September 8, 2015

Andy Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1631-P
P.O. Box 8013
Baltimore, MD 21244-1850

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY2016; Proposed Rule (CMS-1631-P)

Dear Mr. Slavitt:

On behalf of the members of the Advanced Medical Technology Association (AdvaMed), we are writing to provide comments on the Proposed CY 2016 Physician Fee Schedule Rule. AdvaMed will separately submit comments regarding proposed changes to the Physician Compare Website included in the rule.

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 are committed to ensuring patient access to life-saving and life-enhancing devices and other advanced medical technologies in the most appropriate settings.

AdvaMed supports the establishment of payment rates under the physician fee schedule that are appropriate to ensure access to advanced medical technologies by Medicare beneficiaries. We appreciate the effort you and your staff have devoted to the development of the proposed Medicare Physician Fee Schedule rule (PFS). While we are pleased with some of the proposed changes announced in the rule, we remain concerned with other proposals and welcome the opportunity to provide several recommendations. We will comment on the following issues raised in the proposed 2016 PFS rule:

I. Provisions of the Proposed Rule for PFS
   A. Potentially Misvalued Services Under the Physician Fee Schedule – Transprostatic Urethroscopy

Bringing innovation to patient care worldwide
B. Changes for Computed Tomography (CT) Under the Protecting Access to Medicare Act of 2014 (PAMA)

C. Valuation of Specific Codes
   a. Brachytherapy Payments and Cancer Care
   b. New Remote Afterloading High Dose Rate Brachytherapy Codes
   c. Allocation of Equipment Maintenance
   d. Lower GI Endoscopy

D. Radiation Treatment and Related Image Guidance Services
   a. Image Guidance- Direct Practice Expense Inputs for IMRT and IGRT
   b. Valuation of Specific Codes–Equipment Utilization Rate for Linear Accelerators and Valuations of On Board Imaging

E. Chronic Care Management

II. Other Provisions of the Proposed Regulations
   A. Appropriate Use Criteria for Advanced Diagnostic Imaging Services
   B. Physician Payment, Efficiency, and Quality Improvements – Physician Quality Reporting System
   C. Medicare Shared Savings Programs Proposed Policy for Measures No Longer Aligning with Clinical Guidelines, High Quality Care or Outdated Measures May Cause Patient Harm
   D. Value-Based Payment Modifier and Physician Feedback Program (MIPs)

I. Provisions of the Proposed Rule for PFS

   A. Potentially Misvalued Services Under the Physician Fee Schedule– Identification of Potentially Misvalued Services for Review

The proposed rule includes a recommendation to review CPT codes 52441 and 52442 on the grounds that they are potentially misvalued. AdvaMed disagrees with this recommendation as both of these codes were reviewed by the RUC in 2014 and were added to the CPT code set in 2015. It is uncommon for codes that have been active for less than one year to be reviewed. Additionally, the RUC has already recommended that both codes be re-reviewed in September 2018 to assess any changes in RVU valuation.

- **Given the existence of a date certain timeline for reviewing these codes and based on their newness, AdvaMed would recommend that CMS not review the values for CPT codes 52441 and 52442 in advance of the 2018 date recommended by the RUC.**

   B. Changes for Computed Tomography (CT) Under the Protecting Access to Medicare Act of 2014 (PAMA)

Section 218(a)(1) of the Protecting Access to Medicare Act (PAMA) of 2014 included a provision to reduce the technical component payment for certain computed tomography (CT) services furnished using equipment that fails to meet NEMA standard XR-29-2013. Pursuant to
the PAMA provision, effective January 1, 2016 certain CT services which do not satisfy the NEMA standard will experience reductions in payment of -5% in 2016 and -15% in 2017 and subsequent years.

