June 13, 2017

Ms. Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1677-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 2018 Rates, CMS-1677-P

Dear Administrator Verma:

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 2018 rates published in the Federal Register April 28, 2017 (CMS-1677-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.

AdvaMed supports many of the proposals in the rule. However, we also have identified several areas of concern where we recommend modifications to the rule to ensure adequate reimbursement and access to medical technologies used in patient care. We also provide several recommendations to respond to CMS’s request for areas that regulatory efficiencies can be created. Our letter includes comments under the following categories:

- MS-DRG Changes and Reimbursement Issues
- Hospital Inpatient Quality Reporting Program (IQR)
- Hospital Value-Based Purchasing Program (HVBP)
- Long-Term Care Hospital Quality Reporting Program (LTCH QRP)
- Accounting for Social Risk Factors Across Various Quality Programs
- Request for Information on CMS Flexibilities and Efficiencies
MS-DRG CHANGES AND REIMBURSEMENT ISSUES

Transition Period for Substantial Reductions in MS-DRG Relative Weights Due to ICD-10 Implementation

The FY 2018 Proposed Rule represents the first year in which the proposed MS-DRG weights are based on ICD-10 code mappings as well as costs and volumes calculated from hospitals’ claims on which the ICD-10 codes were reported. AdvaMed believes that because of this transition we are seeing significant fluctuations in the proposed payment weights calculated for FY 2018 relative to FY 2017. For example, the FY 2018 Proposed Rule includes several major payment reductions, including a 34.8 percent reduction in the relative weight for MS-DRG 215 (Other Heart Assist System Implants), a 17.5 percent reduction for MS-DRGs 515-517 (Other Musculoskeletal System and Connective Tissue OR Procedures), and a 27 percent reduction for MS-DRGs 332-334 (Rectal Resection).

In general, we are concerned that the proposal to implement such dramatic swings are inconsistent with the significant effort CMS has put forth thus far to ensure a smooth transition from ICD-9 to ICD-10, and contrary to CMS’s articulated goal in the FY 2017 IPPS Final Rule of ensuring accurate replication of ICD-9 DRG assignments in its ICD-10 implementation. CMS stated in that Final Rule that the failure of the ICD-9 and ICD-10 versions of the MS-DRG to replicate each other could lead to “unintended payment redistributions.”

We believe the lengths CMS has gone to in ensuring the stability of the MS-DRG assignments during the crossover from ICD-9 to ICD-10 underscores the importance of payment stability within the IPPS year-to-year. CMS has adhered to a broad principle of payment stability throughout the history of the IPPS. For example, when CMS converted the IPPS to MS-DRGs from DRGs in FY 2008, CMS acknowledged that a payment transition methodology during periods of significant changes under the IPPS is warranted to mitigate the impact of those changes on hospitals in any single year (72 FR 47200). CMS also referenced in the FY 2007 final rule that “we have in the past provided for transition periods when adopting changes that have significant payment implications” (71 FR 47895) when discussing the rationale for the 3-year transition from charge-based weights to cost-based weights.

In accordance with this principle of payment stability, and consistent with CMS’s past actions to guard against significant fluctuations in hospital payments year to year, we ask that CMS take action in the FY 2018 IPPS final rule to moderate the fluctuations in MS-DRG weights – specifically, to establish a cap of 10 percent on the degree to which a payment weight may decline in FY 2018 relative to FY 2017.

As referenced above, the relative weight for MS-DRG 215, which includes the insertion and revision of heart assist pumps, would decline nearly 35 percent under this proposed rule. These pumps are provided to critically ill cardiovascular patients who require the implantation of a heart pump after events such as a heart attack or decompensating heart failure. This proposed payment reduction, the largest for any DRG in FY 2018, is not explained in the preamble to the Proposed Rule.
Our analysis indicates that this very large reduction, as well as other significant reductions in relative weights for other MS-DRGs, can be attributed to full implementation of ICD-10 coding. In addition, we expect that sicker, costlier patients will be assigned to MS-DRG 215 as a result of recent American Hospital Association (AHA) coding guidance. These costlier therapies are currently underrepresented in the data that will set the payment for this DRG in FY 2018.

Hospitals require predictable reimbursement for the care they provide Medicare beneficiaries and should not experience the levels of reduction proposed for MS-DRGs and other DRGs as well. As stated above, to address problems resulting from the transition to ICD-10, AdvaMed recommends that CMS cap in its Final Rule declines in payment weights at 10 percent.

**ICD-10 Endobronchial Valve (EBV) Insertion Procedure Codes Should Map to MS-DRG 163 (Major Chest Procedure with MCC)**

In the FY 2014 Inpatient Prospective Payment System (IPPS) Final Rule, CMS opened consideration on mapping the ICD-9 procedure codes for endobronchial valve insertion. At that time, the endoscopic insertion of bronchial valves was captured by ICD-9 procedure codes 33.71 (Endoscopic insertion or replacement of bronchial valve(s), single lobe) and 33.73 (Endoscopic insertion or replacement of bronchial valve(s) multiple lobes). CMS considered these nonoperating procedures that do not affect MS-DRG assignment. CMS declined to change its policy, citing among other arguments, a lack of data on the cost of these procedures.

The implementation of ICD-10 effective Oct 1, 2015 resulted in use of new ICD-10-PCS codes for the insertion of endobronchial valves, which are represented in the codes 0BH[3,4,5,6,7,8,9,B][0,3,4,7,8]GZ. Almost all these codes are assigned to Major Chest Procedures (DRGs 163-165).

