



June 27, 2016

Andrew Slavitt, Acting Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attn: CMS-5517-P  
Mail Stop C4-26-05  
7500 Security Blvd.  
Baltimore, MD 21244-1850

**Re: Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models; Proposed Rule**

Dear Acting Administrator Slavitt:

On behalf of the Advanced Medical Technology Association (AdvaMed), I am pleased to offer comments on the proposed rule on the Medicare Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, published in the *Federal Register* May 9, 2016 (CMS-5517-P). AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

We commend CMS for the extensive effort required to implement the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) provisions establishing MIPS and APMs for the physician fee schedule and a value-based approach in setting payments for physician services. AdvaMed supports many of the proposals in the rule and offers comments and recommendations related to specific proposals. Our comments are organized into several sections related to the following overarching categories:

- **MERIT-BASED INCENTIVE PAYMENT SYSTEM (MIPS)**
  - GENERAL COMMENTS ON THE MERIT-BASED INCENTIVE PAYMENT SYSTEM (MIPS)
  - MIPS: RESOURCE USE/COST PERFORMANCE CATEGORY
  - MIPS: QUALITY PERFORMANCE CATEGORY

- MIPS: CLINICAL PRACTICE IMPROVEMENT ACTIVITIES (CPIA) PERFORMANCE CATEGORY
- MIPS: ADVANCING CARE INFORMATION PERFORMANCE CATEGORY
- **ALTERNATIVE PAYMENT MODELS (APMS)**

## **MERIT-BASED INCENTIVE PAYMENT SYSTEM (MIPS)**

### **GENERAL COMMENTS ON THE MERIT-BASED INCENTIVE PAYMENT SYSTEM (MIPS)**

#### **1. Performance Period**

The proposed implementation period for the first year of the MIPS program provides little time for physicians to prepare and fully understand the new system. Because implementation of the final MIPS/APM rule is slated to begin with the first performance measurement year starting on January 1, 2017, physicians and vendors that will be required to report will have little time to understand how to operationalize the rule and begin reporting. **Although we understand the potential issues related to implementing a shorter reporting period, AdvaMed recommends that, for the first year of the MIPS program, CMS consider a shorter initial reporting period and implement a grace-period or delay of six months. We recommend that the first performance measurement period start on July 1, 2017.** Delaying implementation would provide physicians additional time to understand the program requirements, adopt new processes for reporting, and minimize confusion.

#### **2. Peer-Review Publication Requirement**

In the proposed rule, CMS notes that prior to finalizing new measures for inclusion in the MIPS program, those measures that CMS determines will move forward must also go through notice-and comment rulemaking and in addition, the new proposed measures must be submitted for publication in applicable specialty-appropriate peer review journals. CMS notes that the submission must include the method for developing and selecting such measures, including clinical and other data supporting such measures. **AdvaMed recommends that new measures be posted to journals associated with the American Board of Medical Specialties (ABMS), related subspecialty journals or journals associated with the American College of that specialty (e.g., Journal of the American College of Surgeons) and non-ABMS recognized clinical specialty journals that are trusted resources for specialists (e.g., Journal of the Academy of Nutrition and Dietetics; Journal of Wound, Ostomy and Continence Nursing) to ensure a wide range of readership and distribution.**

## **MIPS: RESOURCE USE/COST PERFORMANCE CATEGORY/EPISODES OF CARE**

### **1. Payment and Quality Score Adjustments for New Tests/New Technologies**

AdvaMed is concerned that the MIPS/APM proposed rule may create disincentives to incorporate new medical technologies including new diagnostic tests, new devices or any advanced technologies that might have an associated cost because there are no measures or adjustments proposed by CMS to account for them. We are concerned that the MIPS quality structure as laid out in the proposed rule could have the unintended effect of limiting the number and types of tests and technologies offered due to higher associated risks/costs. **We urge CMS to provide adjustments in the MIPS which can provide Medicare beneficiaries the benefits of innovations in health care without undermining the overarching goals of the program.**

The payment and quality score adjustments we are recommending for the MIPS should also be applied to the Advanced Payment Models (APMs). The APM section of this comment letter provides additional details regarding these adjustments.

