June 17, 2016

Andrew Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1655-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: Medicare Program: Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and FY 2017 Rates

Dear Acting Administrator Slavitt:

On behalf of the Advanced Medical Technology Association (AdvaMed), I am pleased to offer comments on proposed changes to the Medicare hospital inpatient prospective payment system and FY 2017 rates published in the Federal Register April 27, 2016 (CMS-1655-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.

NEW TECHNOLOGY ADD-ON PAYMENTS (NTAP)

At the February 16, 2016 Town Hall Meeting on New-Technology Add-On Payments, AdvaMed argued for changes in new technology add-on policies in order to ensure that Medicare beneficiaries have access to innovative treatments and cited a February 2015 Health Affairs study, “US Hospital Payment Adjustments for Innovative Technology Lag Behind Those in Germany, France, and Japan” that found that Medicare approved considerably fewer innovative technologies for add-on payments, compared to similar payment mechanisms in Germany, France, and Japan.

We are concerned that an overly restrictive Medicare NTAP policy is compromising beneficiary access to the best that American medicine has to offer. In addition, we have seen two local Medicare Administrative Contractors (MACs) denying coverage and add-on payments for a new technology approved by the Secretary under the NTAP program. On top of restricted access, our
members increasingly report that hospitals are declining to purchase NTAP technologies because of financial losses they would face from unnecessarily inadequate Medicare payments under the NTAP program.

It is critical that CMS maintain and improve incentives for hospitals and other providers to provide beneficiary access to innovative technologies. Uncertainties in reimbursement for new medical technologies create disincentives for companies, regardless of size, to invest in research and development that lead to medical technology innovation and improvements in the quality and efficiency of health care. Small firms may be particularly vulnerable to these uncertainties, because, even if they have FDA approval for marketing a product, they are dependent on coverage and payment policies of public and private payers to produce revenues that will allow them to continue to innovate. These small companies are particularly critical to U.S. technology ecosystem because they are often the source of breakthrough technologies that drive medical technology innovation. Continued medical progress and access of Medicare beneficiaries and other patients to care that can improve their health outcomes are at stake.

We have several different policy recommendations which we believe will greatly improve Medicare beneficiary access to important new innovative technologies used in the hospital setting. CMS can implement each of these through changes in regulations and the recommendations do not require changes in law for CMS to move forward. We summarize our recommendations here and appreciate the proposed rule’s suggestion that we resubmit all of our recommendations for consideration by CMS, beyond our specific recommendation on the substantial clinical improvement criterion, which was the subject of the Town Hall meeting. Our specific recommendations include the following:

1. AdvaMed recommends increasing the add-on payment levels from 50 to 80 percent of the difference between the standard MS-DRG payment and the cost of the procedure with the new technology. This is a critically needed reform that will encourage more medical technology innovation and beneficiary access to that technology. We note that an analysis by Avalere Health LLC found that despite receiving $40.5 million in NTAP payments between FY 2006 and FY 2013, hospitals also received $23.2 million in outlier payments on these same cases. We argue that this demonstrates that NTAP payments are set at too low a threshold to cover the costs incurred by hospitals for using the new technology and that hospitals are experiencing significant losses while they offer these new and innovative services.

2. Local Medicare Administrative Contractors (MACs) should be prohibited from denying coverage and add-on payments for new medical services or technologies approved by the Secretary. During 2015, two local MACs issued non-coverage determinations for a medical technology that CMS had approved for NTAP, effectively denying beneficiaries in many States access to a new technology that met each of the three criteria CMS considers in making decisions for NTAP approval, and by implication approval for coverage and payment.
3. CMS should use the most recently available cost data and information available (including data from surveys of hospitals and suppliers conducted by the Secretary, private payers, health plans, physician specialty societies, as well as commercial price data and data from manufacturer invoices) for assigning new technology procedures to appropriate MS-DRGs. This will ensure greater accuracy in assigning the new technology procedures to the most appropriate MS-DIG.

4. The process for defining period of “newness” for purposes of add-on payments should be simplified. Under current policy, the period of “newness” for a technology or medical service to receive add-on payments is based generally on the date of FDA approval, and not when the assignment of a new ICD code allows specific identification of the new technology in claims data. Although CMS has taken steps to consider delaying the start of the newness period in cases where an applicant can demonstrate a documented delay in market availability, CMS should simplify the process by requiring the use of the later of either the assignment of a new code or FDA approval as the controlling date for starting add-on payments.