However, the ICD-10-PCS codes for the insertion of EBVs throughout the lung when performed *via natural or artificial opening endoscopic* (namely ICD-10-PCS codes 0BH[3,4,5,6,7,8,9,B][8]GZ) are not assigned to 163-165 and are classified as nonoperating codes that do not map to any DRG.

An analysis of the May 2017 Update of the FY 2016 MedPAR Proposed Rule File data indicates that average costs for EBV cases are similar to cases currently assigned to MS-DRG 163. We identified 172 EBV cases within MDC 04. Of these cases, 67 were assigned to medical MS-DRGs and 105 were assigned to surgical MS-DRGs. Of the 67 EBV cases assigned to medical MS-DRGs, all had an ICD-10-PCS code 0BH[3,4,5,6,7,8,9,B][8]GZ. We then compared the 67 EBV medical MS-DRG cases to all cases assigned to MS-DRGs 163 to 165 per the original proposal considered for FY2014 by CMS, and found that the average costs of EBV cases closely resemble cases assigned to MS-DRG 163. Using standardized costs for fee-for-service discharges only, the 67 EBV discharges assigned to Medical MS-DRGs have an average cost of $32,337. The 12,991 cases in MS-DRG 163 (Major Chest Procedures with MCC) have an average cost of $35,238.

Therefore, we recommend CMS designate the insertion of endobronchial valves using any approach, which are represented in the codes 0BH[3,4,5,6,7,8,9,B][0,3,4,7,8]GZ as operating
room procedures and assign them to MS-DRG 163 and edit the descriptor to read: MS-DRG 163 Major Chest Procedures With MCC or Insertion of Endobronchial Valve. This designation would be consistent with other MS-DRG changes such as: MS-DRG 129 Major Head & Neck Procedures W CC/MCC Or Major Device; and MS-DRG 518 Back & Neck Proc Exc Spinal Fusion W MCC Or Disc Device/Neurostim.

**Assignment of the Transcatheter Mitral Valve Replacement (TMVR) Transseptal Codes and Transcatheter Tricuspid Valve Replacement Codes to MS-DRGs 266-267**

AdvaMed supports the proposal to reassign Transcatheter Mitral Valve Replacement (TMVR) procedure codes and Transcatheter Tricuspid Valve Replacement (TTVR) procedure codes to DRGs 266-267, which were developed to capture “Endovascular Cardiac Valve Replacement” for all heart valves. AdvaMed agrees that it is clinically coherent for transseptal TMVR and TTVR procedures to be aligned with other percutaneous replacement cardiac valve procedures of the aortic, mitral and pulmonary valves.

**Retain Operating Room (O.R.) Procedure Designation for Endoscopic/Transorific Destruction ICD-10-PCS Codes**

In the FY 2018 IPPS proposed rule, CMS has proposed to designate the Endoscopic/Transorific Destruction grouping of ICD-10-PCS procedure codes as “NON-O.R. PROCEDURES”. CMS agreed with a commenter who submitted this request (as part of the FY 2017 rulemaking process) indicating that these procedures generally would not require the resources of an operating room and can be performed at the bedside. AdvaMed is concerned that the commenter has misrepresented the nature of these procedures to CMS. According to consultations with interventional pulmonologists who perform these procedures, the only time these procedures would be performed at bedside is if the patient is in the ICU and transport to an O.R. setting would pose a risk. Otherwise, these procedures would typically be performed in the O.R.

An analysis of Medicare IPPS claims data validates the clinical resources required for these procedures. A review of cases with ICD-10 codes from this Endoscopic/Transorific Destruction grouping identified a total of 647 cases reported. The majority of cases contained costs from 2 of the 19 cost centers found in the CMS Cost Report data: Operating Room (89%) and Anesthesia (74%). The weighted average claims cost for the 647 claims was $32,713 and FY2017 weighted average payment was $26,134. The proposed designation change to “NON-O.R. PROCEDURE” would result in a reassignment of the claims to a medical MS-DRG and ultimately result in a 39% reduction in hospital payment, going from FY 2017 weighted average payment of $26,134 down to $15,900 in FY 2018. This payment reduction would only cover 48.6% of the costs of the inpatient stay, making it very difficult for hospitals to provide the appropriate care to these very sick patients. This cost analysis further supports the designation of “O.R. PROCEDURES” for these codes as the current payment for the surgical MS-DRGs that these codes map to more closely align with the costs of these procedures.

CMS’s IPPS proposal also conflicts with CMS’s CY 2017 PFS rule. Based on what CMS identified as changes in practice patterns, moderate sedation was removed from the overall physician reimbursement for several endoscopic procedures. CMS now requires physicians to report moderate sedation services separately, when performed. The assumption here is that the
majority of procedures are done using general anesthesia, which would be consistent with our findings of 74% of cases containing anesthesia costs. The CY 2017 PFS policy change aligns with an IPPS designation of “O.R. PROCEDURES” for this group of codes.

AdvaMed believes that the Endoscopic/Transorifice Destruction grouping of ICD-10-PCS procedure codes should be designated as “OR PROCEDURES,” due to both their clinical and resource use characteristics.