### **2. Analysis Showing Episode Cost Variation in Resource Use**

AdvaMed believes that more information is needed for external stakeholders to fully understand and assess the validity and reliability of the proposed episodes. **We urge CMS to conduct and provide data analysis showing the variation in resource use within and across episodes. This will help CMS and stakeholders to more fully understand and assess whether it is possible to reliably predict, within any particular episode, the average cost, median and range of the episode at a per member/patient level. We also urge CMS to provide analysis showing the longitudinal distribution of clinical events identified in the claims in order to provide meaningful comments about appropriate episode endpoints.** The claims data should assess both homogeneous and heterogeneous patient populations to best address the generalizability of the data and impact of significant co-morbidities. Also, as early adopters of new, cutting edge, more costly technologies/devices – which potentially reduce costs over time and improve patient outcomes beyond times captured by an episode – could fall on the tail of a cost analysis curve, it is important that CMS provide a deeper evaluation in these circumstances to differentiate whether they represent true outliers of cost versus outliers for use of new technologies that are being incorporated into new standards of care.

### **3. Risk Adjustment**

Risk or severity adjustment is intended to account for patient-related clinical factors that exist prior to the patient's encounter with the provider being measured. Risk adjustment provides safeguards that providers are accurately being measured on outcomes or processes that they can reasonably influence, rather than underlying differences in patient severity. There are also some inherent limitations in the handling of risk in the development of episodes. Given that many episode groupers use administrative claims data, there may not be sufficient granularity in the data in many cases to capture clinical characteristics or severity for certain episode types.

Risk adjustment is a key element that must be valid, reproducible, sensitive and specific. Any flaws that may be present in the methodology to examine risk adjustment can potentially lead to flawed conclusions and therefore compromise the validity of the resultant conclusions. It is important to consider as many relevant variables as possible in developing episode groups. For example, absent many times from the discussion on determination of risk stratification factors concerning hip/knee implants are individual patient measures in the orthopedic context such as functional/range of motion status, presence or absence of specific orthopedic pre-operative deformities, and other indicators and/or disorders involving variability of bone quality, including diseases/disorders affecting bone growth/functions and medications affecting mineral absorption and bone quality.

Patient-specific factors should be included in the risk stratification for episodes, as they vary from patient-to-patient and can play a very significant role in the post-surgical complication rate. CMS might consider the significance and development of ICD-10 codes in the future that could capture these types of patient-specific variations in all clinical fields and which could be included in the risk adjustment model. AdvaMed also recommends that CMS work closely with stakeholders to address the existing shortcomings of the CMS Hierarchical Condition Category model as they consider risk adjustment methodologies for the MIPS and other APMs.

Additionally, adjustments to account for socioeconomic/demographic status are very important. CMS notes in the proposed rule that it will closely examine the recommendations from the HHS' Office of the Assistant Secretary for Planning and Evaluation (ASPE) study, when they are made available on the issue of risk adjustment for socio-economic status on quality measures and resource use, as required by the IMPACT Act and incorporate them as feasible through future rulemaking. **We urge CMS to develop an appropriate adjustment for socioeconomic/demographic status.**

## **MIPS: QUALITY PERFORMANCE CATEGORY**

### **1. Specialty-Specific Measure Sets: Cross-Functional Specialty-Specific Measure Sets for non-ABMS Recognized Clinical Specialties Such as Wound Care and Malnutrition.**

CMS notes that it proposed the specialty-specific measure sets in Table E to address feedback in past rules that the quality measure selection process can be confusing. CMS states that a common complaint about PQRS was that EPs were asked to review close to 300 measures to find applicable measures for their specialty. The specialty measure sets in Table E are sorted consistent with the American Board of Medical Specialties (ABMS) specialties.

AdvaMed appreciates CMS' efforts to combine numerous related MIPS measures into clinically-related specialty groups by ABMS approved specialty. However, CMS should also recognize that there are areas of clinical practice that are not represented by an ABMS approved specialty, such as wound care. The delivery of wound care is performed by clinicians in several specialties including surgeons, plastic surgery, physical therapists/rehabilitation medicine, internists, family practitioners and others. In some of these specialties, such as plastic surgery, wound care may

account for the majority of the provider's practice. Similarly, malnutrition care may be provided by multiple eligible professionals/specialties (e.g., gastroenterologists, oncologists, geriatricians, cardiologists, family practitioners, and hospitalists).

