June 24, 2019

Ms. Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1716-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 Fiscal Year 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs
Proposed Requirements for Eligible Hospitals and Critical Access Hospitals, CMS-1716-P

Dear Administrator Verma:

On behalf of the Advanced Medical Technology Association (AdvaMed), I am pleased to offer comments on proposed changes to the fiscal year (FY) 2020 Medicare hospital inpatient prospective payment system published in the Federal Register May 3, 2019. (CMS-1716-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. AdvaMed especially applauds CMS for the proposals that would allow FDA-designated breakthrough technologies to more easily qualify for New Technology Add-on Payments and increase the NTAP payment amount from 50 percent to 65 percent. These are important and significant policy proposals that we strongly support, and we believe they will improve patient’s access to life-changing and saving technologies and will help to spur innovation of new breakthroughs that can only be imagined at this time.

Our letter also includes many other comments highlighting other areas in the rule where we recommend modifications to specific proposals to ensure adequate reimbursement and access to
medical technologies used in patient care. Our letter includes comments under the following categories:

- Proposed Changes to New Technology Add-on Payment
- Other Proposed Changes to MS-DRGs and Relative Weights
- Hospital Inpatient Quality Reporting (IQR) Program
- PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program
- Long-Term Care Hospital Quality Reporting Program (LTCH QRP)
- Medicare and Medicaid Promoting Interoperability Program

**PROPOSED CHANGES TO NEW ADD-ON TECHNOLOGY PAYMENT (NTAP)**

**Proposed Alternative NTAP Pathway for Breakthrough Devices**

CMS is proposing to create an alternative payment pathway for transformative medical devices that are approved as breakthrough devices by the FDA and have received FDA marketing authorization. For such transformative medical devices, CMS is proposing that, beginning with applications for 2021, such technologies would automatically be considered to meet the inpatient NTAP criteria for “newness” and “substantial clinical improvement,” and would be approved for add-on payments once they demonstrate that they meet the program’s cost criterion of having costs above a specified threshold.

AdvaMed applauds CMS’s proposal to create this alternative payment pathway for breakthrough technologies. AdvaMed has long advocated for the immediate transitional coverage and add-on payments for breakthrough technologies and we enthusiastically support CMS’s efforts to create a more streamlined pathway for approving add-on payment applications for these transformative innovative medical devices. We believe that the proposed changes will provide Medicare beneficiaries more rapid access to breakthrough technologies and encourage investment in development of these technologies.

AdvaMed believes that this proposal will help ensure that patients have seamless access to new innovations and we urge CMS to apply the NTAP add-on for breakthrough technologies for the full two-to-three-year period, depending on the time of FDA marketing authorization and the availability of data that CMS needs for recalibrating relevant MS-DRGs. The NTAP add-on time period should be the same for both traditional NTAP products and products receiving expedited access to NTAP because they are an FDA designated breakthrough.

In addition, AdvaMed encourages CMS to similarly create a streamlined pathway for approving add-on payment applications for transformative innovative medical devices in the outpatient hospital setting as part of its upcoming outpatient prospective payment system (OPPS) proposed rule. For instance, CMS could consider establishing a parallel pathway to streamline eligibility requirements for transitional pass-through device payment under the OPPS for those devices that receive FDA marketing authorization via the Breakthrough Devices Program. Likewise, CMS could provide that FDA Breakthrough Device approval satisfies the newness requirement for
OPPS New Technology Ambulatory Payment Classification purposes (that is, the service is one that could not have been adequately represented in the claims data).

**Proposed Change to the Calculation of the NTAP Payment Amount**

CMS is proposing that beginning with discharges on or after October 1, 2019, if the costs of a discharge involving a new technology exceed the full DRG payment by the specified threshold, Medicare will make an add-on payment equal to the lesser of (1) 65 percent of the costs of the new medical technology; or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment.