The proposed rule includes a proposal to establish a modifier “CT” to be used on claims which will allow CMS to identify and reduce the payment for “non- XR-29-2013 compliant” CT services. AdvaMed supports the development and use of a modifier by CMS to impose appropriate payment reductions. We also recommend that CMS monitor claims to assess the overall impact of the PAMA requirement and to ascertain the shift in usage patterns of providers to CT equipment which emits reduced levels of radiation.

C. Valuation of Specific Codes

AdvaMed would like to address specific concerns related to the proposed valuation for brachytherapy and lower GI endoscopy procedures in the CY 2016 proposed rule. Our comments on these specific coding concerns appear below.

a. Brachytherapy Payments and Cancer Care

A variety of factors including implementation of three new high dose rate (HDR) brachytherapy procedure codes in 2009 (i.e., 77785, 77786, 77787), corrections to HDR brachytherapy direct practice expense inputs in 2010, and utilization of the new AMA Physician Practice Information Survey data has resulted in significant reductions in HDR brachytherapy reimbursement for freestanding cancer centers.

Reductions in relative value units (RVUs) and MPFS payments have caused several freestanding cancer centers, including many high volume Centers of Excellence, to abandon HDR brachytherapy cancer treatment, which has negatively impacted access for Medicare beneficiaries.

A review of the CMS Medicare fee-for-service physician claims data indicates that the number of HDR brachytherapy procedures provided in the office-setting (which includes freestanding cancer centers) has continued to decrease since 2009 (see table below).

<table>
<thead>
<tr>
<th>Year</th>
<th>CPT Codes</th>
<th>Total Number of Office-Based Procedures</th>
<th>Percentage of Office-Based Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>77781-77784</td>
<td>29,499</td>
<td>43%</td>
</tr>
<tr>
<td>2009</td>
<td>77785-77787</td>
<td>31,037</td>
<td>44%</td>
</tr>
<tr>
<td>2010</td>
<td>77785-77787</td>
<td>27,274</td>
<td>42%</td>
</tr>
<tr>
<td>2011</td>
<td>77785-77787</td>
<td>26,679</td>
<td>40.2%</td>
</tr>
<tr>
<td>2012</td>
<td>77785-77787</td>
<td>24,816</td>
<td>39.5%</td>
</tr>
<tr>
<td>2013</td>
<td>77785-77787</td>
<td>25,106</td>
<td>41.0%</td>
</tr>
<tr>
<td>2014</td>
<td>77785-77787</td>
<td>22,954</td>
<td>40.2%</td>
</tr>
</tbody>
</table>
AdvaMed is concerned by this trend and recommends that CMS consider alternatives to stave off further reductions to payments for HDR brachytherapy.

b. New Remote Afterloading High Dose Rate Brachytherapy Codes

Effective January 1, 2016, CMS proposes five (5) new Remote Afterloading High Dose Rate (HDR) Brachytherapy procedure codes (7778A, 7778B, 7778C, 7778D, and 7778E), which bundle the basic radiation dosimetry calculation (i.e. CPT 77300). The rule also includes proposed work relative value units (RVUs) for the new HDR brachytherapy procedures.

AdvaMed supports the work RVUs recommended by CMS for these HDR procedures.

CMS also proposes direct practice expense recommendations for the new HDR brachytherapy codes without refinement for 2016 and included a new direct practice expense equipment input for the Brachytherapy treatment vault. AdvaMed believes that the brachytherapy treatment vault is a direct practice expense cost, as it is required for each session of patient-specific treatment delivery.

AdvaMed supports the direct practice expense inputs recommended by CMS for 2016.

c. Allocation of Equipment Maintenance

In the proposed rule, CMS acknowledges that the relationship between maintenance costs and the price of equipment is not necessarily uniform across equipment items. The current maintenance factor of 5 percent, used to determine the equipment costs per minute, was finalized in the 1998 MPFS final rule. The estimated maintenance costs for Remote Afterloading HDR Brachytherapy may be more than twice that amount.