**AdvaMed urges CMS to expand the specialty-specific measure sets listed in Table E beyond the ABMS approved specialty frame work to include a specialty set for wound care and malnutrition, as well as other cross-functional clinical areas for which there are significant volumes of patient care delivery across multiple specialties.** We urge CMS to also accommodate additional patient and clinician-desired needs into Table E as additional areas are identified in future rulemaking.

## **2. Radiation Oncology Specialty-Specific Measure Set**

In the proposed rule, the specialty-specific measures sets listed in Table E categorize the individual measures based on the American Board of Medical Specialties (ABMS) system. We are concerned that several radiation oncology measures have been listed under the main header of Radiology. It is important to note that Radiation Oncology is not a subspecialty of radiology, but is a separate and distinct medical specialty. **We recommend that CMS provide a separate category in the specialty measure set for "Radiation Oncology" and transfer all Radiation Oncology Measures listed under Radiology in Table E to this section.**

## **3. Inclusion of General Surgical Site Infection Measures in All Surgically-Related Specialty Measure Sets.**

AdvaMed is pleased that CMS has included the Surgical Site Infection (SSI) Measure as part of several specialty measure sets, such as urology, surgery, otolaryngology and thoracic surgery in Table E of the proposed rule. **In addition to these clinical specialties, AdvaMed recommends that CMS also include the same SSI measure to the following specialty measure sets: vascular surgery, dermatology, plastic surgery and obstetrics/gynecology.**

As an example regarding obstetrics, caesarean section is the most common major surgery performed on women, however surgical site infections (SSIs) following caesarean section poses a significant health burden due to extended hospital stay, return to the hospital, additional nursing care, medication and wound care. Research is showing that improved care protocols and application of negative pressure wound therapy (NPWT) devices and other specialized wound care dressings can play a critical role in significantly reducing the risk of complications after C-section.<sup>1</sup> This builds on a growing body of evidence showing that NPWT can play a critical role in addressing these post-operative wound complications. In a systematic review and meta-analysis of randomized clinical trials of NPWT compared with standard postoperative dressings on closed surgical incisions, NPWT significantly reduced the rate of wound infection and seroma when applied to closed surgical wounds.<sup>2</sup> While we understand that Medicare is not a high-volume payer for births, it does cover about 14,000 deliveries annually. Given CMS's continuing

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<sup>1</sup> Hickson Evelyn, Harris Jeanette, and Brett David. Surgical Infections. April 2015, 16(2): 174-177.

<sup>2</sup> Br J Surg. 2016 Apr;103(5):477-86. doi: 10.1002/bjs.10084.

focus on harmonizing quality measures across payers, we believe that the addition of SSI measures to all surgical specialties contained in the specialty measure sets in Table E would be an important first step towards future awareness and adoption of similar measures by private payers and Medicaid state agencies.

## **MIPS: CLINICAL PRACTICE IMPROVEMENT ACTIVITY (CPIA) PERFORMANCE CATEGORY**

### **1. Recommendation to Incorporate an Additional CPIA Activity Regarding Shared Decision Making in Considering Use of New Technologies in Patient Care.**

AdvaMed applauds CMS for providing innovative and creative ways to advance patient care for eligible clinicians or groups to satisfy the CPIA reporting requirements in multiple subcategories. In this regard, **AdvaMed recommends that CMS incorporate an additional CPIA activity for the subcategory of Beneficiary Engagement that would require shared decision making for discussion of new technologies in patient care.** The activity would encourage practitioners and groups to take time and provide thoughtful engagement with their patients when potential new technologies may be used as an option in their care. For some practitioners, this would allow them a new way to practically incorporate new technology and new procedures in their practice for the benefit of their patients.

**Therefore, AdvaMed recommends a CPIA titled, “Implementation of Shared Decision Making for Utilization of New Technologies in Patient Care.”** This activity could also be incorporated into the additional CPIA subcategories of expanded practice access, patient safety and practice assessment or the care coordination subcategory. Additionally, this new activity would meet the CPIA inclusion criteria included in the proposed rule by achieving improved beneficiary health outcomes and reducing health care disparities. This new CPIA is also representative of an activity that multiple MIPS eligible clinicians or groups could perform and implement.