AdvaMed supports CMS’s proposal to increase the add-on payment levels from 50 to 65 percent of the costs of the new medical technology or the amount by which the costs of the case exceed the standard DRG payment with an alternative recommendation. AdvaMed believes that this change will improve hospitals and patients’ access to innovations in care, and further incentivize medical technology companies to develop additional innovative and transformational technologies, both breakthrough and other technologies using the regular NTAP application process for approval. We greatly appreciate CMS’s decision to increase the add-on payments for approved technologies. However, we believe that the add-on payment level for approved NTAPs should be increased 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 and, for this reason, we believe that 80 percent of the difference is the more appropriate level for add-on payments. We believe that an 80 percent level would mitigate these losses, further encourage adoption of new technologies, and continue to provide incentives for hospitals to act as prudent purchasers.

**Potential Revision to the Substantial Clinical Improvement Criteria**

i. **Criteria Met through Broad Adoption**

CMS is proposing to add a provision at §412.87(b)(1) and §419.66(c)(1) stating that “substantially improves” means, *inter alia*, broad adoption by applicable providers and patients and requesting comments on what is the appropriate way to define and measure “broad adoption”.

AdvaMed appreciates CMS’s openness to rethink the definition of substantial clinical improvement by expanding the eligibility for the new medical technologies that would be broadly adopted among applicable providers and patients. However, it is our understanding that NTAP was intended to bridge the challenge many new technologies face in adoption because they are different from the existing standard of care and because they may be more expensive than existing treatments. The NTAP should serve as a mechanism to ensure broader adoption of new innovations, rather than “broad adoption” being a prerequisite for NTAP eligibility as
proposed in this rule. AdvaMed is not supportive of this proposal and we recommend that the Agency continue to work with stakeholders to refine the definition of the substantial clinical improvement criterion.

ii. Criteria Met through Comparison to Existing Technologies

Additionally, CMS is proposing to adopt a definition that the term “substantially improves” means, *inter alia*, new technology has demonstrated positive clinical outcomes that are different from existing technologies. CMS would also specify that the term “improves” can always be met by comparison to existing technology and that such improvement may always be demonstrated by reference and comparison to the diagnosis or treatment achieved by existing technologies.

AdvaMed recognizes the value of a standard for innovators that is predictable and clear as to how a new technology substantially improves positive clinical outcomes compared to existing technologies, but we are concerned that such a standard might restrict alternative study designs or impose standards that exceed realistic requirements. In fact, for many novel technologies, there may be no existing technologies that could appropriately serve as a comparator.

AdvaMed recommends that such a comparison should not be a requirement for meeting the criterion. If, however, CMS decides to advance a comparison to existing technologies as a standard for demonstrating substantial clinical improvement, it is important to note that the comparator should be the standard of care, which may be a procedure or no intervention, rather than existing technology.

iii. Criteria Met through Real-World Evidence

CMS also proposes to adopt a policy specifying that “substantially improves” can be met through real-world data and evidence, also noting that this standard would not require a technology to use real-world data and that CMS might provide a non-exhaustive list of data and evidence that could be used to demonstrate substantial clinical improvement. AdvaMed supports the continued development of real-world data as evidence to demonstrate substantial clinical improvement. We agree with CMS that real-world evidence should not be required for meeting the substantial clinical improvement criterion since it may not necessarily be available when a new technology is first approved or cleared by the FDA. If CMS allows real-world evidence to be used for demonstrating substantial clinical improvement, we recommend that CMS should also consider real-world evidence obtained from markets outside the U.S. since U.S.-based real-world evidence may not be available.

iv. Non-Exhaustive List of Particular Formats or Sources of Information

Furthermore, CMS states that it is considering providing clarity on the types of relevant information—peer-reviewed journal articles, particular formats or sources of information, systematic reviews, meta-analyses, consensus statements, etc.—that it would consider for making its decision about whether a technology meets the substantial clinical improvement criterion. AdvaMed supports this proposal to provide greater clarity on the types of information CMS will
consider for making decisions about the substantial clinical improvement criterion—so long as the clarity does not restrict consideration of other formats or sources of information that are not on the list. In other words, the list should be illustrative, not exhaustive in order to maintain flexibility.

