June 25, 2018

Ms. Seema Verma, Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attn: CMS-1694-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 2019 Rates, CMS-1694-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 2019 rates published in the Federal Register May 7, 2018, (CMS-1694-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. 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)
MS-DRG CHANGES AND REIMBURSEMENT ISSUES

Chimeric Antigen Receptor (CAR) T-Cell Therapy

The rule proposes two different approaches for paying for CAR T-cell therapy as an inpatient service. One approach would assign ICD-10-PCS procedure codes used for CAR T-cell therapy to the existing MS-DRG 016 and revising this MS-DRG's existing title to Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy. A second option would establish a new MS-DRG for CAR T-Cell Therapy. CMS also asks for comments on approaches that encourage value-based care for the procedure.

Like CMS, AdvaMed is concerned with the redistributive effect this new and expensive procedure will have on other MS-DRGs, given the requirement that the annual DRG recategorization and recalibration of relative weights be budget neutral. For this reason, AdvaMed strongly recommends that CMS explore and test alternative payment methods for CAR T-cell therapy, as well as other costly therapies.

As a first step for addressing the redistributive effect of including CAR T-cell therapy among MS-DRGs, AdvaMed recommends that CMS consider a different reimbursement framework for paying for CAR-T cell therapy on a fee-for-service basis. Instead of assigning the procedure to an existing or new MS-DRG, we recommend separating the hospital services generally used by CAR-T patients into two separate payment streams. Our understanding is that CAR-T patients generally have their initial blood draw as a hospital outpatient patient. In this instance, the date of service would be the outpatient encounter and the hospital would be paid ASP+6% for drawing the T-cells and their subsequent genetic engineering in a laboratory and the addition of a chimeric antigen receptor that binds to a certain protein on the patient's cancerous cells. This approach would remove the most expensive component of the therapy from its impact on the weights of other MS-DRGs.

Subsequent infusion of the engineered product would be done on an inpatient basis and these services would be paid under an appropriate MS-DRG. This assumes, of course, that the date of service for the outpatient encounter is more than 3 days prior to the date of the inpatient admission and the outpatient services would not be bundled into the inpatient admission under the 3-day payment window policy.

We recognize that this approach is not without its complications. For 340B hospitals, payment for the CAR T-cell drug at ASP-22.5% could create a major disincentive for certain hospitals to treat patients. Some of these hospitals might be academic medical centers with specialized expertise in treating patients needing CAR T-cell therapy. Alternatively, to avoid paying at ASP-22.5%, the product could be paid on a pass-through basis for up to 3 years and all providers would be paid ASP+6%. However, OPPS pass-through payments are capped at 2 percent of
OPPS payments. If pass-through payments exceed the cap, there would be a pro rata reduction to all pass-through payments. In addition, some patients needing CAR T-cell therapy are so seriously ill that they may need inpatient care through the entire period of their therapy from the point at which the T-cells are drawn through the time the re-engineered cells are infused and for days after treatment when they are being observed and monitored. In these cases, care could not be separated into two different payment streams.

We do not believe, however, that these complications should get in the way of finding alternative payment methods, which will provide access to patients needing this therapy and which at the same time will avoid the expected redistributive impact on other MS-DRGs.

AdvaMed also notes that last August, following FDA approval of Kymriah, a CAR T-cell therapy for certain pediatric and young adult patients with B-cell precursor acute lymphoblastic leukemia, CMS issued a press release indicating that it would be exploring the development of payment models and arrangements for new and potentially life-saving treatments. The press release for this announcement noted that these arrangements may include outcome-based pricing for medicines in relation to clinical outcomes to reflect the value delivered to patients and to help payers and providers to manage the cost of new therapies and cures.

We urge that CMS/CMMI consider such models and arrangements for CAR T-cell therapy, using perhaps a bundled payment model that reflects the alternative fee-for-service reimbursement structure discussed above or some variation thereon, with the goal of avoiding the redistributive effects of MS-DRG assignment for all cases and providing incentives for the delivery of efficient and quality care.

In the interim, if CMS decides to approve CAR T-cell therapy for NTAP, we support the use of a cost-to-charge ratio (CCR) of 1.0 to calculate NTAP and outlier payments as CMS has described in the proposed rule. We do not believe that such a method should be limited to CAR T-cell therapy, however, and that CMS should establish a broad policy that would apply to all therapies approved for NTAP. CMS has provided no rationale in the proposed rule for narrowly applying a CCR of 1.0 to hospital charges for CAR T-cell therapy, to the exclusion of other technologies, and we see no basis for doing so.