AdvaMed recommends that CMS use different maintenance adjustments for different types of medical equipment, to account for substantial maintenance costs associated with highly specialized radiation therapy equipment.

AdvaMed also encourages CMS to work with stakeholders to define service/maintenance contracts, collect data on their associated costs, and update the equipment maintenance adjustment factor as necessary.

d. Proposed Lower GI Endoscopy

CMS is proposing cuts in the facility payments for lower GI endoscopy procedures. Pursuant to the proposal, the facility RVUs for many of these procedures would be reduced by more than 10 percent. The rationale for continued cuts to lower GI endoscopy procedures is unclear especially in light of Medicare colorectal cancer screening coverage for lower GI endoscopy procedures and PQRS adenoma detection rate measures. The proposed significant payment reductions for these procedures do not appear to align with CMS’s goals for early detection and treatment of
colon cancer. Such significant payment cuts may also negatively impact Medicare beneficiary access to colorectal cancer screening and treatment.

- **AdvaMed asks CMS to consider a more conservative payment adjustment for CY 2016 to ensure continued access by Medicare beneficiaries to lower GI endoscopy screening and treatment procedures.**

## D. Radiation Treatment and Related Image Guidance Services

CMS has proposed significant changes to radiation oncology codes in several recent PFS rules. For CY 2016 CMS is proposing to change its radiation therapy equipment utilization assumptions. Specifically, CMS proposes to increase their equipment utilization assumption by 20 percent phased in over a two year period. In addition, it is revisiting the introduction of several radiation therapy procedure codes that were proposed but not finalized in the CY 2015 rule.

The methods used by CMS to propose changes to radiation oncology appear to be inconsistent, especially as they relate to calculation of payment rates. For example the proposed payment rate for an intermediate 3D conformal procedure is more than the rate paid for a complex procedure. This does not make sense as levels of complexity are meant to reflect additional resources. AdvaMed urges CMS to exercise caution in implementing coding and corresponding payment changes for radiation therapy codes as much still needs to be understood about workflow and inputs for the various technologies.

### a. Image Guidance - Direct Practice Expense Inputs for Revised IMRT Treatment Delivery Codes (77385 and 77386) and the New IGRT Code (77387)

Information in the proposed rule related to rate setting for Intensity Modulated Radiation Therapy (IMRT) codes 77385 and 77386 and Image-Guided Radiation Therapy (IGRT) code 77387 is based on incorrect assumptions regarding the cost of image guidance (Linac) equipment. CMS believes that the cost of the Linac equipment used with these treatment delivery codes, includes “onboard imaging/image guidance” costs. Consequently, CMS did not accept the RUC recommendations for these codes and did not include the Linac costs as a separate item in the CY 2016 proposed direct practice expense inputs for CPT codes 77385, 77386, and 77387.

AdvaMed is concerned by CMS’ proposal to exclude the capital equipment costs associated with image guidance and on board imaging. We understand, as part of the RUC recommendations, a series of invoices were provided for on board imaging as a separate line. CMS should not ignore these invoices.

The cost of a basic Linac does not include the costs for on board imaging equipment associated with the revised IMRT treatment delivery codes and the new IGRT code. These new codes encompass all forms of image guidance including ultrasonic guidance, computed tomography guidance, stereoscopic x-ray guidance, and intra-fraction localization and tracking.
AdvaMed recommends that CMS accept the direct practice expense inputs recommended by the RUC for the two revised IMRT treatment delivery codes (77385 and 77386) and the new IGRT code (77387).

IMRT treatment delivery generally requires image guidance. IMRT is a more complex form of radiotherapy that requires accurate delivery of high radiation doses near critical organs and structures. Additionally, image guidance should not be assumed with conventional treatment delivery. Depending on the disease site and case complexity, it is common for multiple forms of IGRT to be used prior to and during treatment delivery. Conventional radiotherapy encompasses a broad range of cases from simple to complex with highly variable clinical demands for image guidance. All capital and work costs related to guidance are not included in the payment for conventional radiation treatment delivery.