**Assignment of all Primary Total Ankle Replacement (TAR) procedures to MS-DRG 469, even when there is no MCC reported**

AdvaMed strongly supports CMS’s proposal to assign all Primary TAR procedures to MS-DRG 469 to address the current hospital cost-to-payment inequity for Primary TAR procedures compared with that of primary total hip and total knee arthroplasty procedures. CMS has correctly recognized the cost and clinical complexity of TAR procedures in the proposed rule, and AdvaMed urges CMS to adopt this change effective for FY 2018, as proposed.

**Revision of Total Ankle Replacement (TAR) Procedures**

AdvaMed is concerned that the transition to ICD-10 and the assignment logic process for revision TAR procedures has failed to capture fully and accurately all of the codes and code combinations that are used for these procedures. We note that both the American Hospital Association Coding Clinic and the ICD-10-PCS Reference Manual have identified additional codes that should be used for removal and revision with replacement TAR components and it is the omission of these codes that led to the relative lack of cases in CMS’s analysis. AdvaMed recommends that CMS revisit its analysis and consider expanding the codes included in revision TAR procedures. AdvaMed also recommends that this analysis be completed for the final rule so that appropriate amounts are paid by Medicare for revision procedures in FY 2018.

**HOSPITAL INPATIENT QUALITY REPORTING PROGRAM (IQR)**

**AMI / CABG 30-Day Mortality Rate Measures**

AdvaMed supports CMS’s proposal for continued inclusion of AMI and CABG 30-day mortality rate measures in the IQR Program. These measures address high-volume, high-cost episodes of care with significant variation in performance; the variation in performance signals the need for broad incorporation of evidence-based care processes to improve AMI and CABG mortality rates.

**Severe Sepsis and Septic Shock: Management Bundle**

AdvaMed supports CMS’s proposal for continued inclusion of the Severe Sepsis and Septic Shock: Management Bundle measure in the IQR Program. Sepsis is a severe and potentially preventable condition that is a significant driver of cost for the Medicare program. In addition to supporting continued inclusion of the Sepsis Bundle in the IQR Program, AdvaMed urges CMS to seek stakeholder input into adding this measure in the Hospital VBP Program to further raise awareness of the disease burden of sepsis, both to critically ill patients who face 75% increases in hospital length of stay and mortality rates up to 40%, as well as to the healthcare system as a
whole which faces unsustainable and increasing cost to manage and treat these patients.\textsuperscript{1,2} Given that early identification of sepsis and initiation of treatment has been demonstrated to improve in-hospital mortality, with patients treated after 3 hours having 14\% higher odds of in-hospital death than patients who receive treatment including antibiotics within the first 3 hours\textsuperscript{3}, use of this measure is critically important for improving patient outcomes and will likely spur incorporation of evidence-based practices such as hemodynamic monitoring for evaluation and management of these critically ill patients at risk for sepsis.

**Inclusion of Malnutrition Electronic Clinical Quality Measures (eCQMs) in Hospital IQR with Reporting in CY 2018 and a Future Malnutrition Composite Measure, When Available.**

CMS is soliciting comments on whether certain eCQMs, including a malnutrition composite measure, should be included in the Hospital IQR. AdvaMed commends CMS on continuing to advance proposals to help improve patient safety, care coordination, and outcomes for malnourished and at-risk beneficiaries. We specifically appreciate the opportunity to provide input on the potential inclusion of malnutrition eCQMs in a future Hospital IQR Program and the potential inclusion of a future composite malnutrition measure.

Hospitalization provides an opportunity for immediate intervention by the interdisciplinary care team. Early identification of Medicare beneficiaries at risk for malnutrition, prompt nutrition intervention and implementation of an effective care transition plan has been shown to reduce length of stay, 30-Day Readmissions, mortality, and costs.\textsuperscript{4,5,6} Implementation of an effective care plan and discharge plan for patients diagnosed as malnourished or at-risk for malnutrition is critical to improving outcomes and patient safety by reducing complications which can lead to readmissions including infections, falls, and pressure ulcers. As recovery, rehabilitation time and functional independence may be significantly improved by preventing and treating malnutrition, the malnutrition eCQMs are “measures that matter” for patients, families and providers.

Due to the gap in diagnosis and significant burden of malnutrition on patients, their families and the healthcare system, AdvaMed urges CMS to adopt the malnutrition eCQMs that address screening, assessment, care planning, and diagnosis of malnutrition, with reporting in CY 2018 versus waiting for a future year. Because there are currently no quality measures to address gaps and variations in management of malnutrition for malnourished or at-risk older adults, reporting the malnutrition eCQMs will facilitate care coordination and safe transitions of care and has the potential to impact metrics across multiple quality programs and care settings.

\begin{itemize}
  \item IBID
  \item https://www.healthcatalyst.com/success_stories/improve-sepsis-mortality-rate
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While recognizing the need to avoid imposing unnecessary burdens on hospitals associated with measure reporting, we support adoption of critical cross-cutting measures necessary to improve patient outcomes and care coordination, while decreasing costs across the healthcare system. If there is a need to limit the number of eCQMs adopted in a single calendar year, CMS could consider a phased-in approach with adoption of one or more measures in CY 2018 and the other malnutrition eCQMs in CY 2019. If a phased-in approach is selected, we recommend CMS prioritize adoption of MUC16-296: “Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition within 24 Hours of a Malnutrition Screening” immediately with reporting in CY 2018 to start to fill gaps and improve outcomes as soon as possible.

