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September 6, 2016

Via Electronic Mail

Andy Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1654-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 CY 2017; Proposed Rule (CMS-1654-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 2017 Physician Fee Schedule 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 have concerns with other proposals and welcome the opportunity to provide several recommendations. We will comment on the following issues raised in the proposed 2017 PFS rule:

I. Provisions of the Proposed Rule for PFS

A. Medicare Telehealth Services

- a. Adding Services to the List of Medicare Telehealth Services**
- b. Place of Service (POS) Code for Telehealth Services**

B. CY 2017 Identification and Review of Potentially Misvalued Services

- a. Identification of Potentially Misvalued Services for Review**
- b. Creation of Non-Facility PE Inputs for Endoscopic Sinus Surgery Procedures**

C. Improving Payment Accuracy for Primary Care, Care Management Services, and Patient-Centered Services—Reducing Administrative Burden and Improving Payment Accuracy for Chronic Care Management (CCM) Services

II. Other Provisions of the Proposed Regulations

A. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

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

C. Recommendations for Future Quality Measures

- a. Adopt a Malnutrition Composite Quality Measure in MSSP Preventive Health Domain**
- b. Adopt a Transitions of Care Measure in the MSSP Care Coordination/Patient Safety Domain that Address Nutritional and Wound Concerns**

I. Provisions of the Proposed Rule for PFS

A. Medicare Telehealth Services

a. Adding Services to the List of Medicare Telehealth Services

AdvaMed appreciates CMS's commitment to the annual process it has established for evaluating services on the List of Telehealth Services covered by the program. AdvaMed supports CMS's proposed expansion of services that would be included on the list beginning in CY 2017. Expansion of services on this list is important for two reasons: 1. they become a critical source of care for Medicare beneficiaries who have limited access to health care, including specialist services, and who would otherwise have to travel long distances for such consultations or go without care altogether; and 2. restrictions that CMS has waived for certain alternative payment models (APMs) to provide telehealth services, under current law, do not extend to the different types of services that may be covered by those programs. In other words, APMs may only provide those services included on the List of Telehealth Services. Therefore, expansion of services on the list provides the only flexibility that APMs have for improving the efficiency and quality of care that they deliver. AdvaMed encourages CMS and its Innovation Center to undertake demonstrations, under both the traditional fee-for-service program and APMs, focused on specific services beyond those on the list, or configurations of services, targeted at specific population groups, e.g. persons with multiple chronic conditions, to determine whether these services can be cost effective and improve quality of care for Medicare beneficiaries.

- ***AdvaMed supports CMS's proposed expansion of services that would be included on the List of Telehealth Services beginning in CY 2017. AdvaMed also encourages CMS and its Innovation Center to undertake demonstrations, under both the traditional fee-***

for-service program and APMs, focused on specific services beyond those on the list, or configurations of services, and targeted at specific population groups, e.g. persons with multiple chronic conditions, to determine whether these services can be cost effective and improve quality of care for Medicare beneficiaries.

b. Place of Service (POS) Code for Telehealth Services

For CY 2017 CMS is proposing that a telehealth POS code, if available, be used by physicians or practitioners to indicate if a telehealth service is furnished from a distant site. The code would only be used for telehealth services furnished by the physician at the distant site; it would not be used by the originating site practitioners since that site receives a national fee as required under Medicare law. This new code would be in addition to a modifier CMS currently uses for telehealth services for tracking utilization and spending for these services.

CMS's proposal to use a new code for POS for practitioners in distant sites is intended to improve payment accuracy and consistency in telehealth claims submissions, since some practitioners use the POS where they are located when the service is furnished, while others use the POS corresponding to the patient's location. It will also lead to improved accuracy in understanding the resources associated with the provision of these services at the distant site. AdvaMed supports this proposal.

CMS is also proposing to use the facility practice expense relative value units (RVUs) to pay for telehealth services reported by physicians or practitioners with the telehealth POS code, regardless of whether the practitioner provides the service in a facility or non-facility setting. Since this could have negative impact on certain covered telehealth services provided by practitioners in non-facility locations, and potentially affect beneficiaries' access to telehealth services, AdvaMed opposes this proposal and we urge CMS, in future rulemaking or via other means, to provide additional and more specific information showing estimated impact on individually covered telehealth services by setting of service.