AdvaMed recommends that CMS provide a separate technical and professional fee for IGRT services rendered during conventional treatment when clinically indicated.

b. Valuation of Specific Codes—Equipment Utilization Rate for Linear Accelerators

The proposed rule contains a recommendation to adjust the equipment utilization assumption for linear accelerator equipment from 50 percent to 70 percent. This recommendation is based on the assumption that this type of equipment is now being used for a broader range of services which results in increased overall utilization compared to the prior, 50 percent, default assumption. CMS further recommends that the increase be phased in over a two-year period with the assumption increasing to 60 percent in 2016 and to the full 70 percent in 2017.

AdvaMed is concerned by the methodology and assumptions employed by CMS in developing the utilization increase proposal. CMS fails to cite specific data to support its request for a utilization assumption increase and appears to rely largely on anecdotal information to make its case. AdvaMed is very uncomfortable with using information gathered through these means to make a determination which could significantly impact beneficiary access to these technologies.

AdvaMed recommends that CMS not move forward with any changes in the utilization assumption for this equipment.

We are aware of other data that is being developed by providers of services which utilize these technologies and strongly urge CMS to consider these data findings prior to finalizing any decision to increase the utilization rate assumption for linear accelerator equipment.

E. Chronic Care Measures

CMS is soliciting input related to payment of care for Medicare beneficiaries with multiple chronic conditions. AdvaMed applauds CMS for considering these issues and believes that the agency has accurately identified a number of professional services that are critical to meeting the needs of these patients. AdvaMed believes that services such as enhanced evaluation and
management services, collaborative care involving primary care physicians and specialists, and appropriately priced chronic care services are critical in expanding the reach and impact of these services for the patients who require them.

Identifying the population of patients who suffer from multiple chronic conditions can be difficult. Therefore, special expertise is often required to both identify and tier the patients requiring these higher intensity services and can frequently require the assistance and involvement of individuals other than physicians. Additionally, persons including social workers, case workers, suppliers, and advocates are frequently needed to help manage these patients in a way that assures their access to appropriate and timely interventions for their various health conditions. Creating a mechanism within the physician fee schedule whereby the services provided by these individuals can be recognized is critical.

- **In order to ensure access to these services AdvaMed recommends that CMS consider creating of an enhanced chronic care management fee payable to highly specialized personnel and specially certified suppliers.**

Effective treatment of patients with multiple chronic conditions is also being hampered by ongoing problems with interoperability between electronic health record (EHR) systems. Lack of connectivity between these systems limits the ability of the caregivers who treat these patients from timely and effectively sharing critical information.

- **AdvaMed urges CMS to aggressively work towards development and adoption of secure data platforms that can be used to resolve EHR interoperability issues.**

While CMS has been working to adopt policies to cover chronic care management services, AdvaMed does not believe that the approach used to date adequately acknowledges factors outside of the provider space. The approaches currently in use tend to focus on the providers without acknowledging the role that technology plays in making treatment decisions for these beneficiaries.

- **AdvaMed recommends that CMS consider developing and testing an alternative payment model demonstration, through CMMI, which would encompass the full range of providers, suppliers, and technologies used in treating this vulnerable patient population.**

II. Other Provisions of the Proposed Regulations

A. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

Pursuant to the requirements contained in PAMA CMS is soliciting feedback on a number of issues related to the establishment of evidence-based appropriate use criteria that can be used to identify outlier patterns of ordering advanced diagnostic imaging services. AdvaMed is supportive of the approach outlined by CMS with regards to engagement of provider-led groups in this process. We are especially supportive of the inclusion of requirements which make the evidence-based criteria development open and transparent. Lastly, we support including a public
comment component which will allow stakeholders outside of the provider-led entities process to provide comment and feedback on appropriate use criteria identified by these groups.