The malnutrition eCQM set addresses CMS IQR priorities as these clinically relevant process measures collectively will help to fill a measure gap, improve quality across the patient-focused episode of care, and engage patients and their families as partners in care delivery. The malnutrition eCQMs also align with National Quality Strategy priorities by improving patient safety (decreased preventable readmissions and complications), care coordination, patient and family centered care (activation/engagement), population health (prevention and management of elderly and high impact Medicare conditions), and efficiency (reduced costs).

HOSPITAL VALUE-BASED PURCHASING PROGRAM (HVBP)

Proposed New Measure for the FY 2022 Program Year and Subsequent Years: Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode of Care for Pneumonia

AdvaMed supports CMS’s proposal to include the Hospital-Level, Risk-Standardized Payment Associated with a 30-day episode of pneumonia measure in the VBP Program in FY 2022. In particular, AdvaMed continues to support that this measure captures patients with a principal diagnosis of aspiration pneumonia, or a principal diagnosis of sepsis with a secondary diagnosis of pneumonia, which addresses stakeholder 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.

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 higher cost of care for pneumonia patients will likely be driven by exacerbation of pneumonia leading to more critical, and potentially preventable conditions, such as sepsis. This measure will allow for identification of outlier performers in managing pneumonia and will spur incorporation of evidence-based practices for monitoring and managing pneumonia patients, such as incorporation of hemodynamic monitoring for these critically ill patients.

CABG 30-Day Mortality Measure

AdvaMed supports CMS’s proposal for continued inclusion of a CABG 30-day mortality measure to the VBP Program. This measure addresses 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.

**CLABSI and CAUTI Infection Outcome Measures**

AdvaMed supports CMS’ proposal for continued inclusion of CLABSI and CAUTI infection outcome measures in the IQR and VBP Programs, acknowledging that these healthcare associated infections (HAIs) are a significant cause of illness and death with severe financial and medical consequences. Recent statistics show that approximately one in every 25 hospitalized patients has an HAI and over 1 million HAIs occur annually across the US healthcare system.⁷

These HAIs in particular are potentially preventable through evidence-based practices, and thus ensuring such practices are utilized is of the utmost importance. Additionally, by incentivizing surveillance of CLABSI and CAUTI, infection can be identified earlier, when such measures to ensure proper treatment and patient monitoring can be implemented to improve patient outcomes and avoid more serious infection such as sepsis.⁸

**LONG-TERM CARE HOSPITAL QUALITY REPORTING PROGRAM (LTCH QRP)**

**Replacement of Current Pressure Ulcer Measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) with a Modified Measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury**

In the proposed rule, CMS invites public comment on their proposal to replace the current pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), with a modified version of that measure, entitled Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, for the LTCH QRP beginning with the FY 2020 LTCH QRP. The measure has been modified to include the definition of “pressure injuries” by the National Pressure Ulcer Advisory Panel (NPUAP) in the numerator. The NPUAP definition states that:

“A pressure injury is localized damage to the skin and underlying soft tissue usually over a bony prominence or related to a medical or other device. The injury can present as intact skin or an open ulcer and may be painful. The injury occurs as a result of intense and/or prolonged pressure or pressure in combination with shear. The tolerance of soft tissue for pressure and shear may also be affected by microclimate, nutrition, perfusion, co-morbidities and condition of the soft tissue.”

Although the NPUAP has released a Position Statement on the new staging commenting that the diagnosis of “pressure injury” does not mean that the health provider(s) “caused” the injury⁹, it is

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⁷ https://www.performance.gov/content/improve-patient-safety?view=public
self-evident that many providers, forums and organization including the Symposium on Advanced Wound Care (SAWC) and Academy of Physicians in Wound Healing (APWH) have significant concerns regarding the potential medical legal issues raised by changing “pressure ulcer” to “pressure injury.”

Importantly, the modified definition may have a future cascading negative chilling unintended effect to potentially restrict access to much needed medical devices by providers who may be apprehensive for fear medical legal issues related to the use of the device. In the proposed rule, CMS notes that the MAP only conditionally supported the measure due to several concerns. One of these conditions is that CMS continues analyzing the proposed measure in order to investigate unexpected results reported in public comment. CMS notes that they intend to fulfill these conditions by offering additional training opportunities and educational materials in advance of public reporting, and by continuing to monitor and analyze the proposed measure. A measure that raises this level of concern for providers and others, should be further analyzed.

Currently the newly proposed measure is not NQF endorsed and CMS notes in the proposed rule that they intend to submit the proposed measure to NQF for endorsement as soon as feasible. AdvaMed recommends that CMS delay implementation of this measure until it has been vetted via the NQF endorsement process which examines measures not only for the importance to measure and report, but also for testing regarding feasibility, usability, reliability and validity of the measure, which are critical to accountability.

Integration of Standardized Patient Assessment Data Elements in the Long-Term Care Hospital Continuity Assessment Record & Evaluation (CARE) Data Set.

AdvaMed commends CMS for acknowledging the importance of care coordination and safe care transitions for malnourished and at-risk beneficiaries in LTCHs and other PAC settings. Continuity of nutritional care is essential for older adults. As we noted in previous comments, the integration of nutritional status and diet orders in discharge planning, standardized assessment and other transfer of health information documents will serve to alert the receiving facility and practitioners that these concerns should be incorporated into their own notes, current treatment plan, and daily SOAP (subjective, objective, assessment and plan) or similar types of notes.

