications that affect this patient population and likely lead to measures focused on improving clinical outcomes for these patients.

Additionally, CMS should consider an outcome measure evaluating blood transfusion rates during CABG procedures. Perioperative red blood cell transfusion is the single factor most reliably associated with increased risk of postoperative morbidity events after CABG.⁶ Yet, there continues to be significant variation across hospitals even after controlling for differences in hospital case-mix and despite well-established clinical guidelines.^{7,8} AdvaMed also recommends that CMS consider adding the existing measure for 30-day readmissions following CABG: *Hospital 30-day, all-cause, unplanned, risk-standardized readmission rate (RSRR) following coronary artery bypass graft (CABG) surgery (NQF# 2515)*. This measure was added to Medicare's Readmissions Reduction program as of October 1, 2016. If added to the CABG quality metrics, it would further align hospital care around quality for this high-volume cardiac surgery. If adopted, CMS should consider the entire measures package for each model in the ACC-EPM final rule with an eye to any double jeopardy created and adjust the composite score weights accordingly

Finally, as part of the AMI PCI EPM, AdvaMed supports the inclusion of a measure concerning in-hospital risk-adjusted bleeding events within 72 hours of admission for patients undergoing PCI (NQF #2459). This measure is important because bleeding complications after PCI are

¹ <http://www.sts.org/sts-public-reporting-online/cabg-composite-score>

² <http://www.sts.org/quality-research-patient-safety/quality/quality-performance-measures>

³ Witt-Majchrzak et al. Preliminary Outcome of Treatment of Postoperative Primarily Closed Sternotomy Wounds Treated Using Negative Pressure Wound Therapy. *Polski Przegląd Chirurgiczny*; Vol 86 (10): 456-65, 2014.

⁴ Reddy VS (Seenu). Use of Closed Incision Management with Negative Pressure Therapy for Complex Cardiac Patients. *Cureus*. 2016;8(2):1–10. doi:10.7759/cureus.506.

⁵ Grauhan O, Navasardyan A, Tutkun B, et al. Effect of surgical incision management on wound infections in a poststernotomy patient population. *Int Wound J*. 2014;11 Suppl 1:6–9. doi:10.1111/iwj.12294.

⁶ Koch et al. Morbidity and mortality risk associated with red blood cell and blood-component transfusion in isolated coronary artery bypass grafting. *Critical Care Medicine*. 2006;34(6): 1608-16.

⁷ Bennet-Guerro et al. Variation in Use of Blood Transfusion in Coronary Artery Bypass Graft Surgery. *JAMA*. 2010;304(14):1568-1575.

⁸ Ferraris et al. Blood Transfusion/Conversation in Cardiac Surgery. *Ann Thorac Surg*. 2007;83:S27–86.

common and associated with increased short- and long-term risk of morbidity and mortality.⁹ It is important to note, that this measure is already included in CMS's Core Quality Measure Set for PCI procedures.¹⁰

2. Surgical Hip/Femur Fracture Treatment (SHFFT)

AdvaMed appreciates that, in the absence of specific measures for hip fracture care, using the total joint arthroplasty quality measure, *Hospital-level Risk-Standardized Complication Rate (RSCR) following elective primary THA and/or TKA (NQF #1550) (Hip/Knee Complications)*, serves as perhaps an adequate surrogate at this time. As CMS moves forward with the SHFFT bundle, **AdvaMed urges the agency to establish, as quickly as practicable, specific hip fracture quality measures that capture key clinical endpoints which reflect higher quality care.** Examples of additional potential measures that could be developed in this space to address these concerns include the following:

- Surgical site infection (SSI) rate following hip fracture
- Complications rate following hip fracture
- 30-day readmissions following hip fracture
- 90-day reoperations rate following hip fracture
- Percent of patients returning to pre-fracture ambulatory status at 90 days

Addressing hip fractures with quality measures focused on specific endpoints in the future would likely provide more focused information that would result in improving outcomes for this patient population.

Implementation Timeline

AdvaMed urges CMS to work closely with stakeholders most immediately affected by the proposed implementation timeline and consider carefully their comments regarding implementation. AdvaMed urges CMS to incorporate the monitoring/evaluation and transparency patient protections discussed above for ensuring beneficiary and provider access to devices that are appropriate for patients' particular needs before finalizing the rule and implementing the model. Doing so will allow for the continued delivery of high-quality care across a 90-day episode.

⁹ Rao SV et al. An updated bleeding model to predict the risk of post-procedure bleeding among patients undergoing percutaneous coronary intervention: a report using an expanded bleeding definition from the National Cardiovascular Data Registry CathPCI Registry. *JACC Cardiovasc Interv.* 2013 Sep;6(9):897-904. doi: 10.1016/j.jcin.2013.04.016.

¹⁰ <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-02-16.html>

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We thank you again for this opportunity to comment on the proposed rule on EPMS. If you have questions, please contact Richard Price at rprice@advamed.org or 202-434-7227, or Steve Brotman on quality measure issues at sbrotman@advamed.org or 202-434-7207.

Sincerely,

A handwritten signature in black ink that reads "Donald May". The signature is written in a cursive style with a long, sweeping tail on the "y".

Donald May
Executive Vice President
Payment and Health Care Delivery Policy