5. The criteria for “newness” should be modified so that certain 510(k) devices are not unfairly excluded from NTAP. These criteria should be expanded to include products that involve a significant technological change that do not raise different questions of safety and effectiveness (in comparison to the predicate device) and result in enhanced clinical advantages or reduced costs over an episode of care (outside the payment for the indexed MS-DRG), even though they use the same or similar mechanism of action or are assigned to the same MS-DRG. In addition, the Secretary should not disqualify a new service or technology as not meeting the newness criterion on the basis of a finding of a de minimis number of claims in Medicare claims data.

6. The criteria for “newness” should be modified to a take a broader view of a new mechanism of action to recognize an innovative deployment mechanism as substantially different.

7. The criteria applied in making substantial improvement determinations should be broadened to require, in addition to existing criteria, that the Secretary consider whether the new technology or medical service meets one or more of the following criteria: (a) results in a reduction of the length of a hospital stay; (b) improves patient quality of life; (c) creates long-term clinical efficiencies in treatment; (d) addresses patient-centered objectives as defined by the Secretary; or (e) meets such other criteria as the Secretary may specify.

8. An entity that submits an application for NTAP payments should be entitled to administrative review of an adverse determination by the Secretary. This will provide a safeguard both for the manufacturer submitting an application as well as to the beneficiary for ensuring access to innovative technologies that improve patient care outcomes. AdvaMed further recommends that administrative review of an adverse
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determination should not preclude resubmission of a modified application at a later point in the future.

MS-DRG CHANGES

1. **MS-DRG Updates – Transcatheter Mitral Valve Repair with Implant**

The proposed rule discusses three options CMS considered for reassignment of transcatheter mitral valve repair with implant to specific MS-DRGs. After analysis of the options, the rule recommends reassignment of transcatheter mitral valve repair with implant to restructured MS-DRGs 228 and 229 (Other Cardiothoracic Procedures) with and without MCC. AdvaMed supports this proposal. It will provide a more appropriate level of payment for the procedure as demonstrated by CMS’s MedPAR data analysis and will improve clinical coherence by placing the procedure with other complex cardiac procedures. In addition, the proposal will help to assure patient access to the therapy following the expiration of New Technology Add-on Payments effective October 1, 2016.

2. **MS-DRG Updates—MDC 7 (Diseases and Disorders of the Hepatobiliary System and Pancreas): Bypass Procedures of the Veins**

The proposed rule discusses a request to assign ICD-10-PCS code 06183DY (Bypass portal vein to lower vein with intraluminal device, percutaneous approach) to MDC 7 (Diseases and Disorders of the Hepatobiliary System and Pancreas) under MS-DRGs 405, 406, and 407 (Pancreas Liver and Shunt Procedures, with MCC, with CC, and without CC/MCC, respectively). Currently, ICD-10-PCS procedure code 06183DY is assigned to only MDC 5 (Diseases and Disorders of the Circulatory System) and MS-DRGs 270, 271, and 272 (Other Major Cardiovascular Procedures with MCC, with CC, and without CC/MCC, respectively) under ICD-10 MS-DRGs Version 33. After analyzing this issue, CMS agrees that the ICD-10 MS-DRGs do not fully replicate the ICD-9-CM MS-DRGs and agrees that ICD-10-PCS procedure code 06183DY should be assigned to MDC 7 and MS-DRGs 405, 406, and 407 in order to replicate the ICD-9-CM, MS-DRGs. AdvaMed agrees with the analysis and supports the CMS proposal.

3. **Proposed Medicare Code Editor Changes**

AdvaMed supports CMS’ proposal to correct an ICD-10/ICD-9 transition error that has been erroneously resulting in denials for mechanical embolectomy procedures using stent retrievers that are coded under ICD-10 code 03CG3ZZ (Extirpation of matter from intracranial artery, percutaneous approach). AdvaMed requests that CMS direct Medicare Administrative Contractors (MACs) to promptly reverse any claims denied as a result of this error. CMS also should make conforming changes to the Intracranial PTA with Stenting National Coverage Determination.
HOSPITAL INPATIENT QUALITY REPORTING (IQR) MEASURES