Therefore, AdvaMed supports CMS’s proposals to include 1) malnutrition and risk of malnutrition data elements as co-morbid conditions; and 2) nutritional approach data elements for the Assessment of Special Services, Treatments and Interventions (i.e., Parenteral/IV Feeding, Feeding Tube, Mechanically Altered-Diet, and Therapeutic Diet).

We recommend, however, that CMS align the definition of the therapeutic diet data element with the following Academy of Nutrition and Dietetics definition to help clarify the data to be reported and ensure consistent data collection:

“A therapeutic diet is a diet intervention prescribed by a physician or other authorized non-physician practitioner that provides food or nutrients via oral, enteral and parenteral routes as part of treatment of disease or clinical conditions to modify, eliminate, decrease, or increase identified micro- and macro-nutrients in the diet.” (Academy of Nutrition and
ACCOUNTING FOR SOCIAL RISK FACTORS ACROSS VARIOUS QUALITY PROGRAMS

In the proposed rule, CMS seeks comments on whether to account for social risk factors and how social risk factors can be incorporated into Medicare’s quality reporting and value-based payment programs. Social risk factors, also sometimes referred to as socioeconomic status (SES) factors or socio-demographic status (SDS) factors, play a major role in health and include factors such as income, education, race and ethnicity, employment status, disability, community resources, and social support. CMS notes that it continues to be concerned about the potential for risk adjustment for social factors to mask potential disparities or minimize incentives to improve outcomes for disadvantaged populations.

Highlighting the importance of the effects of social risk factors on quality and resource use measures, CMS refers in the proposed rule to the December 2016 report to Congress by the Office of the Assistant Secretary for Planning and Evaluation (ASPE), which evaluated nine Medicare payment programs, including the HRRP, HVBP, and HACRP. The ASPE report determined that beneficiaries with social risk factors had worse outcomes on many quality measures, regardless of the providers used. CMS also cites the findings of another report by The National Academies of Science, Engineering, and Medicine, which reached similar conclusions.

AdvaMed believes that examination of social risk factors continues to be a major challenge as more quality measures are considered for reporting and value-based purchasing programs. These factors have put many populations at risk of worse health outcomes based on the social conditions in which they live. Research reveals that those hospitals serving populations with more social risk factors may be disproportionally impacted by quality programs and potentially more at risk to receive financial penalties.

AdvaMed supports the efforts by CMS to continue to work with stakeholders on issues related to social risk factors in quality reporting and value-based payment programs. AdvaMed agrees that CMS should review the recommendations of the National Quality Forum (NQF) at the conclusion of their ongoing two-year trial period, during which social risk factors are being included in the risk adjustment of some measures. Additionally, AdvaMed recommends that CMS closely monitor the related recommendations and reports of the NQF Disparities Standing Committee. AdvaMed looks forward to providing future input to CMS regarding addressing social risk factors in upcoming proposed rules.

REQUEST FOR INFORMATION ON CMS FLEXIBILITIES AND EFFICIENCIES

AdvaMed applauds CMS’s decision to seek information on potential regulatory reform to improve the Medicare program and reduce unnecessary burdens on patients and their families. We submit the following recommendations for your consideration.
Medicare’s historic mission has been to assure senior citizens’ affordable access to the best care the U.S. health care system can offer. As the federal government’s largest health program, Medicare should also support the national mission to advance medical progress. A number of Medicare’s regulations, policies, and procedures place unnecessary burdens on medical technology companies’ ability to provide and Medicare patients’ ability to benefit from new technology-based treatments, diagnostics, and cures. These burdens not only deprive Medicare patients of prompt access to appropriate treatments for their conditions but have also contributed to a significant slow-down in early stage investment in the treatments and cures of the future. The number of early-stage start-up companies receiving venture capital funding is at its lowest level since 1995. Investors indicate that the key deterrent to investment is uncertainty about the possibility of timely coverage and reimbursement.

**Problems and Potential Solutions**

1. **Coverage of clinical trials.** Access to clinical trials offers important benefits to patients and is critical to supporting the research endeavor that drives medical progress. A CMS regulation in 1995 and a presidential executive order in 2000, as well as congressional legislation in 2003 established the principle that Medicare patients should have access to clinical trials and that Medicare should cover at least part of the costs. CMS deems FDA-approved drug trials as automatically meeting Medicare’s criteria for coverage, but has chosen to require a separate CMS review and approval of FDA-approved device trials.

Until recently, CMS approved about 97 percent of the applications for coverage of investigational device exemption (IDE) clinical trials that were approved by the FDA. With the institution of a new, centralized review process, however, AdvaMed’s member companies have seen increasing denials by CMS of coverage for certain IDE clinical trials, particularly early feasibility, or first-in-human trials.

To its credit, CMS leadership is working with the FDA to address this issue and to find a way to cover early feasibility studies. But the requirement that CMS re-review and approve clinical trials that have already been approved by the FDA should be eliminated. Before any medical technology trial can be conducted, it must be approved both by the FDA and by an institutional review board (IRB) as scientifically sound and meeting ethical requirements for protection of human subjects and for informed consent. Separate CMS review of device trials is redundant, sets up an unnecessary bureaucratic barrier to research, extends the time required to get a trial underway, and discourages small companies, in particular, from conducting trials in the United States—denying Medicare patients the opportunity to participate in trials that the executive orders and legislation were intended to achieve. Importantly, it diverts CMS coverage division resources from more important activities.