### **2. Recommendation to Include a CPIA Activity Regarding Providing Timely Access to Medical Technologies**

AdvaMed believes that timely access to medical technology is a key component to the success of any Clinical Practice Improvement Activity. CMS has pointed out that the subcategory of “Promoting Health Equity and Continuity” should incorporate maintaining equipment and other accommodations (for example, wheelchair access, accessible exam tables, lifts, scales, etc.) which are necessary to provide comprehensive care for patients with disabilities. **Likewise, AdvaMed recommends that there should be similar emphasis on providing timely access to medical technologies such as those dealing with chronic conditions, imaging, diagnostic testing/screening, wound care and nutrition/malnutrition – especially for patients that are in need of social services including disabled patients and underserved populations.** **AdvaMed recommends that the CPIA be titled “Ensure Timely Access to Medical Technologies in Practice Improvement.”** Advanced medical technologies should also be an

inherent part of the subcategories dealing with “Patient Safety and Practice Assessment” and “Emergency Preparedness and Response.”

### **3. Recommendation to Include Continuing Medical Education (CME) Activities as a CPIA**

Although CMS provides a wide range of activities to fulfil the CPIA requirements as listed in the CPIA Inventory in Table H, continuing medical educational activities are not included. CME activities are well-regarded and have demonstrated improvement in physicians’ competence and practice resulting in improved care for patients. CME activities provide up-to-date medical education/training and have long been recognized as an efficient means by which physicians can pursue professional development, including introduction to and incorporation of innovative technologies into their practice to advance patient care. CME encourages physicians to develop/maintain knowledge, skills, and practice performance that leads to improved performance with optimal patient outcomes. These outcomes are consistent with the intent of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), as well as the "Three Aims of Healthcare" established by the National Quality Strategy (NQS). In addition, many accredited CME activities have been certified by individual ABMS specialties and can be used by physicians toward Board Certification. **Therefore, AdvaMed recommends that CMS include continuing medical education activities set-forth by nationally-recognized accreditors, as a clinical practice activity within the MIPS.**

### **4. Recommendation to Provide a CPIA Subcategory Specific to those Non-Patient-Facing Physicians.**

AdvaMed recognizes that CMS has worked to provide numerous choices in each sub-category of the listed CPIA Inventory in Table H. However, despite the number and diversity of activities listed, the majority of these revolve around patient care and accommodate patient-facing physicians. As a result, non-patient-facing physicians, such as many pathologists and radiologists, have limited choices. **AdvaMed recommends expanding the choices of CPIAs for non-patient-facing physicians. In addition, we suggest creating a separate sub-category – or additional denotation of existing sub-categories – specifically indicating use by non-patient-facing physicians.** These approaches would serve to focus patient facing and non-patient-facing physicians on applicable activities and lessen confusion while providing additional choices.

### **5. CPIA Data Submission Criteria; Weighted Scoring**

CMS requests comments on which criteria should be considered in determining whether to weight an activity as medium or high in the scoring for CPIAs. AdvaMed recommends that the criteria should consider effective care coordination that can be accomplished through regular monitoring of the patient’s health status, needs and services through frequent communication and exchange of information such as through the “effective use of electronic tools (for example, remote physiologic monitoring, electronic data acquisition and reminders, patient education modules,

and informed decision making tools).”<sup>3</sup> The use of such tools would also correlate with many of the proposed activities under the Clinical Practice Improvement Activities Inventory (Table H of the Proposed Rule) set forth by CPIA subcategories including Care Coordination, Beneficiary Engagement, Expanded Practice Access, Population Management, Patient Safety and Practice Assessment, Achieving Health Equity and Integrated Behavioral and Mental Health.

Additionally, regarding submissions mechanisms under the CPIA data submission criteria, AdvaMed recommends that CMS consider FDA listed (Class I), cleared (Class II) or approved (Class III) medical devices (including mobile medical) or those digital health tools under the agency’s enforcement discretion, for purposes of evaluating remote monitoring and telehealth contributions towards composite performance scores.