B. CY 2017 Identification and Review of Potentially Misvalued Services

a. Identification of Potentially Misvalued Services for Review

In previous comments AdvaMed has expressed our appreciation and support for CMS's decision to allow stakeholders the opportunity to provide comments on proposed re-valuation recommendations via comments on the proposed PFS rule. This has been of tremendous assistance in allowing stakeholders the opportunity to express concerns and to provide additional information to CMS regarding the proposed values for their products and for procedures that they perform.

This year's proposed rule contains many examples of proposed valuation changes wherein CMS has decided to assess a value different from that recommended by the specialty society representing the clinicians who perform the procedures or the Relative Value Update Committee (RUC). While AdvaMed understands that CMS is the ultimate arbiter in making valuation

decisions, as they relate to services paid on the physician fee schedule, we are nonetheless concerned by the level of transparency associated with the proposed changes.

In many instances there is no explanation on the part of CMS regarding their decision to go with a valuation decision different from that recommended by the RUC. In other instances CMS suggests that they are foregoing the RUC recommendations and are instead pursuing RUC values that are based on crosswalks to unrelated codes. For instance, in the case of CPT codes 77332, 77333, and 77334 CMS determined that it would implement reduced values for these procedures based on a crosswalk to work RVUs for codes for peri-procedural device evaluation and orthotic management and training. AdvaMed questions the decision to not accept values based on survey data and to instead rely on these types of crosswalks, and other undisclosed reasons, for deviating from the RUC recommendations.

- *AdvaMed recommends that CMS accept the RUC values for CPT codes 77332, 72333, and 77334.*
- *In an effort to improve stakeholder understanding of CMS's decisions on these issues AdvaMed recommends that CMS provide more information regarding the basis for its valuation decision when it deviates from the recommendation made by the RUC.*

Greater transparency will provide stakeholders with the level of information needed to provide comments on the proposed recommendations and could assist stakeholders in providing more useful information to CMS in comments on the proposed rule.

AdvaMed also has concerns related to the revaluation of certain G -codes whose rates were supposed to be frozen for CY 2017 and CY 2018. Pursuant to the Protecting Access and Medicare Protection Act of 2015 certain G-codes used in the provision of radiation therapy treatments for cancer patients including for treatment delivery, IMRT, and IGRT were to remain frozen for the years indicated. Specifically, section 3 of the legislation states:

SEC. 3. TRANSITIONAL PAYMENT RULES FOR CERTAIN RADIATION THERAPY SERVICES UNDER THE MEDICARE PHYSICIAN FEE SCHEDULE.

(a) In General.--Section 1848 of the Social Security Act (42 U.S.C.

1395w-4) is amended--

(1) in subsection (b), by adding at the end the following

new paragraph:

“(11) Special rule for certain radiation therapy

services.--The code definitions, the work relative value units

under subsection (c)(2)(C)(i), and the direct inputs for the

practice expense relative value units under subsection (c)(2)(C)(ii) for radiation treatment delivery and related imaging services (identified in 2016 by HCPCS G-codes G6001 through G6015) for the fee schedule established under this subsection for services furnished in 2017 and 2018 shall be the same as such definitions, units, and inputs for such services for the fee schedule established for services furnished in 2016."; and

(2) in subsection (c)(2)(K), by adding at the end the following new clause:

“(iv) Treatment of certain radiation therapy services.--Radiation treatment delivery and related imaging services identified under subsection (b)(11) shall not be considered as potentially misvalued services for purposes of this subparagraph and subparagraph (O) for 2017 and 2018.”.

Despite the legislation, CMS is proposing reductions in the valuations for G6011 (radiation treatment delivery) by 10 percent effective in CY 2017. AdvaMed believes that this may likely be an oversight but is nonetheless concerned and opposes the proposed changes.

- *AdvaMed urges CMS not to finalize the proposal to change the valuation for G6011 for CY 2017.*

b. Creation of Non-Facility PE Inputs for Endoscopic Sinus Surgery Procedures

CMS’s CY 2016 proposed rule included a recommendation to establish direct practice expense (PE) inputs for certain sinus surgery procedures that can be performed in the physician office setting. However, CMS has not yet finalized this proposal. We urge CMS to reexamine site of service and claims data that support the development of non-facility PE inputs for sinus surgery procedures, especially those ranging from CPT codes 31254 to 31288. Creating non-facility

payment values for these procedures is consistent with the migration of sinus surgery to the office setting.