1. Hospital-Level, Risk-Standardized 30-day Episode-of-Care Payment Measure for Pneumonia

AdvaMed supports CMS’ proposal and associated rationale for incorporating the refinements to the patient populations for the pneumonia episode of care measure, which was previously adopted in the Hospital IQR Program. These refinements, which arose out of the National Quality Forum (NQF) Measure Applications Partnership, address concerns that there is variation in coding of pneumonia as a principal diagnosis in order to avoid patients being captured by the pneumonia episode of care measure and also aligns the measure specifications for this measure with the pneumonia readmissions and pneumonia mortality measures already included in the IQR program. We agree with CMS that refining the population for these measures will ensure better collection of more complete, accurate and comparable data across hospitals. In summary, AdvaMed supports CMS’ proposal to refine the measure cohorts for the Hospital-Level, Risk-Standardized 30-day Episode-of-Care Payment Measure for Pneumonia to include patients with a principal diagnosis of aspiration pneumonia, or a principal diagnosis of sepsis with a secondary diagnosis of pneumonia.

2. Excess Days in Acute Care after Hospitalization for Pneumonia Measure

AdvaMed supports CMS’ proposal to include an Excess Days in Acute Care after Hospitalization for Pneumonia measure to the Hospital IQR Program for the FY 2019 payment determination and beyond. This measure aligns with the National Quality Strategy and addresses a condition that is a significant driver of cost for the Medicare program. Further, variation in measure performance resulting in excess days in acute care for pneumonia patients will likely be driven by exacerbation of pneumonia leading to more critical and potentially preventable conditions, such as sepsis. Importantly, this measure will allow for identification of outlier performers in managing pneumonia and will encourage incorporation of evidence-based practices for monitoring and managing pneumonia patients, such as incorporation of hemodynamic monitoring for these critically ill patients.

HOSPITAL-ACQUIRED CONDITION (HAC) REDUCTION PROGRAM

PSI-90 Patient Safety and Adverse Events Composite Measure (Modified PSI-90)

AdvaMed supports CMS’ proposal to adopt the modified PSI-90 Patient Safety and Adverse Events Composite measure, as endorsed by NQF, for the HAC Reduction Program and adopting this measure beginning with the FY 2018 payment determination and subsequent years. The modified PSI-90 measure includes the addition of three indicators: PSI 09 Postoperative Hemorrhage or Hematoma Rate; PSI 10 Physiologic and Metabolic Derangement Rate, and PSI 11 Postoperative Respiratory Failure Rate. These refinements, which arose out of the National Quality Forum (NQF) Measure Applications Partnership, further
identify “harmful healthcare related events that are potentially preventable.” The measure received support for inclusion in the HAC Reduction Program as referenced in the MAP Final Recommendations Report. The PSI-90 measure components currently include significant indicators of patient safety events, such as post-operative sepsis, that hospitals could prevent through incorporation of additional evidence-based processes, including such technologies as enhanced patient monitoring.

HOSPITAL VALUE-BASED PURCHASING PROGRAM (HVBP)

1. Risk-Standardized Payment Associated with a 30-Day Episode of Care for AMI and Heart Failure.

AdvaMed supports CMS’ proposal to include two new condition-specific, hospital-level risk-standardized episode payment measures addressing AMI and Heart Failure in the HVBP Program beginning in 2021. Both measures are NQF-endorsed and address conditions that are significant drivers of cost for the Medicare program, including care for several common cardiovascular conditions and pneumonia, which can often lead to further complications requiring intensive monitoring including sepsis. When used in tandem with the already implemented readmissions and mortality measures, these episode cost measures can help to incentivize incorporation of evidenced-based processes of care to reduce cost per episode while improving quality of care, potentially through improved monitoring and management of patients.

2. Hospital 30-Day, All Cause, Risk-Standardized Mortality Rate following CABG Measure (NQF #2558).

AdvaMed supports CMS’ proposal to include a hospital 30-day all-cause, risk standardized mortality rate following CABG measure (NQF #2558) to the VBP program beginning in FY 2022. This measure would address a high-volume, high-cost procedure with significant variation in performance; the variation in performance signals the need for broad incorporation of evidence-based care processes to improve CABG mortality rates. Additionally, an all-cause, risk-adjusted mortality measure for patients who undergo CABG surgery would provide hospitals with an incentive to reduce mortality through improved coordination of perioperative care and discharge planning.