**Substantial Reductions in MS-DRG Relative Weights Due to ICD-10 Implementation**

Last year, in its comment letter on the FY 2018 IPPS Proposed Rule, AdvaMed pointed to several proposed significant reductions in certain MS-DRG payment weights that could be explained by the transition from ICD-9 to ICD-10. We stated then and continue to maintain that large payment swings are inconsistent with the principle of payment stability and recommended mitigation against significant fluctuations. In response to our comments, CMS adopted a one-year temporary transition that would limit reductions in weights for any DRG to 20% of the FY17 relative weight.
For FY 2019 we once again see large payment reductions in several MS-DRGs, with a number that will experience a greater than 20 percent reduction over the last 2 years. These range from 20.6 percent for MS-DRG 290, Acute and Subacute Endocarditis w/o CC/MCC to 40.1 percent for MS-DRG 215, Other Heart Assist System Implant. For MS-DRG 215, the proposed reduction for 2018/2019 would be an additional 25.2 percent on top of the 20 percent reduction for 2017/2018. CMS’s acknowledgment of claims data not reflecting updated AHA Coding Clinic Guidance from October 2017 and March 2018 further supports extending the transition.

AdvaMed recommends that CMS extend the FY 2018 transition policy and cap the two-year reduction for any MS-DRG to 20 percent for the period FY 2017 through FY 2019.

CMS has provided for transition periods when adopting changes that have significant payment implications, particularly large negative impacts. For example, in FY 2015 CMS adopted a 3-year hold harmless transitional wage index adjustment for hospitals formerly located in urban counties that became rural under new OMB rules. CMS determined that the 3-year hold harmless transition was appropriate because CMS expected this group of hospitals to experience a steeper and more abrupt reduction in their wage index due to the labor market revisions compared to other hospitals. For the period FY 2015-17, CMS assigned these hospitals the urban wage index for the areas in which they were located in FY 2014.

**Heart Transplant or Implant of Heart Assist System (MS-DRGs 001/002, 003 (ECMO), and 268/269)**

AdvaMed supports CMS’s proposal to maintain the current payment structure and configuration for procedures used to report heart transplant or implant of heart assist procedures (MS-DRGs 001/002, 003, and 268/269).

**MDC 5 – Pacemaker Insertions**

In the proposed rule, CMS solicits comments on three proposals regarding pacemaker insertion procedures:

1. Creating pairs of procedure code combinations involving the insertion of a pacemaker device with the insertion of a pacemaker lead that act as a procedure code combination pair in the GROUPER logic for designation as operating room (O.R.) procedures outside of MDC 5 when the codes are reported together.
2. Designating all procedure codes describing the insertion of a pacemaker device or the insertion of a pacemaker lead as non-O.R. procedures when reported as a single, individual code outside MDC 5.
3. The procedure codes describing the insertion and revision of intracardiac pacemakers should also be considered for classification into all surgical unrelated MS-DRGs outside of MDC 5.

AdvaMed agrees with proposal 1 to designate all pacemaker system insertion (generator and lead) procedures as O.R. procedures when the codes are reported together. Finalizing this proposal will ensure alignment for pacemaker system insertions to be designated as O.R. both inside and outside MDC 5 and will correct MS-DRG logic for these procedures.

We believe the current DRG assignments of intracardiac pacemaker insertions are appropriate. We note that the few instances (153) of intracardiac pacemaker insertion identified by CMS that occur outside of MDC 5 are already assigned to surgical DRGs, including many to 981-983. Because the current MS-DRG assignments for cases outside of MDC 5 appear to correctly reflect the clinical and cost characteristics of these cases, we do not believe there is a need for any changes to the intracardiac pacemaker MS-DRG assignments at this time.

MS–DRG Classifications for Spinal Fusion Procedures

CMS proposes to delete orthopedic fusion procedure codes with device value “Z” (No Device), effective October 1, 2018, because a spinal fusion procedure always requires some type of device. CMS does not propose to modify the spinal fusion MS-DRGs until coding inaccuracies, such as the “No Device” code, are no longer reflected in claims data.

AdvaMed agrees with CMS that the “no device” fusion procedures should be deleted because they are clinically invalid. We note that while CMS provided a detailed analysis of the costs in the claims files attributable to “no device” spinal fusion cases, CMS did not conduct such an analysis for other fusion procedures, such as involving hip, knee, and ankle fusion procedures. We recommend that CMS include this analysis for the proposed FY 2020 rule, since, as CMS observes, the “no device” fusion cases could remain in the MedPAR files until that time. We believe that these data will be useful for several reasons: for determining the extent of hospital reporting of such invalid cases, for analyzing the impact on reported procedure costs, and for assessing any potential changes to the MS-DRG assignments for fusion procedures in the future, once the invalid/no-device codes are removed from the claims files.