- *AdvaMed urges CMS to create and implement non-facility RVUs for CPT codes 31254-31288 effective January 1, 2017 on an interim basis.*

c. Input Discrepancies relating to ENT and Other Endoscopy Procedures

For CY 2017 CMS is proposing a pricing structure that separates the scope and the associated video system. The PUF-Equipment, endoscopic capital and disposable items and costs are not fully identified and listed in the rule addenda. Prior to finalizing the practice expense device related cost inputs, CMS needs to confirm the configuration of the capital and disposable items that are used in endoscopy procedures.

For example, the proposed Updated Price in CMS code ES031, Video System, Endoscopy, in Table 26 – Invoices Received for Existing Direct PE Inputs, was decreased by 55% from \$33,233 to \$15,045 based on one invoice for laryngoscopy procedures. One invoice does not represent the average costs of these systems. Additionally, the methodology used by CMS to make this pricing recommendation is unclear.

The proposed pricing for ES031 includes the following components: a processor, digital capture, monitor, printer and cart. The updated price for each component is significantly lower than manufacturer average invoice prices. Pricing of the processor and digital capture alone are large cost items; however, the digital capture price is even not included in the price of ES031. We are very concerned that this updated pricing does not reflect healthcare providers' costs.

We know that CMS has also reviewed flexible laryngoscopy procedures. We appreciate the more detailed review of the capital related costs but believe that some important device costs integral to the procedure are not identified and/or may be undervalued. We encourage CMS to seek more input on the flexible fiberoptic laryngoscopy procedure practice expense valuation so that the final CY 2017 rule reflects all of the cost inputs that should be considered for reimbursement.

- *AdvaMed requests that CMS obtain endoscopic manufacturer inputs so that capital and disposable costs will be appropriately identified and priced. We also ask CMS to obtain a representative sample of invoices from manufacturers before making a determination on the direct practice expense inputs.*

C. Improving Payment Accuracy for Primary Care, Care Management Services, and Patient-Centered Services—Reducing Administrative Burden and Improving Payment Accuracy for Chronic Care Management (CCM) Services

AdvaMed appreciates CMS's recognition of the value of health information systems that provide primary care physicians and others 24-hour remote access to a care plan or the full Electronic Health Record (EHR). This functionality helps ensure that patients receive necessary follow-up after an emergency department visit, as required under the CCM element of Management of Care Transitions. AdvaMed supports CMS's efforts in this regard.

AdvaMed agrees with CMS that adoption of technologies that promote remote access care planning is beneficial for CCM and other PFS services and procedures (including various other care management services). We ask that CMS continue to work with stakeholders to identify PFS services and procedures that would benefit from the use of such technology, particularly digital health tools.

The proposed rule points out that CMS has not required the adoption of certified or non-certified health IT or other digital health modalities as a condition of payment for any other PFS service, and notes that requiring such technologies could create technological disparities among providers. AdvaMed questions whether imposing health IT or technological requirements at the service level as a condition for PFS payment would create disparities among services and others under the fee schedule. The goal of health IT and digital health tools is to allow passive, active, real-time, or near real-time monitoring or communications between care providers and their patients. While AdvaMed welcomes the removal of any CCM requirement that could impede access to care, we caution that eliminating the ability of individuals to have access to their care plans 24/7 could have the unintended and opposite effect of undermining the significant contribution digital health can play in empowering patients to be engaged in decision-making about their health care.

II. Other Provisions of the Proposed Regulations

A. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

AdvaMed appreciates CMS's ongoing efforts to solicit 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 continues to be supportive of efforts to engage provider-led groups in this process and the continued inclusion of requirements which make the evidence-based criteria development open and transparent. Lastly, we appreciate the proposed inclusion of several additional vehicles to facilitate public comment and feedback on appropriate use criteria identified by CMS and others.

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

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 and timely access to medical innovation and technology in their care.*

C. Recommendations for Future Quality Measures

AdvaMed supports the CMS proposal to align the Shared Savings Program Quality Measure Set with the measures recommended by the Core Quality Measures Collaborative. As CMS evaluates future measures for use in establishing quality performance standards that ACO's must meet for Shared Savings we recommend the Agency consider the following:

- *Adopt a malnutrition quality measure set in the MSSP Preventive Health Domain as soon as feasible to ensure high quality, timely and coordinated malnutrition care.*
- *Adopt a “transitions of care measure” in the MSSP Care Coordination/Patient Safety Domain that includes nutritional/wound status and nutrition/wound care plan as medically necessary information that is transferred with a patient to home or other post-acute care settings.*

AdvaMed also welcomes the opportunity to work with CMS and the Core Quality Measures Collaborative to evaluate these as part of the core set.

a. Adopt a Malnutrition Composite Quality Measure in MSSP Preventive Health Domain As Soon As Feasible.