3. Proposed inclusion of selected ward non-intensive care unit (ICU) locations in the National Healthcare Safety Network (NHSN) Central Line Associated Blood Stream Infection (CLABSI) and Catheter Associated Urinary Tract Infection (CAUTI) measures in the VBP Program

AdvaMed supports CMS’ proposal to include selected ward non-intensive care unit (ICU) locations in the NHSN Central Line Associated Blood Stream Infection (CLABSI) and

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Catheter Associated Urinary Tract Infection (CAUTI) measures in the VBP Program. The Hospital VBP Program has used the CLABSI measure since the FY 2015 program year and has used the CAUTI measure since the FY 2016 program year. Both measures use adult, pediatric, and neonatal intensive care unit (ICU) data to calculate performance standards and measure scores. In the proposed rule, CMS proposes to expand these measures to include non-ICU locations beginning in FY 2019, in line with the changes made to the measures in the Hospital IQR Program specifications as of January 1, 2015.

The additional wards (adult or pediatric medical, surgical, and medical/surgical wards) are important targets for CLABSI and CAUTI surveillance and prevention efforts. Use of these measures in expanded hospital settings will allow for identification of outlier performers in both preventing and managing both CLABSI and CAUTI. These modifications to the measures should also serve to spur incorporation of evidence-based practices for monitoring and managing critically ill patients at risk for CLABSI and CAUTI, such as incorporation of hemodynamic monitoring.

4. Considerations for Possible Future Additions to the Hospital IQR/VBP Programs

- New Quality Measure to Capture SSI Rates After C-Section Would Strengthen Patient Care.

We commend Medicare for making very significant strides in promoting quality for major surgical procedures, such as creating measures on 30-day readmissions after total joint replacement and coronary bypass graft surgery. Surgical site infections post caesarean section (CS) is another similar surgical gap area which we wish to highlight for CMS to support development of new quality measures. Caesarean Section is the most common major surgery performed on women, however surgical site infections (SSIs) following CS poses a significant health burden due to extended hospital stay, return to the hospital, additional nursing care, medication and wound care.

A recent study in England looked at post-operative complications following 4,107 Caesarean deliveries across 14 hospitals. The overall SSI rate was 9.6%, however it increased to 19.3% in women with a BMI>35. While SSI rates may typically appear lower in the US due in-part to different means of collecting SSI data, SSIs clearly pose an important health risk to women, especially those at high risk comorbid chronic conditions such as diabetes or obesity.

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. 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

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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.  

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 focus on harmonizing quality measures across payers, we believe that this would be an important first step towards future awareness and adoption of similar measures by private payers and Medicaid state agencies.

AdvaMed encourages CMS to support development of a new Medicare quality measure that would capture hospital performance on caring for mothers delivering their baby via caesarean section (CS), such as a measure for 30-day surgical site infection (SSI) rates for patients undergoing C-sections. This type of measure could include SSIs observed prior to discharge from the hospital or at any point up to 30 days post-discharge and likely would be suitable for the Inpatient Quality Reporting program or the Value-Based Purchasing program.

- **Malnutrition Quality Measure for Future Hospital IQR and VBP Programs.**

As CMS seeks to improve the health of the U.S. population by supporting proven interventions to deliver higher-quality care, we urge the agency to address timely malnutrition screening, assessment, diagnosis and intervention in future quality and incentive alignment programs across the care continuum and starting with the acute care hospital setting. AdvaMed urges CMS adopt newly developed De Novo Malnutrition Electronic Clinical Quality Measures (eCQMs) for consideration by CMS for IQR and VBP.

Malnutrition, a nutrition imbalance that affects both overweight and underweight patients, is a common issue. Up to 1 in 2 older adults are already malnourished when they’re admitted to the hospital and when a person has a health issue, like a heart attack or pneumonia, malnutrition can worsen their health outcomes including higher chances of complications, readmissions and mortality. Chronic disease increases the risk of malnutrition in older adults. Studies estimate the prevalence of malnutrition in cancer patients is 20-87 percent, in chronic kidney disease is 20-50 percent, and in chronic obstructive pulmonary disease is 19-60 percent.

Malnutrition is a patient safety risk, as those who are malnourished are more likely to experience a healthcare acquired condition. An indication of the growing awareness of the importance of malnutrition as a safety issue, malnutrition is one of the five patient safety risk areas represented