## **6. Inclusion of Permissible Medicare Telehealth Services in CPIA Inventory**

**AdvaMed recommends that CMS include in appropriate activities the list of covered telehealth services for distant site practitioners as mentioned in the List of Telehealth Services.**<sup>4</sup> Although physicians may furnish and receive payment for these covered Medicare telehealth services if billed and performed under requirements of the law, for purposes of clinical practice improvement activities many of these services may be performed through the use of store and forward electronic tools that are not covered by Medicare. These services could include, among other things, follow-up inpatient telehealth consultations furnished to beneficiaries in hospitals or SNFs, office or other outpatient visits, individual and group education, and disease management services. CMS should also include store and forward electronic tools among the covered technologies that should be included in CPIA activities, which would serve to provide a wide range of services for patient care.

## **7. CPIA Inventory: Subcategories for the Clinical Practice Improvement Activity Performance Category**

Both the authorizing law for MIPS and the proposed rule enumerate subcategory activities that MIPS eligible clinicians may select from in order to meet the requirements of the clinical practice improvement activity performance measure. Subcategories include: expanded practice access, population management, care coordination, beneficiary engagement, patient safety and practice, and participating in an APM. The proposed rule adds additional subcategories: achieving health equity, emergency preparedness and response, and integrated behavioral and mental health. The proposed rule includes examples to illustrate the kinds of activities that might be included in each of the subcategories to help stakeholders understand distinctions between the separate subcategories. **While AdvaMed recognizes that the examples cited in the statute and**

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<sup>3</sup> <https://pcmh.ahrq.gov/page/coordinating-care-adults-complex-care-needs-patient-centered-medical-home-challenges-and>

<sup>4</sup> <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3476CP.pdf>. At 190.3 “List of Telehealth Services.” The various telehealth services and corresponding current procedure terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) codes are listed on the CMS Telehealth fact sheet found here: <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/telehealthsrvcfsctst.pdf>.

**proposed rule are not intended to be all-inclusive, we note that the use of remote monitoring or telehealth is mentioned only in the care coordination subcategory. We believe that use of remote monitoring and telehealth technologies could be cited as a relevant example of activities for each of the statute’s subcategories as well as the additional ones added by the proposed rule. We request that CMS include telehealth technologies among the examples in each of the subcategory activities included in a CPIA performance category.**

**In addition, AdvaMed commends CMS for planning to solicit activities for inclusion in the CPIA Inventory for future years of MIPS from MIPS eligible clinicians or groups and other relevant stakeholders.** As part of the process, MIPS eligible clinicians or groups should be able to nominate additional activities that CMS could consider adding to the CPIA Inventory. In developing future activities for the CPIA Inventory, CMS should continue to draw upon working sessions with AHRQ, ONC, HRSA, and other federal agencies. In particular, ONC has undertaken recent efforts to create a patient-generated health data (PGHD) framework that could be helpful to CMS as it continues to implement CPIA.<sup>5</sup>

## **8. CPIA Policies for Future Years**

AdvaMed agrees that the inclusion of additional measures and activities captured by Qualified Clinical Data Registry (QCDRs) could enhance the ability of MIPS eligible clinicians and groups to report on more meaningful activities. QCDRs may provide for a diverse set of measures under CPIA and may also provide the opportunity for long-term data collection. **AdvaMed supports the concept of allowing QCDRs to define specific CPIAs through the already established QCDR approval process for measures and activities.** A prime example would be the use of QCDR measures appearing on the US Wound Registry<sup>6</sup> which would allow MIPS eligible clinicians from various specialties to report on this specific topic in a succinct manner.

## **MIPS: ADVANCING CARE INFORMATION PERFORMANCE CATEGORY**

**AdvaMed commends CMS for including “Coordination of Care Through Patient Engagement” in the Advancing Care Information (ACI) objectives and measures, as outlined in Table 6 of the proposed rule.** In particular, we support inclusion in the ACI base score of the patient-generated health data measure, which was adopted in the 2015 EHR Incentive Programs Final Rule for Stage 3 of “meaningful use.” The proposed ACI measure requires the acquisition of patient-generated health data or data from a non-clinical setting to be incorporated into the certified EHR technology for at least one patient seen by the MIPS eligible clinician during the performance period. For purposes of this measure, we note that under the final rule for meaningful use Stage 3, the types of data that would satisfy the measure are broad and may include, but are not limited to, social service data, data generated by a patient or a patient's authorized representative, advance directives, medical device data, home health