RFI on the Substantial Clinical Improvement Criteria

i. New NTAP Review Process

CMS solicits public comments on announcing the annual NTAP determinations in the Federal Register separate from the annual updates to the IPPS. We recommend that CMS consider this question in the context of expanding the number of cycles in a year when CMS would consider NTAP applications. Currently, CMS considers applications and makes decisions on approval or disapproval only once a year. But the agency uses a quarterly process for Transitional Pass-Through Payment in the Hospital Outpatient Prospective Payment System. AdvaMed offers two different proposals for expanding the number of times a year CMS would consider NTAP applications.

First, we recommend that CMS should review NTAP applications on a semi-annual basis. This would allow companies to have their applications considered closer to the time when their evidence and data are ready to be considered by CMS rather than having to wait, perhaps for most of the year until a new cycle begins. We recognize this change would require establishing an additional New Technology Town Hall Meeting, new application submission deadlines, accommodation to ICD-10 coding application deadlines, new final rule deadlines, and assignments to relevant MS-DRGs. But this could be a significant improvement and we urge CMS to consider it, especially for breakthrough technologies where only the cost criterion would be evaluated (if CMS finalizes the previously discussed proposal related to breakthrough technologies qualifying for NTAP).

Alternatively, AdvaMed proposes a slightly modified cycle that is intended to avoid the necessity of companies having to wait almost a full year because they fail to obtain FDA approval by the current July 1 deadline, while minimizing the additional burden to CMS. Under this proposal, CMS could establish October 1 as a second deadline for FDA approval in addition to the existing July 1 FDA approval deadline. All other current deadlines for submission of applications and a single Town Hall Forum would remain as they are now.

In this proposal, all applications would still need to be submitted by the current November 1 annual submission date of the prior calendar year for CMS to consider in the IPPS Proposed Rule. All applications still would be discussed at the single New Technology Town Hall Meeting and all applicants that also submitted an ICD-10 application would have the applications discussed at the ICD-10 committee meeting. Applicants who receive FDA approval by the current July 1 deadline would receive a determination from CMS in the final rule, with approved NTAPs taking effect on October 1, consistent with current CMS policy.
The one additional step to this process relative to the current process would be for CMS to issue a new brief final rule on its decisions for NTAP applications that receive FDA approval after July 1 and before October 1. For applicants who do not receive FDA approval by July 1, CMS would institute a new second deadline of October 1 for FDA approval. Applicants who receive approval from the FDA by this second deadline would then receive a final determination from CMS, with approved NTAPs following this second FDA approval deadline taking effect January 1. Applicants that did not obtain FDA approval by October 1, could resubmit their application for a subsequent IPPS payment rule cycle on November 1. CMS would also have to take action to implement the NTAP payment on January 1.

This proposal reduces the burden associated with the submission of an NTAP application; extending the time-frame for CMS consideration would potentially reduce the need for submission of another NTAP application for the same product. Since add-on payments are not required to be budget neutral, CMS could easily update relevant MS-DRGs that could be effective January 1 of the new calendar year. We urge CMS to adopt this proposal effective for FY 2020.

ii. Clarity on the Types of Evidence or Study Designs

AdvaMed appreciates CMS’s attempts to provide more specificity and clarity on the types of evidence or study designs that may be considered in evaluating substantial clinical improvement. However, we recommend that this specificity and clarity not restrict alternative study designs or limit future flexibility in the evaluation of applications.