B. Physician Payment, Efficiency, and Quality Improvements – Physician Quality Reporting System

a. PQRS Quality Measures for 2016 and Beyond for EPs and Group Practices

The proposed rule contains 45 proposed new PQRS measures to begin with 2016 reporting. AdvaMed is concerned that almost all of these have not been NQF-endorsed, nor were they fully supported for inclusion by the Measure Applications Partnership (MAP). These include:

- Adult Kidney Disease: Referral to Hospice;
- Appropriate Follow-Up Imaging for Incidental Abdominal Lesions;
- Appropriate Follow-Up Imaging for Incidental Thyroid Nodules in Patients;
- Door to Puncture Time for Endovascular Stroke Treatment;
- Extravasation of Contrast-Enhanced Computed Tomography (CT);
- Imaging in Adult Emergency Department (ED) Patients with Minor Head Injury;
- Imaging in Pediatric Emergency Department (ED) Patients Aged 2 through 17 years with Minor Head Injury;
- In-Hospital Mortality Following Elective Open Repair of AAAs;
- Overuse of Neuroimaging for Patients with a Primary Headache and a Normal Neurological Examination;
- Patients Treated for Varicose Veins who are Treated with Saphenous Vein Ablation and Receive and Outcomes Survey Before and After Treatment;
- Percentage of Patients with a Retrievable Inferior Vena Cava (IVC) Filter who are Appropriately Assessed for Continued Filtration or Device Removal;
- Performing Cystoscopy at the Time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury;
- Perioperative Temperature Management;
- Photo-documentation of Cecal Intubation;
- Post-Anesthetic Transfer of Care Measure: Procedure Room to a Post-Anesthesia Care Unit (PACU);
- Perioperative Assessment of Occult Stress Urinary Incontinence Prior to any Pelvic Organ Prolapse Repair;
- Preoperative Exclusion of Uterine Malignancy Prior to any Pelvic Organ Prolapse Repair;
- Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques;
- Rate of Surgical Conversion from Lower Extremity Endovascular Revascularization Procedure; and
- Unnecessary Screening Colonoscopy in Older Adults.

AdvaMed suggests endorsement by the NQF and support by the MAP for all the measures in this proposed set prior to placement in the PQRS. We note that the NQF endorsement is particularly important for new types of measures, such as efficiency measures, where appropriateness and
credibility of the measure has not yet been established. The NQF-endorsement process provides a comprehensive examination of a proposed measure, focusing on numerous aspects of the measure such as evidence and measurement testing, including the feasibility, for collection of the measure details in the appropriate patient setting. In addition, although many of these measures have been reviewed by the MAP previously, many have been given the designation of “Encourage Continued Development.” This means that MAP has not provided a thorough review of the measure in the final form. For other measures, it is noted that MAP provided a “Conditional Support” in their 2015 recommendation. However, CMS does not mention in the proposed rule whether or not these conditions have been addressed and meet the MAP’s specifications. In many instances, the MAP’s rationale for “conditional support” was that the measure was: “not ready for implementation; should be submitted for and receive NQF endorsement.”

- *AdvaMed recommends deferring inclusion of these measures into the PQRS program, until such time when they have been endorsed by NQF and fully supported by the MAP (or alternatively met conditions which were earlier specified by the MAP).*

**b. Suggestion for Additional Quality Measures**

AdvaMed recommends that CMS encourage the development and NQF endorsement of future quality measures concerning screening for lung cancer. Lung cancer is the most frequently fatal cancer, with poor survival once the disease is advanced. Lung cancer causes 1.37 million deaths per year worldwide, which represents 18% of all cancer deaths.\(^1\)

The quality measures relevant to this set would include components such as:

- Smoking history;
- Referral for smoking cessation counseling for anyone currently smoking; and
- Annual referral for Low Dose CT for Lung Cancer Screening for anyone meeting USPSTF\(^2\) criteria (for private payers, including Medicare Advantage Plans) and