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10 60 Fed Reg 48417; “Memorandum on Increasing Participation of Medicare Beneficiaries in Clinical Trials,” June 7, 2000; Medicare Modernization Act of 2003 (section 1862(m) of the Social Security Act. For clinical trials of novel devices, Medicare covers the routine costs of the trials, but not the cost of the device itself. For clinical trials of devices that are improvements of existing treatments and the original treatment would be a covered service, Medicare pays for provision of the improved device at the same level and using the same mechanism that would be applied if a patient were treated using the prior device.
Recommendation: CMS should treat medical technology trials the same way it treats drug trials and deem FDA-approved IDE trials automatically approved for CMS coverage.

2. Coverage of breakthrough technologies. The 1997 FDAMA legislation established a category of medical devices and diagnostics that are eligible for priority FDA review. To qualify, products must be designated by the clinical experts at FDA as offering the potential for significant improvements in diagnosis or treatment of the most serious illnesses—those that are life-threatening or irreversibly debilitating. Because these products are typically truly novel technologies, only about half the products that receive this designation are actually approved by the FDA—an average of about three a year. The processes by which products meeting the statutory standard for priority treatment are considered by the FDA were spelled out in greater detail in FDA’s Expedited Access Program (EAP), and in the recently passed 21st Century Cures legislation. A review of eighteen of these products that were approved by the FDA over the last ten years found that almost all were ultimately granted Medicare coverage, but some faced significant delays, depriving patients of timely access to important treatment. It is not surprising that almost all of these products were ultimately found to be “reasonable and necessary,” since the FDA’s criteria for the designation assures that the treatments or diagnostics were effective in treating the most serious illnesses and were superior to existing alternatives.

Recommendation: After FDA approves a device or diagnostic under one of the authorities noted above, CMS should provide immediate transitional coverage and coding for the indications approved by FDA. During the transitional period, CMS could require collection of additional data, if necessary, to make a final determination as to whether the device meets the reasonable and necessary standard. This transitional coverage approach would provide Medicare beneficiaries more rapid access to breakthrough technologies and would also encourage investment in development of these technologies, since investors would know that if the technology were truly safe and effective and passed FDA’s rigorous review, there would be certainty with respect to revenue flow.

3. CMS Timing for Accepting National Coverage Decisions (NCDs). CMS follows clear timelines and processes for national coverage decisions. These timelines and processes have generally worked well in providing a transparent process with reasonable completion times. When a company requests an NCD, however, there is no clear timeline as to when the NCD process will begin and no transparency to the company as to when or on what basis a decision to commence the process will be made. This is frustrating to companies and unnecessarily delays the availability of reasonable and necessary therapies to Medicare patients.

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11 The study, which was conducted internally by AdvaMed, did not analyze whether delays were due to time needed to gain a coverage decision, a new code, or some combination of the two. Even when access was finally granted, it was not necessarily for all the FDA approved indications or in all areas of the country, since many product coverage decisions are made by local Medicare carriers rather than through national coverage decisions and the study characterized the technology as receiving a favorable coverage decision if it was covered anywhere. The technologies that were covered without any delay typically fit into an existing code and payment category, so no special Medicare coverage decision was required. The analysis excluded technologies that did not receive Medicare coverage because they were not approved by FDA for the elderly population or because they were deemed outside the scope of services covered under the Medicare statute.
Recommendation: CMS should establish clear time lines and transparent processes for commencing an NCD requested by external stakeholders such as technology developers.

4. Transparency and fairness in local coverage decisions (LCDs). Most new technologies do not go through a national coverage decision. In some cases, coverage decisions are made by the Medicare Administrative Contractor (the MAC, or local Medicare contractors that process claims). These decisions often lack the transparency and procedural fairness of an NCD and sometimes are made based on inadequate or faulty data.

Recommendation: CMS’s Program Integrity Manual describes a procedure that MACs must follow in making an LCD. However, there is no standardized process for applying the manual procedure and all MACs do not follow the same process for developing LCDs. CMS should enforce the requirements in the Program Integrity Manual.

5. Streamlining CMS/AMA Processes for Coding. CMS’s lengthy process for assigning payment codes to new treatments is a major barrier to timely coverage. The absence of a code that can be used by providers to bill for a new treatment can compromise patient access to the treatment. Many new technologies are similar enough to existing technologies to be billed with an existing code, but most novel and important treatments will likely require a new code before patients can actually receive the treatment. CMS is responsible for providing codes for inpatient procedures, for durable medical equipment, and for hospital outpatient services that are not provided by a physician, as well as care in some other settings. The AMA provides codes for services provided in a physician’s office, for physician-provided hospital outpatient services, and for ambulatory surgery centers. Adoption of a new code by CMS or the AMA takes a minimum of one year and a maximum of two years, even if there are no problems during the application process.

Recommendation: CMS should examine its coding processes and work with the AMA and the stakeholder community to find ways to speed up the process for issuing and making codes effective for providing patients access to new treatments and technologies. The new system for coding diagnostic tests under the Protecting Access to Medicare Act (PAMA) could provide a model for code development for other medical technologies.

6. Medicare Administrative Contractors (MAC) Treatment of Category III codes. The AMA has a process for the assigning temporary (Category III) codes. Most MACs have chosen to treat technologies assigned a temporary code as experimental and automatically deny them coverage, even though the treatments may be FDA approved and are, therefore, not experimental. Moreover, a technology that is eventually moved from Category III to a Category I (permanent) code may continue to experience coverage difficulties because of Medicare contractor reluctance to remove the technology from the non-covered services list.