AdvaMed recognizes that evidence from randomized controlled trials (RCTs) is considered the gold standard for collecting evidence. While RCTs are used when possible for medical technologies, it is not always feasible or ethical to do so. From an ethical perspective, serious issues and risks are associated with RCTs in some instances, such as exposing patients to sham surgeries from which they will likely not benefit. In addition, RCTs cannot usually be used for technologies in clinically emergent situations; for technologies with rapid innovation cycles; for implanted devices where randomization might be challenging and informed consent more difficult; and for very large or capital expensive diagnostic or imaging technologies where side-by-side comparison studies would be impractical. Furthermore, we believe that the need for evidence from RCTs must be balanced against the costs and time involved in collecting data, and how that process can delay the availability of novel technologies that address important unmet clinical needs.

Moreover, other methods may yield equivalent evidence for decision-making sooner and with fewer resources than RCTs, which tend to be one of the most costly and time-consuming forms of research. Examples of situations where certain methods for generating evidence are potentially more appropriate than RCTs include:

- When the historical course of an illness is well-established and an adequate comparator group is known for an intervention, if the study is developed to minimize bias;
• Where the intervention yields a clear clinical change that has previously been documented, observational studies may provide sufficient evidence;
• When there are long-term durability issues (for example, with an implanted mechanical device such as an artificial joint), part of the evidence may come from bench studies that can replicate years of use in a much shorter time; and
• Retrospective analysis of large real-world evidence data sets may provide adequate support for reimbursement of off-label applications of a technology.

AdvaMed recommends that CMS should consider specifying non-inferiority studies, retrospective studies, case studies, RWE, registries, and meta-analyses in evaluating substantial clinical improvement on its non-exhaustive list of data sources that may be used to meet the substantial clinical improvement criterion.

iii. Add-on Payment Be Limited to a Select Subset of Medicare Beneficiaries

Given the limited information provided in this RFI, AdvaMed recommends that CMS should maintain the current flexibility to evaluate and apply add-on payments to subsets of beneficiaries as warranted by the available evidence for a particular technology. We believe this is consistent with CMS’s past actions on certain NTAP applications and therefore additional policies are not required. We urge CMS to provide educational materials, including additional examples, as this would assist the stakeholders better understand the implications.

iv. FDA Pathway

Consistent with CMS’s current practice, the agency is considering specifying that the substantial clinical improvement criterion can be met without regard to the FDA pathway for the technology. That is, a device would not need to be approved or cleared through a basis other than a 510(k) clearance to be considered to demonstrate substantial clinical improvement, as is the case today. AdvaMed supports this proposed clarification. The existence of a predicate device does not preclude technological advancements or meaningful improvements in patient outcomes.

v. Evidence Regarding Off-Label Use

Given the limited information provided in this RFI, AdvaMed recommends that CMS provide additional discussion of why the Agency asks the questions about the evidence related to off-label use in the context of NTAP. If CMS pursues new policy direction in this area, it should do so through a notice of proposed rulemaking (NPRM) with an opportunity for public comment.

Other Comments

AdvaMed recommends that the Local Medicare Administrative Contractors (MACs) should be prohibited from denying coverage and add-on payments for new medical technologies approved for NTAPs by the Secretary and the related physician services. During 2015, two local MACs issued non-coverage determinations for a medical technology that CMS had approved for NTAP.
In addition, in FY 2017 and FY 2018, all MACs denied coverage for the related physician service (which used a CPT Category III code) of another medical technology even though it had been approved for inpatient NTAP. The result of these non-coverage decisions was that Medicare beneficiaries were inappropriately denied access to these new technologies that met each of the eligibility criteria for NTAP approval. With an approved NTAP application, the treatment or technology, and the related physician service should be covered by Medicare for all beneficiaries who are eligible for the new technology. We believe that this recommendation on prohibiting MACs from denying coverage and add-on payments for a new medical service or technology approved for NTAP ensures the intent of the program is followed and would not interfere with the CMS Coverage and Analysis Group’s authority to make a coverage determination or requirement for Coverage with Evidence Development if such a policy was pursued by CMS.

OTHER PROPOSED CHANGES TO MS-DRGS AND RELATIVE WEIGHS

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

In our past comment letters in response to the FY 2018 and FY 2019 IPPS Proposed Rules, 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 the significant reductions, CMS adopted a one-year temporary transition for FY 2018 that would limit reductions in weights for any DRG to 20 percent of the FY 2017 relative weight and extended the transition policy through FY 2019.