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\(^2\) In their Final Recommendation Statement regarding Lung Cancer-Screening on December 2013, the USPSTF recommends annual screening for lung cancer with low-dose computed tomography (LDCT) in adults aged 55 to 80 years who have a 30 pack-year smoking history and currently smoke or have quit within the past 15 years. Screening should be discontinued once a person has not smoked for 15 years or develops a health problem that substantially limits life expectancy or the ability or willingness to have curative lung surgery. ([http://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/lung-cancer-screening](http://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/lung-cancer-screening)).
CMS criteria (for Medicare and Medicaid patients) after a “shared decision-making” session with their primary care physician (or other qualified practitioner).  

The USPSTF’s recommendation is in-part based upon the findings of the on-going National Lung Screening Trial (NLST). The NLST is a lung cancer screening trial sponsored by the National Cancer Institute (NCI) and conducted by the American College of Radiology Imaging Network (ACRIN) and the Lung Screening Study group. Launched in 2002, NLST compared two ways of detecting lung cancer: low-dose helical (spiral) computed tomography (CT). The NLST researchers found approximately 15 percent to 20 percent fewer lung cancer deaths among trial participants screened with low-dose helical CT relative to chest X-ray. Additionally, the NLST showed that all-cause mortality (deaths due to any factor, including lung cancer) was 6.7 percent lower in those screened with low-dose helical CT relative to those screened with chest X-ray. This difference was largely due to the decrease in lung cancer mortality.

In addition, CMS issued a Final National Coverage Determination on Screening for Lung Cancer with Low Dose Computed Tomography (LDCT) on February 5, 2015. In the NCD-associated memo, CMS stated that they had determined that the evidence is sufficient to add a lung cancer screening counseling and shared decision making visit, and for appropriate beneficiaries, annual screening for lung cancer with low dose computed tomography (LDCT), as an additional preventive service benefit under the Medicare program, if certain criteria are met.

It is evident that there is sufficient consensus amongst medical and policy-related organizations that lung cancer screening, as described above, would aid in decreasing mortality. Having quality measures developed and endorsed related to the various components of lung cancer screening would be the next logical step and serve to fill a much needed clinical gap.

- **Advamed, therefore, urges CMS to begin the process of encouraging the development and endorsement of lung cancer screening-related measures to improve clinical outcomes in this area.**

### c. Requests for Input on Provisions Included in MACRA

CMS seeks comments on several provisions of MACRA including clinical practice improvement activities. CMS specifically seeks comment on what activities could be classified as clinical practice improvement activities according to this definition.

MACRA specifies clinical practice improvement activities as one of the performance categories used in determining the composite performance score under the MIPS. These are defined as activities that relevant eligible professional organizations and other relevant stakeholders identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, are likely to result in improved outcomes. The following subcategories of clinical practice improvement must be included:

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3 Annual low dose computed tomography has shown a survival benefit in screening individuals at high risk for lung cancer.
1. Expanded practice access, such as same day appointments for urgent needs and after-hours access to clinician advice.
2. Population management, such as monitoring health conditions of individuals to provide timely health care interventions or participation in a qualified clinical data registry.
3. Care coordination, such as timely communication of test results, timely exchange of clinical information to patients and other providers, and use of remote monitoring or telehealth.
4. Beneficiary engagement, such as the establishment of care plans for individuals with complex care needs, beneficiary self-management assessment and training, and using shared decision-making mechanisms.
5. Patient safety and practice assessment, such as through use of clinical or surgical checklists and practice assessments related to maintaining certification.
6. Participation in an alternative payment model.