Removal and Reinsertion of Knee and Hip Spacers

For the proposed rule, CMS analyzed four sets of ICD-10-PCS procedure codes that describe procedures involving open removal and insertion of spacers into the knee or hip joints. In the ICD-10 MS-DRGs, these four procedure code combinations are not now recognized as operating room procedures for purposes of MS-DRG assignment. CMS proposes to designate these four
sets of procedure code combinations as operating room procedures and to assign them to specific MS-DRGs.

AdvaMed agrees that the insertion and removal of hip and knee spacers require the resources of an operating room. However, we believe that additional cost data are necessary to determine whether the proposed MS-DRG assignments fully account for hospital resources and the clinical complexity of these procedures. We also recommend that CMS confirm that the MS-DRG assignments apply only to stand-alone procedures or combined spacer removal/insertion procedures, rather than combinations involving other ICD-10 codes, such as insertion of permanent joint implant.

New Technology Add-On Payments (NTAP)

Last February AdvaMed presented several regulatory reform recommendations, which we believe will improve Medicare beneficiary access to important innovative treatments and technologies. We appreciate CMS’s responses to our recommendations concerning substantial clinical improvement issues. Included below are several additional recommendations that could improve the NTAP program:

1) 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.

2) Local Medicare Administrative Contractors (MACs) should be prohibited from denying coverage 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.

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

4) 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 beneficiaries 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.

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

**Improvements to Public Reporting on Hospital Compare**

In the proposed rule, CMS specifies a number of quality measures for retention and removal in order to improve the data posted on Hospital Compare. AdvaMed believes that this public reporting serves an important purpose and that relevant outcomes data can help patients become more informed consumers of health care services. To that end, we recommend that CMS consider posting data to provide consumers with useful clinical outcomes information.

This data would be helpful especially as it relates to elective surgery, such as total joint replacement. CMS could post patient-reported outcomes, return to activities of daily living and revision rates with appropriate risk-adjustment.

This information would be meaningful to patients and complement short-term TJA outcomes data such as readmissions and complications, which beneficiaries can currently view on Hospital Compare. Medicare beneficiaries would benefit from knowing more about the outcomes of TJA care beyond the immediate post-discharge period when evaluating quality of care. This would also advance CMS policy objectives by helping patients make more informed choices when picking providers.

For some of the measures, CMS could use Medicare claims data to determine longer-term TJA outcomes data on revisions, using existing risk-adjustment methods or other more advanced risk-stratification methodologies that CMS views appropriate. Importantly, the use of claims data would not impose any additional burden on hospitals. Advancing availability of outcomes measures for TJA would help enable consumers to make more informed choices in the future that would drive value and quality.
Future Potential Measures

a. Opioid-Related Measures

In the proposed rule, CMS seeks public comment on the possible future inclusion of a new measure in the Hospital IQR Program regarding an eCQM addressing hospital harm opioid-related adverse events ("Hospital-Harm—Opioid-Related Adverse Events eCQM").

This in-hospital outcome measure assesses the proportion of a hospital’s patients who had an opioid-related adverse event as measured by administration of naloxone. The measure was previously included in the 2017 Measures Under Consideration (MUC) list submitted to the Measure Applications Partnership (MAP), which recommended it be refined and resubmitted. Specifically, the MAP suggested adjusting the numerator to account for the impact of chronic opioid users. The MAP also suggested testing in additional facilities, and CMS notes that it is currently using output from the Measure Authoring Tool in multiple hospitals using multiple EHR systems. CMS plans to submit the measure for NQF endorsement through the Patient Safety Committee in November 2018.

AdvaMed applauds CMS’s efforts to address the opioid crisis by considering future quality measures in hospital programs. We support the continued development of this opioid related measure according to the MAP’s recommendations and look forward to the resubmission of this measure later in 2018. Possible inclusion of this measure, and similar ones that may be proposed, serve to highlight the overwhelming need to confront this issue not only from the perspective of reducing patient exposure to opioids, but importantly by examining and utilizing non-pharmacologic technologies and therapies which can be used to reduce dependence on opioids. We recommend that CMS consider including non-pharmacologic technologies in the development of future similar measures such as:

- Medical devices which serve as alternatives to treat acute and chronic pain;
- Diagnostics that can monitor pain medication use;
- Devices which help patients block difficult withdrawal symptoms and prevent overdose;
- Technologies that may prevent complications from post-op opioid use;
- Technologies that can improve medication management, lower dependence and addiction, and monitor dosage; and
- Dispensing, storage, and disposal technologies that can prevent diversion and inappropriate access to opioids.
b. Malnutrition Focused Measures

AdvaMed supports the Meaningful Measures Initiative in its effort to identify high-priority areas for quality measurement that are closely linked to improved clinical outcomes for patients, reduced administrative burden for providers, and lower healthcare costs. As CMS seeks to align future quality measures with the core principles of the Initiative, AdvaMed continues to recommend that the Agency prioritize inclusion of a malnutrition-focused measure or measures as soon as feasible in the Hospital IQR. These measures have a strong link to clinical outcomes and are a gap area in current quality reporting systems.