For FY 2020 we once again see large payment reductions in several MS-DRGs, with a number that will experience a greater than 20 percent reduction in each of the last 2 years. AdvaMed recommends that CMS extend the FY 2019 transition policy.

Transcatheter Mitral Valve Repair (TMVR) with Implant

CMS proposes to reassign TMVR and other transcatheter valve repair with implant procedures to re-titled MS-DRGs 266 and 267 (Endovascular Cardiac Valve Replacement and Supplement Procedures with and without MCCs, respectively).

AdvaMed supports CMS’s proposal to reassign TMVR with implant procedures to MS-DRGs 266/267 and believes that the proposal will improve clinical coherence by placing the procedure with other complex cardiac procedures and provide a more appropriate level of payment for the procedure.

In addition, AdvaMed also supports CMS’s proposal to move other transcatheter valve supplement procedures to MS-DRGs 266/267. We agree that these procedures should be grouped together based on clinical coherence. Harmonizing the MS-DRG assignments now will remove barriers to innovation by providing a predictable, appropriate reimbursement framework for
transcatheter valve interventions. We encourage CMS to continue to evaluate this area as the landscape evolves.

**Non-supplement Cardiac Valve Procedures by Percutaneous Approach**

CMS proposes to reassign cases involving non-supplemental endovascular cardiac valve procedures within MS-DRGs 216, 217, 218, 219, 220, 221, 273, and 274 to two new MS-DRGs that would be adjusted for severity level. As a part of this proposed change, CMS would create two new DRGs: MS-DRG 319 (Other Endovascular Cardiac Valve Procedures with MCC) and MS-DRG 320 (Other Endovascular Cardiac Valve Procedures without MCC).

CMS states that the cases placed into MS-DRGs 319 and 320 should be grouped together because they all involve procedures on cardiac valves with a percutaneous (transcatheter/endovascular) approach, can be performed in a cardiac catheterization lab, require that the interventional cardiologist have special additional training and skills, and often require additional ancillary procedures and equipment. CMS further added that these procedures are believed to be more complicated and form a more clinically coherent group.

AdvaMed recommends CMS delay the reassignment of non-supplement cardiac valve procedures by percutaneous approach to newly created MS-DRGs 319 and 320. To ensure all stakeholders are defining these cases consistently under ICD-10-PCS, we offer that non-supplement root operation procedures are traditionally defined as procedures that do not involve implanting a biological or synthetic material that physically augments the function of a body part. The list of non-supplement procedure codes proposed for reassignment includes an expansive group of procedures with the root operation of repair, resection, restriction, revision, destruction, dilation, or excision.

AdvaMed recommends delaying the reassignment of non-supplement valve procedures by percutaneous approach to newly created MS-DRGs 319 and 320 because CMS’s impact analysis does not completely capture all of the cases potentially impacted by this reclassification and because it is too early to carve out a homogenous group of cases within an evolving subsection of cardiac valve procedures.

CMS’s analysis of the proposed reclassification of cases to MS-DRGs 319 and 320 is incomplete because it does not fully account for all of the non-supplemental valve procedures by percutaneous approach. Among the 25 non-supplement valve procedures by percutaneous approach proposed for reassignment, only 22 of these procedures are included in CMS’s analysis of 2018 MedPAR data. Further, among the 22 procedures used in this analysis, 19 procedures had 50 or fewer cases in 2018. Therefore, the data used for this analysis may not sufficiently project the potential impact on hospitals in FY 2020 and CMS should conduct this analysis again at a later time when more complete data are available.