- **AdvaMed recommends that in regard to Subcategory (1) (Expanded Practice Access), this definition should include same-day access to medical technologies, when needed on an urgent basis, as well as expedited access to medical technologies for less urgent clinical situations. In this regard patients who are acutely and chronically ill will not be needlessly contributing to the burden of Emergency Department over-crowding and allow for appropriate access of those patients in most need of access to emergency services.**

- **Additionally, AdvaMed recommends that in regard to Subcategory (5), relevant clinical or surgical checklists should also include the consideration of utilizing medical technologies (e.g., planning for the use of specific wound care therapy) when appropriate, in order to ensure patient safety.**

Planning at this earliest stage would help to reduce the time to vet and implement proper clinical treatment and alert all eligible professionals involved in the patient’s care of the proposed treatment plan.

C. **Medicare Shared Savings Program—Proposed Policy for Measures No Longer Aligning with Clinical Guidelines, High Quality Care or Outdated Measures May Cause Patient Harm**

CMS is proposing to adopt a general policy to maintain measures as pay-for-reporting, or revert pay-for-performance measures to pay-for reporting measures, if the measure owner determines the measure no longer meets best clinical practices due to clinical guideline updates or when clinical evidence suggests that continued measure compliance and collection of the data may result in patient harm. AdvaMed agrees that CMS needs to respond more quickly to needed changes without waiting for a future rulemaking cycle to remove a pay-for-performance measure. However we have concerns that, under the proposal, measures which are no longer
operating under best clinical practices or are determined to potentially harm will remain in effect as pay-for-reporting measures. Ongoing reporting on these measures would promote the inappropriate clinical standards.

- **AdvaMed recommends that CMS re-examine this proposed policy so that reporting on measures that are determined to cause patient harm or are no longer clinically relevant is suspended immediately.**

After the suspension, CMS could implement any necessary changes to the measure in the next rulemaking cycle by either retiring the measure or sending it back to the measure developer for re-tooling.

**D. Value-Based Payment Modifier and Physician Feedback Program (MIPs)**

**a. Quality Measures for the Shared Savings Program**

CMS is proposing that beginning with the 2016 performance period and the 2018 payment adjustment period, the ACO CAHPS survey will be required as an additional component of the VM quality composite for TINs participating in the Shared Savings Program.

- **AdvaMed understands the important value of patient experience data and supports the adoption of CAHPS for use in this VM quality composite. AdvaMed also recommends that the CAHPS measures evolve quickly to include patient surveys that, in addition to querying on access to specialists, assess whether or not patients thought that they were provided sufficient access to medical innovation and technology in their care.**

**b. Minimum Episode Count for the Medicare Spending Per Beneficiary (MSPB) Measure**

In the 2014 final rule, CMS finalized a minimum of 20 MSPB episodes of inclusion of the MSPB in a TIN’s cost composite; the non-specialty-adjusted version of the measure using 2011 data had high reliability with a 20 episode minimum. CMS states that by using a more appropriate methodology for calculating reliability, they found that the specialty-adjusted measure does not have moderate or high reliability with a 20 episode minimum for many groups. As a result, beginning with the 2017 payment adjustment period (2015 performance period), CMS proposes to increase the episode minimum to 100 episodes.

CMS notes they considered increasing the episode minimum to 75 instead of 100; this would allow inclusion of the MSPB measure in the cost composite for a larger number of groups. CMS believes, however, that the reliability for solo practitioners with a minimum of 100 episodes was preferable to the reliability when using a 75 episode minimum.

- **AdvaMed supports the decision by CMS to increase the episode minimum to 100 episodes, given that the results for the specialty-adjusted measure were more reliable at higher episode minimums and this will result in increased accuracy of the measure.**
Conclusion

AdvaMed appreciates the opportunity to submit comments on the proposed CY 2016 PFS rule and looks forward to working with CMS to address our concerns. We would be pleased to answer any questions regarding these comments. Please contact me or DeChane L. Dorsey, Esq., Vice President, Payment and Health Care Delivery Policy, at (202) 434-7218, if we can further assist you.

Sincerely,

/s/

Donald May
Executive Vice President
Payment and Health Care Delivery Policy