Recommendation: Medicare contractors should be prohibited from automatically treating FDA-approved technologies and their associated services with Category III codes as experimental and should be required to go through a formal, transparent coverage determination process if they choose to deny coverage. Medicare contractors should be required to automatically remove technologies that have transitioned from a temporary to a permanent code from the non-covered
category, unless they provide a rationale, which includes detail regarding the data and evidence that was considered, for continued non-coverage.

7. New Technology Add-On Payment Program (NTAP). Congress adopted the NTAP program in 2000 to overcome disincentives in the hospital prospective payment system for rapid adoption of clinically superior technologies with higher short-term costs to providers. If a new technology used in treatment is substantially more expensive than the technologies in the MS-DRG to which it is first assigned, hospitals suffer financial losses from using it—even if the treatment reduces overall costs to the Medicare program or significantly improves patient outcomes. As data accumulate over time, CMS may adjust its payments to reflect the cost of the new treatment, but this can take several years to accomplish. (A similar program, called the Transitional Pass-through Payment Program, was established for hospital outpatient treatments.)

The NTAP addresses this problem by providing interim payment adjustments based on the actual cost of the treatment for technologies that CMS judges to be novel and providing significant clinical improvements for patients. After data on the actual cost of the treatment have been accumulated for two-to-three years, CMS makes whatever adjustments are needed to the DRG payment, including creating a new DRG for that technology when necessary.

Unfortunately, the program has been less than effective in achieving its objectives. Only slightly more than a third of applications (26 of 72) have been approved since 2003. While the U.S. was the first country to adopt special payment mechanisms for important new technologies, a recent article in *Health Affairs* found considerably fewer treatments qualify under NTAP than qualify in other countries with similar programs. 12

Moreover, in the current environment of cost-containment, CMS’s level of payment for the technologies it does identify (50 percent of the difference between the hospital’s actual cost for the new treatment and the payment for the established treatment) is too low to effectively eliminate disincentives to providing beneficiaries access to important but more costly treatments. Manufacturers increasingly report that hospitals are declining to purchase NTAP technologies because of the financial losses they would face from inadequate Medicare reimbursement.

**Recommendations**

a) The add-on payment level for approved NTAPs should be increased from 50 to 80 percent of the difference between the standard MS-DRG payment and the cost of the procedure with the new technology. 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. The fact that so many NTAP cases also qualify for outlier payments highlights how inadequate the NTAP payment is to achieve the program’s objectives.

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b) Local Medicare Administrative Contractors (MACs) should be prohibited from denying coverage and add-on payments for new medical services or technologies approved for NTAPs 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. With an approved NTAP application, the treatment or technology should be covered by Medicare for all beneficiaries, both during the add-on period and following that period.

c) 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.

d) 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.

e) An entity that submits an application for NTAP payments should be entitled to administrative review of an adverse determination by an official of the Department of Health and Human Services (other than an official of the Centers for Medicare & Medicaid Services). 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 determination should not preclude resubmission of a modified application at a later point in the future.

9. Medical technology manufacturers as collaborators in episode payment models (EPMs). CMS has recognized that EPM participants may want to engage with organizations that are neither providers nor suppliers to assist with matters such as episode data analysis, local provider and supplier engagement, care redesign planning and implementation, beneficiary care coordination and management, and other related activities. The agency, however, has not authorized manufacturers of medical devices and diagnostics to serve in the role as collaborator. Many medical technology companies have in-depth knowledge of patient care protocols, best practices, and treatments that lead to improved patient outcomes. They are ideally suited to collaborate with EPM participants by integrating data analytics infrastructure and services to optimize care to achieve quality goals, by providing services that streamline the supply chain to reduce cost, or by sharing risk for the performance of innovative technologies used by EPMs to meet their savings and/or efficiencies goals in care delivery.
**Recommendation:** CMS should permit medical technology manufacturers to serve as collaborators in EPMs and clarify the specific circumstances under which manufacturers can do so.

10. **Promoting risk-sharing arrangements between medical technology manufacturers and episode payment model (EPM) participants through Fraud and Abuse law waivers.**

Regulatory uncertainty concerning the application of the criminal Anti-Kickback Statute to EPM participants and medical technology companies chills innovative collaborations and value-based arrangements. Further, the current Anti-Kickback Statute (AKS) safe harbors are narrowly constructed. While there are ways to construct some limited engagements currently, they do not offer the fluidity that would be possible with new value-based AKS safe harbors (see AdvaMed safe harbor proposals for value-based arrangements at [http://www.advamed.org/resource-center/advamed-aks-safe-harbor-proposals-value-based-arrangements](http://www.advamed.org/resource-center/advamed-aks-safe-harbor-proposals-value-based-arrangements)).

Current safe harbor protection is afforded only to those arrangements that meet all of the conditions set forth in the safe harbor regulations. Unfortunately, the safe harbor constructs are narrowly fashioned around fee-for-service payment models and this serves to inhibit using delivery reform models that have the potential for improving both quality and efficiency of care delivery. For example, the provision of items and services that are not reimbursed under the same payment methodology may not qualify for protection under Discount Safe Harbor includes the limitation that the bundled good or service be reimbursed by the Federal health care program using the same methodology and be earned based on purchases of that same good or service within a single fiscal year. The “same methodology” limitation can materially restrict the range of possible devices and services that may be integrated to deliver the best value because of the uncertainty around what items or services would be considered to fall under the “same methodology.” Furthermore, one episode of care may span two fiscal years, which would also disqualify an arrangement from protection. Additionally, the warranty safe harbor does not expressly allow a seller to provide anything as part of a warranty in excess of the cost of the item itself. As such, the warranty safe harbor was intended to address defective products, rather than a warranted outcome not being achieved. Until new value-based safe harbors are issued, we believe that it would be beneficial for CMMI to use its fraud and abuse law waiver authority to promote greater investments in more fulsome value-based solutions.