Despite significant negative impact on patient outcomes and costs¹, malnutrition is an area that has largely remained unaddressed and has opportunity for improved performance.² Implementation of patient-driven and team-based malnutrition care plans, and care coordination between providers, patients, and community-based services are critical for improving outcomes for malnourished and at-risk patients³.

While CMS has acknowledged the impact of under-nutrition and over-nutrition (and obesity) on patient outcomes with the implementation of a body mass index (BMI) quality measure in the Medicare Shared Savings Program, patients may be malnourished regardless of BMI as they may be deficient in the macro and micro nutrients needed to help promote healing and reduce medical complications. Malnutrition care quality is a benchmark of an effective integrated care delivery system. While malnutrition is a prevalent and potentially costly problem, it is also preventable. Effective and timely screening is essential to help providers make accurate diagnoses and early nutrition interventions have been shown to substantially reduce readmission rates^{4,5,6} as well as complication rates, length of stay, cost of care, and in some cases, mortality.

¹ Corkins, et al, JPEN J Parenter Enteral Nutr 2014 38: 186

² Avalere Health, November 2014, Dialogue Proceedings: Launching the Malnutrition Quality Improvement Initiative

³ Tappenden et al, JPEN J Parenter Enteral Nutr 2013 37: 482

⁴ Brugler L, DiPrinzio MJ, Bernstein L. The five-year evolution of a malnutrition treatment program in a community hospital. Jt Comm J Qual Improv. 1999;25(4):191-206

⁵ Gariballa S, Forster S, Walters S, Powers H. A randomized, double blind, placebo-controlled trial of nutritional supplementation during acute illness. Am J Med. 2006;119(8):693-699

Importantly, measuring malnutrition care aligns with all six national quality strategy priorities, addresses a gap where there is variation in clinical practice⁷ and provides an opportunity to address measure gaps across care settings in future programs.^{8,9,10}

Disease-Associated Malnutrition (DAM) affects about 10% of chronically ill patients in the community and between 30% and 50% of patients admitted to hospitals. Significantly the morbidity, mortality, and direct medical costs associated with DAM in the U.S. are estimated to be \$157 billion with \$51.3 billion attributed to age 65+ years.¹¹ Malnutrition is an independent predictor of mortality, length of stay, unplanned readmissions and hospital costs.¹² Malnutrition is also an underlying risk factor for other HHS priorities including patient safety (e.g., healthcare-acquired conditions (HACs)), high impact and multiple chronic conditions, diabetes control¹³, and healthcare disparities. Patients who are malnourished while in the hospital have a greater risk of complications, falls, pressure ulcers, infections, readmissions, and length of stay, which is associated with up to a 300% increase in costs¹⁴ Studies have also shown hospital patients at risk for malnutrition are more likely to be discharged to another facility or require ongoing health services after leaving the hospital than patients not at risk for malnutrition.¹⁵ As recovery, rehabilitation time and functional independence may be significantly improved by preventing and treating malnutrition, malnutrition is a “measure that matters” for patients and their families.

Because malnutrition also impacts patient care across the care continuum, we also recommend that CMS encourage coordination and shared accountability by including a malnutrition measure set across all CMS quality programs including Merit Incentive Payment Programs, Quality Reporting and Value-Based purchasing for acute and post-acute care.¹⁶ This can start with the adoption of the following four new electronic clinical quality measures (eCQMs) recently submitted by the Academy of Nutrition and Dietetics through the 2016 pre-rulemaking process for the Hospital Quality Reporting Program and to NQF for endorsement consideration:

- NQF #3087: Completion of a Malnutrition Screening within 24 hours of Admission
- NQF #3088: Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition within 24 hours of a Malnutrition Screening

⁶ Philipson TJ, Snider JT, Lakdawalla DN, Stryckman B, Goldman DP. Impact of oral nutritional supplementation on hospital outcomes. *Am J Manag Care*. 2013;19(2):121-128

⁷ Patel, et al, *Nutr Clin Pract* 2014 29: 483

⁸ Avalere Health, May 2014, Dialogue Proceedings: Measuring the Quality of Malnutrition Care

⁹ Pereira et al, *Annals of Emergency Medicine* January 2015 Volume 65, Issue 1

¹⁰ Chow, et al, *J Am Coll Surg* Vol. 215, No. 4, October 2012

¹¹ Snider JT, et al, *JPEN J Parenter Enteral Nutr* 2014 38: 77S

¹² Su Lin Lim, et al, *Clin Nutr* 2012; 31: 345-350

¹³ Hamdy, 2014 American Society for Parenteral and Enteral Nutrition (ASPEN) Poster

¹⁴ Isabel TD and Correia M. The impact of malnutrition on morbidity, mortality, length of hospital stay and costs evaluated through a multivariate model analysis. *Clinical Nutrition*. 2003;22(3):235–239.