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5 CMS 2016 Quality Strategy
6 Coats KG et al. J Am Diet Assoc. 1993; 93: 27-33
9 Norman K et al. Clin Nutr 2008; 27: 5-15
in the 2015 Leapfrog Group Hospital Survey.\textsuperscript{11} Malnutrition is linked to increased rates of morbidity, increased incidence of healthcare acquired pressure ulcers and infections, falls, delayed wound healing, and decreased respiratory and cardiac function, poorer outcomes for chronic lung diseases, increased risk of cardiovascular and gastrointestinal disorders, reduced physical function, and development of nosocomial infections. In an epidemiologic analysis of 887,189 major surgery cases drawn from the Healthcare Cost and Utilization Project (HCUP) Nationwide Inpatient Sample (NIS), malnutrition was associated with an increased risk of severe events. Patients with malnutrition were four times more likely to develop pressure ulcers, two times more likely to develop surgical site infections, sixteen times more likely to develop intravascular device infections, and five times more likely to develop catheter-associated urinary tract infections.\textsuperscript{12}

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,\textsuperscript{13,14,15} as well as complication rates, length of stay, cost of care, and in some cases, mortality.\textsuperscript{16} In a recent study Advocate Healthcare significantly decreased 30-day unplanned hospital readmissions and costs among the malnourished inpatient population by initiating a comprehensive Quality Improvement Program (QIP) that included primarily a validated malnutrition screening tool and administration of oral nutritional supplements (ONS).\textsuperscript{17,18} Another recent study also supports these increased patient outcomes with nutritional interventions using a QIP focusing on ONS, and ONS documentation on the medication administration record.\textsuperscript{19}

While people may be at-risk or become malnourished in any setting, the trigger of a hospitalization can exacerbate and accelerate disease-associated malnutrition or the risk of malnutrition. Early identification of Medicare beneficiaries at risk for malnutrition, prompt nutrition intervention and implementation of an effective care transition plan for patients diagnosed as malnourished or at risk of malnutrition are critical to help reduce morbidity, mortality, and costs. Hospitalization provides an opportunity for immediate intervention by the

\textsuperscript{17} Sriram K et al. Rapid Comprehensive Oral Nutritional Supplement Quality Improvement Program Reduces 30-day Readmission in Malnourished Hospitalized Patients. JPEN. 2016; 40(1):1
care team. Despite guidelines and standards, there are variations in malnutrition care that can negatively impact time to nutrition intervention and care coordination.

The Academy of Nutrition and Dietetics has partnered with Avalere Health and a Technical Expert Panel to develop de novo malnutrition electronic clinical quality measures (eCQMs). The eCQMs will be submitted to the CMS in July 2016 for the agency Measures Under Consideration (MUC) List.²⁰ **AdvaMed urges CMS to adopt this malnutrition measure set as soon as feasible for subsequent Hospital IQR and VBP program.**

- NHSN Antimicrobial Use Measure (NQF #2720)

AdvaMed supports the newly adopted NQF #2720 measure for antimicrobial use that is calculated based on electronic drug administration records. In order for measures of this kind to become widely used, there is a need for a broadly adopted interoperability standard. This standard should be suitable to be adopted across all vendors providing accessibility of the requisite electronic drug administration data. In the interim evaluation of other metrics for antimicrobial use should be considered and evaluated.

**LONG-TERM CARE HOSPITAL QUALITY REPORTING (LTCHQR) PROGRAM**

We appreciate the opportunity to comment on quality measures and measure concepts under consideration for future years for Long Term Care Hospital Quality Reporting. Malnutrition is not only a patient safety risk for hospitalized patients, it can negatively impact patient outcomes in any healthcare setting. According to the National Resource Center on Nutrition, Physical Activity and Aging, nearly 35-50 percent of older residents in long-term care facilities are malnourished. In previous rule-making CMS agreed that malnutrition is an important quality measure concept for the LTCH setting.²¹

**AdvaMed recommends that CMS adopt a malnutrition-related quality measure in the LTCH QRP as soon as feasible.** Early identification of Medicare beneficiaries at risk for malnutrition, prompt nutrition intervention and implementation of an effective care transition plan for patients diagnosed as malnourished or at risk of malnutrition are critical to improve outcomes and patient safety by reducing complications such as infections, falls, and pressure ulcers.

**Additionally, AdvaMed supports the proposed Impact Act Measure “Transfer of Health Information and care preferences when an individual transitions” and recommends CMS include nutritional status and a nutrition care plan in this transfer of health information for patients, caregivers and medical providers.**

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²¹ CMS-1632-F; Federal Register/Vol.80, No 158/Aug 17, 2015; 49748
AdvaMed appreciates the opportunity to submit these comments in response to the FY 2017 IPPS Proposed Rule. If you have any questions, please contact me or Richard Price at rprice@advamed.org or Steve Brotman at sbrotman@advamed.org.

Sincerely,

Don May
Executive Vice President
Payment and Health Care Delivery