HOSPITAL VALUE-BASED PURCHASING PROGRAM (HVBP)

Retention and Removal of Measures

In the proposed rule, CMS is proposing to remove various measures from several programs when the measures are also currently used in one of the other value-based purchasing programs. The proposals to remove these measures are consistent with CMS’s commitment to using a smaller set of more meaningful measures. Specifically, CMS believes that the Hospital VBP Program should focus on measurement priorities that are not covered by the HRRP or the HAC Reduction Program. This includes measures related to clinical outcomes, patient and caregiver experience, and healthcare costs. AdvaMed supports CMS’s efforts to streamline inpatient quality programs and reduce the reporting burden on hospitals while maintaining a focus on those measures most directly linked to patient quality of care. At the same time, AdvaMed believes that it is important to recognize that each of these programs is structured differently, with different goals and policy mechanisms. We therefore recommend that CMS retain critical patient safety measures in the quality program that will have the most potential to influence provider behavior.

Proposed Changes to Hospital-Acquired Condition (HAC) Reduction Program Scoring

In the proposed rule, CMS is proposing to change the weighting of the HAC Reduction Program domains in calculating the Total HAC Score beginning in 2020. CMS notes that their priority is to adopt a policy that improves the scoring methodology, increases fairness for all hospitals and addresses stakeholders’ concerns about the disproportionate weight applied to Domain 2 measures for low volume hospitals.

Currently, Domain 1 (consisting of only the claims-based Patient Safety and Adverse Events Composite Measure, PSI-90) receives a weight of 15 percent and Domain 2 (5 NHSN measures) receive a weight of 85 percent. CMS notes that for hospitals with scores on all six measures, each measure receives roughly the same weight (17 percent for the Domain 2 measures and 15 percent for PSI-90), but measure weightings become disproportionate when a hospital only has a
score on one or two Domain 2 measures. Additionally, a few hospitals (36 in 2018, or 1 percent of all hospitals) have no Domain 1 score (i.e., no score on the PSI-90 measure) and subsequently, the weight of the Domain 2 measures varies greatly (from 20 to 100 percent) based on how many Domain 2 measures the hospital reports.

CMS discusses two alternative approaches to re-weighting the domain scores. One proposed approach would eliminate the domains and weight each of the six measures equally in calculating the Total HAC Score. Under this “equal measure weights” approach, each measure would receive a weight of 16.7 percent if the hospital had a score on each of the six measures, increasing to 50 percent each if two measures were scored and 100 percent if only one measure was scored. CMS believes this approach would address concerns about the disproportionate weight assigned to Domain 2 measures when a hospital only has scores for one or two such measures.

An alternative proposed approach presented by CMS, the “variable domain weights” approach, proposes that the two domains would be retained, but the weight applied to each domain would depend on the number of Domain 2 measure scores submitted by the hospital. The following summary table combines information from two tables in the proposed rule that show how the weights would be calculated under each alternative.

<table>
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<th>Number of NHSN/Domain 2 measures scored</th>
<th>PSI 90</th>
<th>Each NSHN measure</th>
<th>Domain 1 (PSI 90)</th>
<th>Domain 2</th>
<th>Each Domain 2 measure</th>
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<td>100 Equally divided</td>
<td>n/a</td>
<td>100.0</td>
<td>100 Equally divided</td>
</tr>
</tbody>
</table>

*Domain weights would vary by hospital.

AdvaMed agrees that either approach would address this problem, but prefers that CMS implement the Equal Measure Weights approach for several reasons. We agree that the Equal Measure Weights policy aligns with the intent of the original program to apply a similar weight to each measure and has a larger impact than the Variable Domain Weights approach. Importantly, applying the Equal Measure Weights approach would address the previous issue of substantially lower weight being applied to the CMS PSI-90 compared with Domain 2 measures for hospitals with only one or two Domain 2 measures. The PSI-90 composite measure is an
important safety measure and contains important indicators such as Pressure Ulcer Rate (PSI-03), Postoperative Sepsis Rate (PSI-13), Postoperative Wound Dehiscence Rate (PSI-14) and others. It is therefore appropriate that PSI-90 be provided equal weight with the other Domain 2 measures.

AdvaMed appreciates the opportunity to comment on the proposed rule. If you have any questions about issues raised in the MS-DRG 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