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<sup>5</sup> <https://www.healthit.gov/policy-researchers-implementers/patient-generated-health-data-pghd>

<sup>6</sup> <https://www.uswoundregistry.com/specifications.aspx>

monitoring data, and fitness monitor data. In addition, the sources of data vary and may include mobile applications for tracking health and nutrition, home health devices with tracking capabilities such as scales and blood pressure monitors, wearable devices such as activity trackers or heart monitors, patient-reported outcome data, and other methods of input for patient and non-clinical setting generated health data. We agree with including this measure for purposes of the MIPS advancing care information performance category.

## **ALTERNATIVE PAYMENT MODELS (APMS)**

### **1. Incentives for Participation in Advanced Alternative Payment Models (APMs) – Ensuring Patient Access to Appropriate Care in APMs**

AdvaMed supports alternative payment models and their goals to achieve lower cost and higher quality health care. At the same time, we are concerned that the financial incentives in these and other delivery reform models can have the inadvertent effect of discouraging providers from (1) considering the full array of treatment options, especially if they may increase costs above “benchmark” thresholds—we refer to this as stinting, or (2) using innovative treatments, technologies, and diagnostics that may bring value to the health care system over the longer term, but are more costly in the short run. The potential negative impact of the financial incentives of these models is magnified by a relatively short payment window, one-year, used to compare actual spending against benchmarks in order to determine savings/losses that may be shared among providers. Many medical devices and technologies provide benefits over a long period of time spanning multiple years.

We have argued in the context of CMS/CMMI ACO and bundled payment programs that adjustments for certain new technologies are necessary to ensure Medicare beneficiaries have access to the full range of treatment options and new technologies—to the extent these are more expensive than a current standard of care or are not yet reflected in quality measures. A broad range of medical technologies can be impacted by the incentives in these programs, including new and less invasive technologies for treating heart disease, innovative joint implants that lead to shorter recovery periods and extend durability of the implant for many years, new molecular diagnostic tests that identify more effective treatment therapies for disease, and robotic-assisted surgical technologies that result in better outcomes for patients. We believe that payment and quality score adjustments, discussed in greater detail below, are as relevant to APMs as they are to these other programs and request that CMS consider our recommendations below as the agency develops a proposed rule for calculating benchmarks, actual spending totals and quality score measurement for APMs. We offer the following examples as to why we think such adjustments are necessary. In addition, we point out that we do not expect that many new treatments and technologies will require such adjustments.

Data analysis by one of our member companies of experience with MSSP ACOs points to the potential impact the financial incentives in the ACO model and its one-year timeframe for measuring savings can have on care received by Medicare beneficiaries in this program. The specific data analysis done by our member company focused on utilization rates for several

interventional treatment options for arterial procedures and utilization rates of these options for Medicare beneficiaries served by ACOs. The analysis showed an increase in utilization of a lower cost procedure option and a decrease in utilization of a higher cost alternative procedure for patients served by ACOs. The increase in utilization of the lower cost option could mean more frequent re-interventions for patients in the future, with the result that higher savings for ACOs in the short-term could also mean higher long-term spending for the Medicare program in the subsequent years.

Last year, some of our orthopedic company members learned that certain providers participating in the Innovation Center's Bundled Payments for Care Improvement (BPCI) initiative have radically changed the type of hip and knee implants that they buy and use in patients. While this change is related to the highly targeted incentives in BPCI, the same incentives will exist for an APM.

Prior to their participation in BPCI, hospitals had purchased a range of device implants—including some implants that are more basic, without newer features and with varying levels of performance characteristics that improve range of motion or impact durability (e.g., lower utility implants) and others that included newer features that provided higher levels of performance. Providers made implant selection decisions that corresponded to the particular lifestyle needs of patients, including life expectancy, level of activity, and medical conditions. This process is called demand matching and is an effective method in managing utilization without limiting access to technologies that best meet individual patient needs. With participation in BPCI, these providers now purchase almost exclusively lower utility implants without respect to patient needs. Matching the utility of a device to a particular patient's need is critical to ensuring a positive outcome for the patient and long-term effectiveness of the procedure. For example, an active, tennis-playing 65-year old requires a hip or knee of higher utility and performance characteristics than one that is appropriate for a sedentary 85-year old.