¹⁵ Chima CS, Barco K, Dewitt ML, Maeda M, Teran JC, Mullen KD. Relationship of nutritional status to length of stay, hospital costs, and discharge status of patients hospitalized in the medicine service. *J Am Diet Assoc*. 1997;97:975-978.

¹⁶ Rosen, et al, *JPEN J Parenter Enteral Nutr* 2013 37: 796

- NQF #3089: Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment
- NQF #3090: Appropriate Documentation of a Malnutrition Diagnosis

These malnutrition care eCQMs align with CMS priorities to address clinical variations in care, improve patient outcomes, decrease costs, and reduce burden of data collection for providers.¹⁷ Importantly, to help providers implement quality malnutrition care and adopt these eCQMs into practice, the Academy, along with its partners through the Malnutrition Quality Improvement Initiative (MQii) developed and tested a companion clinical practice improvement tool, the Malnutrition Quality Improvement Toolkit that will be available as online resource Fall of 2016.

b. Adopt a Transitions of Care Measure in the MSSP Care Coordination/Patient Safety Domain that Address Nutritional and Wound Concerns As Soon As Feasible

We recommend that the Shared Savings Program adopt a “transitions of care measure” that includes nutritional status and nutrition care plan, as well as wound status and wound care plan, as medically necessary information that is transferred with a patient to home or other post-acute care settings. The addition of wounds and nutritional status to patient discharge/transfer plans is consistent with the goals and recommendations under the IMPACT Act, AHRQ recommendations,¹⁸ numerous clinical guidelines,^{19,20} multi-stakeholder quality improvement initiatives,²¹ numerous current and forthcoming quality measures and recommendations from other publications and organizations.

It is well recognized that continuity of care is essential for older adults and successful elements considered in transitions in care for patients are necessary to reduce complications, adverse events, avoid hospital readmissions and improve the quality and safety of patient care. There is a growing body of evidence that demonstrates the negative impact that poor transitional care has on contributing to negative patient outcomes and increased health care utilization and costs. As we have noted in our extensive comments earlier this year to the proposed rule pertaining to discharge planning for Hospitals, Critical Access Hospitals, and Home Health Agencies

¹⁷ McCauley, Sharon M., Malnutrition Care: Preparing for the Next Level of Quality, *Journal of the Academy of Nutrition and Dietetics*, Volume 116, Issue 5, 852 – 855)

¹⁸ AHRQ Preventing Pressure Ulcers in Hospitals, A Toolkit for Improving Quality of Care: What are the best practices in pressure ulcer prevention that we want to use. <http://www.ahrq.gov/professionals/systems/hospital/pressureulcertoolkit/putool3.html> Accessed 1/2/2016. Stating that “comprehensive skin assessment should be performed by a unit nurse on admission to the unit, daily, and on transfer or discharge.”

¹⁹ Mueller C, Compher C, Ellen DM. A.S.P.E.N. Clinical guidelines: Nutrition screening, assessment, and intervention in adults. *Journal of Parenteral and Enteral Nutrition*. 2011;35:16–24.

²⁰ Thomas DR, Ashmen W, Morley JE, et al. Nutritional management in long-term care: Development of a clinical guideline. *Council for Nutritional Strategies in Long-Term Care. The Journal of Gerontology*. 2000;55(12):M725–734.

²¹ Dialogue Proceedings / Launching the Malnutrition Quality Improvement Initiative. Avalere and The Academy of Nutrition and Dietetics. November 2014.

(Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies; CMS-3317-P), incorporating specific nutritional and wound information would be an essential component in any transitional care plan and documentation. Adopting a Transitions of Care measure in the MSSP care coordination/patient safety domain that addresses these concerns would be an important substantial step towards aligning and harmonizing quality measures for this program.

Conclusion

AdvaMed appreciates the opportunity to submit comments on the proposed CY 2017 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,

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