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

**Recommendation:** In light of the challenges noted above and until new value-based safe harbors are issued, we believe it would be beneficial for CMMI to use its waiver authority in the context of ACO and episode payment models being tested by the agency to:
Create a waiver that will maintain protections for patients and Federal health care programs while allowing for greater involvement and investment in EPMs, by allowing:

- **Value-Based Pricing Arrangements (VBPA)** – that accommodate Value-Based Price Adjustments dependent on the achievement of a measurable clinical and/or cost outcome and for the bundling of Value-Based Services (analysis, software, equipment, information and/or services provided to providers / patients—at no charge for the purposes of (1) determining the terms of the VBPA; (2) measuring collecting, calculating and reporting the metrics upon which the VBPA is based or the resulting adjustment that is payable; (3) optimizing the effectiveness and clinical utility of the reimbursable items and services; and (4) otherwise achieving clinical/cost outcomes.
  - Value-Based Price Adjustments would include a payment made by a seller to a buyer, or by a buyer to a seller, as a reduction to or increase in such buyer’s price or net cost for one or more reimbursable items and/or services under a VBPA. The terms and conditions of the VB Price Adjustment must be fixed and disclosed in writing in advance (e.g., fixed if the formula or other objective mechanism for determining the amount of the adjustment is set forth in writing).
  - This would allow for Risk-sharing between ACO and EPM participants and medical technology company collaborators that incentivize and reward improvements in clinical outcomes and/or reductions in cost.

- **Value-Based Warranties** – that allow manufacturers of products to make certain clinical and/or cost outcome assurances, and provide an appropriate remedy where such outcomes are not achieved. Similar to VBPA, this would also allow for the bundling of Value-Based Services and require that the terms and conditions of the Value-Based Warranty remedy be fixed and disclosed in writing in advance.
  - This would allow for Outcome warranties that specifically address warranting an outcome instead of a product failure and protect payments for bundled products and services provided when an outcome is not met. For example, this would provide a targeted approach to addressing scenarios where a medical device company agrees to reimburse a hospital not only its aggregate purchase price for the implant device acquisition costs, but also unreimbursed products and services if a patient is readmitted to the hospital within 90 days following the surgical procedure because the surgical site is infected or a revision surgery is needed. Currently when this occurs, there is arguably protection under the safe harbor warranty for only the device cost when the device fails.

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

11. Telehealth. CMS and CMMI have provided, under a number of different value-based models initiatives, waivers of the telehealth originating site and geographic site requirements that allow services to be covered in urban areas and permit in-home telehealth visits for beneficiaries being served under these programs. AdvaMed has strongly supported these waivers and agrees with CMS that the waivers will support care coordination and timely access to high quality care for all EPM beneficiaries.

However, we do not believe that the waivers go far enough in testing the efficiencies and quality of care improvement potential of telehealth technologies, and believe that CMS and its Innovation Center are missing an opportunity, through their existing waiver authorities, to use delivery reform models for creatively testing situations where additional flexibility in the provision of telehealth services would increase overall care efficiency and improve care quality.

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

CMS has clearly signaled that it believes that delivery reform models should be expanded to improve efficiency and quality of care delivery for Medicare beneficiaries. These goals can only be achieved with providers committed to care redesign and infrastructure changes necessary to support greater coordination and care management during a defined episode. Telehealth services can be, and, from our point of view, should be, central in any plan for redesigning care for payment across an episode of care. Waivers of the originating site and geographic site requirements that apply to telehealth services are a step in the right direction. But they are insufficient for allowing providers to maximize the potential of the various telehealth technologies to reduce the cost of care and improve health care outcomes. CMS’s delivery reform models offer the ideal scenario for testing and defining how these services can be cost-effective and AdvaMed urges CMS to actively pursue using delivery reform models for such purposes.
12. Promoting Long-Term Quality for TJA Procedures

AdvaMed continues to support the goals of CMMI’s payment and delivery reform models, which seek to improve both the efficiency and quality of health care through enhanced care coordination and redesigned care processes. However, we believe that one of these models, specifically the Comprehensive Care for Joint Replacement (CJR) model, could be improved with the development of incentives that would promote long-term quality and value outside the 90-day bundle. We believe that a useful path to pursue would be to establish incentives for hospitals and physicians to lower long-term revision rates after total joint replacement during the initial episode. Initially, the focus could be on one-, three-, and five-year revision rates. Ultimately, CMS should strive to include measurements of revision rates over longer periods of time. We will be submitting more detailed proposals in the near future.

AdvaMed appreciates the opportunity to comment on the proposed rule. If you have any questions about issues raised in the MS-DRG and RFI portions of our comment letter, please contact Richard Price at rprice@advamed.org, and for the quality portions, Steve Brotman at sbrotman@advamed.org.

Sincerely,

Donald May
Executive Vice President,
Payment and Health Care Delivery