While it is possible that the patient mix of Medicare beneficiaries treated by the providers has changed since participation in BPCI began, it should be pointed out that lower utility devices are also initially less expensive than the higher utility devices, leading to potentially higher internal savings that can be shared in the short term. The longer term impact of using almost exclusively lower utility devices, when they may not be appropriate for the lifestyle and medical needs of individual patients, may not be known for several years, when active beneficiaries may require earlier than expected revision procedures or experience other negative outcomes. If the choice of a hip or knee device were made solely on the basis of patients' relative health, lifestyle, and life expectancy, patients would be provided a device that appropriately demand matched to their unique needs with cost not being a leading driver of this decision so as to ensure the best possible outcomes and longevity.

In addition, quality standards used for APMs could discourage early adoption of new and better alternative treatments simply because the quality measures do not reflect breakthrough and innovative treatments. If a new approach to care is developed that may be superior to standard practice, and no special exception is provided for the new alternative treatment, physicians or hospitals may avoid adopting it because it will lower the ACO's quality score and, in turn,

reduce shared savings. We have learned from CMMI itself that physicians in Pioneer ACOs had asked to be able to use a new and more effective pneumococcal pneumonia vaccine instead of an older vaccine that is specified in a process quality measure used for both the MSSP and Pioneer programs. The problem that physicians in these ACOs face is a reduction in their quality scores if they do choose to use the new vaccine, simply because this particular measure does not yet reflect a new standard of care and because no special exception is allowed for physicians to use the innovation. Patients may not be harmed by the old vaccine but they are not, at the same time, provided the benefits of the new product. This is another good example of how a technical adjustment in delivery reform programs can provide Medicare beneficiaries the benefits of innovations in health care without undermining the overarching goals of the program.

Another instance of existing quality measures used in ACO programs impeding beneficiary access to innovative technologies involves two new and less invasive screening options for colorectal cancer. These new technologies include a CT Colonography and Cologuard, an at-home non-invasive colon cancer screening test for evaluating DNA mutations and blood in the stool. This latter screening tool was simultaneously approved by FDA and covered by CMS through parallel review in August 2014. The existing ACO quality measure for colorectal screening, however, recognizes only a fecal occult blood test, flexible sigmoidoscopy, and colonoscopy (the latter two according to a specified periodicity schedule). These screening methods have patient compliance issues that can lower screening rates. A provider wishing to use the innovative technologies would be penalized, as described in the previous example, for using the new screening tools instead of one of the three previously named tools specified in the quality measure. Once again, a technical adjustment or inclusion of these two new methods in the measure would provide Medicare beneficiaries the benefits of innovations in health care while enhancing quality of care available to patients.

These negative impacts can be avoided without undercutting the goals of the new payment and delivery systems by incorporating certain technical adjustments in the programs and by adopting other patient protection measures. We believe that these technical adjustments and patient protections become even more important for beneficiaries if CMS requires APMs and other delivery reform models to assume more risk for the cost of care.

AdvaMed notes that CMS has acknowledged the impact a higher cost innovative technology can have on providers' ability or interest in using that technology in patient care when they participate in delivery reform models, specifically BPCI and the Comprehensive Care for Joint Replacement (CJR) bundled payment model. The Innovation Center has approved carve outs of IPPS new technology add-on payments (NTAPs) from both the actual historical episode expenditure data used to set target prices and from the hospital's actual episode spending that is reconciled to the target price for providers participating in these programs. In proposing the carve out of NTAP amounts for the CJR model, CMS noted that it would not be appropriate for the model to potentially hamper beneficiaries' access to new technologies that receive NTAPs or to burden hospitals who choose to use these new technologies with concern about these payments counting toward actual expenditures. AdvaMed recommends that this policy be extended to APMs.

Furthermore, AdvaMed believes that additional innovative technologies, beyond NTAPs, should qualify for similar adjustments to calculation of benchmark and actual expenditure totals. In brief, our recommendation would provide adjustments for a limited number of innovative treatments or diagnostics that are first reviewed and approved by CMS after meeting certain criteria. These adjustments would be used for a limited period of time to allow time for these treatments and diagnostics to be reflected in new benchmarks or incorporated in quality measurement to the extent they become the standard of care. For purposes of payment for innovative treatments, the cost of approved innovative treatments would be removed from the calculation of benchmarks and Medicare expenditures when calculating savings or losses. Where the barrier to adoption is a quality standard, quality measurement would exclude the case with the new treatment from the provider or physician quality score. With these adjustments, the disincentives to use an innovative treatment or diagnostic would be neutralized and APM providers would make decisions purely on medical grounds.

## **2. Broadening the Definition of Advanced APMs**

CMS and CMMI have established frameworks for certain delivery reform models that create a glide path for providers in ACO and bundled payment programs to assume greater financial risk for the cost of care over a period of time as they take on responsibility for care transformation and care improvement activities. Two such programs are the Medicare Shared Savings Program (MSSP) and the Comprehensive Care for Joint Replacement (CJR) bundled payment program. Given the commitment, providers in delivery reform programs must make to care redesign and quality and efficiency improvements in care delivery from the very beginning of their participation in these programs, **AdvaMed recommends that CMS designate all CMS and CMMI APM programs with transitions from upside risk only to upside and downside risk as Advanced APMs.** This will encourage higher levels of participation in Advanced APMs and greater commitment of providers to improvements in quality and efficiency of care delivery.

## **3. Payment Incentives for the Provision of Telehealth Services by APMs**

Telehealth and remote patient monitoring technologies are generally recognized as fundamental tools for improving the efficiency and quality of health care. APMs, with their emphasis on care coordination and improving the efficiency and quality of care delivery, are ideal settings for realizing the benefits telehealth and related technologies.

Currently, Medicare's telehealth benefit severely restricts coverage and payment for these services through limitations on the type of technologies that may be covered, the site of service where beneficiaries may receive care, and the geographic area where they reside. MedPAC estimates that only 69,000 beneficiaries, or 0.2 percent of total Part B beneficiaries, used telehealth services in 2014 in large part because of these coverage restrictions. A similar problem exists for remote monitoring services, with only limited reimbursement for these services, such as for cardiac trans-telephonic monitoring of pacemakers, or remote monitoring of patient physiological data as part of new billable chronic care management services for beneficiaries with multiple chronic conditions.

To the extent that telehealth and remote monitoring services are not covered by Medicare, APM benchmarks will never be able to reflect spending for the services because Medicare does not recognize them for payment. As a result, an APM participant deciding to provide expanded telehealth or remote monitoring services will have to weigh these new costs not recognized in a benchmark against the promise of savings in other areas, or to cover the costs through their shared savings. This creates a disincentive to use these technologies. Coverage and payment restrictions also result in a missed opportunity for APMs to address the complex needs of the 5 percent of Medicare beneficiaries with multiple chronic conditions who account for as much as 50 percent of total Medicare spending.

Under current law, the only way that APMs can realize telehealth's benefits for improving efficiency and quality of care delivery is through waivers of the restrictions in Medicare's fee-for-service telehealth benefit. CMS should use its waiver authority to expand the scope of coverage and payment of telehealth services provided by APMs, and should do so for all APMs regardless of the level of risk they assume. Key to the success of APMs being able to realize telehealth's potential for improving the efficiency of care delivery are waivers to allow the beneficiary's home to be an originating site of care, generally the lowest cost setting for delivering care. This is especially the case for serving Medicare beneficiaries with multiple chronic conditions. By prohibiting the home from serving as an originating site for care, current law restrictions will limit the ability of APMs to efficiently assess the health status of this population on a regular basis, to identify problems early when they can be easily treated, and to track compliance with their care plans. **AdvaMed recommends that, at a minimum, CMS provide waivers to provide APMs the flexibility for using telehealth and remote monitoring technologies for the provision of screening and preventive services, as well as care in the home.**

AdvaMed appreciates the opportunity to submit these comments in response to the Proposed Rule on Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule. If you have any questions, please contact me or Richard Price at [rprice@advamed.org](mailto:rprice@advamed.org) or Steve Brotman at [sbrotman@advamed.org](mailto:sbrotman@advamed.org).

Sincerely,



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