We are also concerned that CMS’s policymaking on this issue is too far ahead of the innovation occurring in the area of cardiac valve procedures. Evidence of this lies in the fact that the proposed policy will reclassify cases into MS-DRGs 319 and 320 that are inconsistent with the
rationale established by CMS in the proposed rule. We applaud CMS’s efforts to create a coherent group of non-supplement valve procedures into separate MS-DRGs; however, AdvaMed asserts that the non-supplement valve percutaneous procedures identified for reclassification include a diverse group of evolving procedures not adequately reflected in current claims data. Contrary to the rationale laid out by CMS in the FY 2020 Proposed Rule, these procedures include surgical procedures that do not require an endovascular/transcatheter approach, are not conducted in a cardiac catheterization lab, and are not performed by an interventional cardiologist.

AdvaMed believes that reassignment of these procedures at this time is premature and believes that a decision by CMS to delay the implementation of this policy specific to non-supplement valve procedures by percutaneous approach would have minimal impact on the adoption and implementation of separate policies related to the reassignment of transcatheter cardiac valve repair (supplement) procedures to MS-DRGs 266 and 267.

Chimeric Antigen Receptor (CAR) T-Cell Therapy

CMS asks for comments on payment alternatives for CAR T-cell therapies, including payment under any potential new MS-DRG. CMS specifically asks for comments related to the potential creation of a new MS-DRG for CAR T-cell therapy procedures.

Like CMS, AdvaMed is concerned about the redistributive effect this new and expensive procedure will have on other MS-DRGs, given the requirement that the annual DRG reclassification and recalibration of relative weights must be budget neutral. For this reason, AdvaMed strongly recommends that CMS explore alternative reimbursement methods (e.g., a value-based payment model) for CAR T-Cell therapy, as well as other emerging costly therapies.

In consideration of a separate MS-DRG, AdvaMed also supports 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, but we do not believe that such a method should be limited to CAR T-cell therapy; instead, we believe that CMS should establish a broad policy that would apply to all therapies approved for NTAP. CMS has provided no rationale 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.

HOSPITAL INPATIENT QUALITY REPORTING PROGRAM (IQR)

Support the Adoption of the Hospital IQR Program Measure: Hospital Harm – Pressure Injury Electronic Clinical Quality Measure (eCQM)

AdvaMed is pleased that CMS is considering the Hospital Harm – Pressure Injury eCQM as a possible new measure, and urge that it be proposed for addition to the IQR Program in future rulemaking. As CMS notes, this measure would help measure the rate at which new hospital-acquired pressure injuries occur during an acute care hospitalization. Added transparency and visibility on the rate of hospital-acquired pressure injuries during acute care hospitalizations
could be a valuable tool for improving patient care. We further agree with CMS that “many of the causes [of pressure injuries] can be mitigated through best care in hospital environments” and that the agency should continue to evaluate the appropriateness of risk adjustment during measure reevaluation.

**Improvements to Public Reporting on Hospital Compare**

AdvaMed believes that public reporting of hospital performance on quality and efficiency measures on the Hospital Compare website 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 on elective surgery, such as total joint arthroplasty (TJA). Specifically, CMS could develop measures of hospital performance on patient-reported outcomes for TJA, 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 develop measures of longer-term TJA outcomes on revisions, using existing risk-adjustment methods or other more advanced risk-stratification methodologies that CMS views appropriate. This data release could be modeled after the UK’s National Joint Registry Surgeon and Hospital Profile, which shows a number of important clinical metrics, including 90-day mortality rates, revision rates and patient-reported improvement data for individual hospitals and surgeons.¹ 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.

**Malnutrition Focused Measures**

In addition, AdvaMed continues to recommend that the Agency prioritize inclusion of a malnutrition-focused measure or measures as soon as feasible in the Hospital IQR. 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. AdvaMed believes that these malnutrition-focused measures have a strong link to clinical outcomes and are a gap area in current quality reporting systems.

¹ More data can be found at the following NJR link: http://www.njrsurgeonhospitalprofile.org.uk.
Confidential Social Risk Factor Reporting

Last year, CMS started the process of incorporating social risk factors into IQR, providing hospitals with stratified confidential reports of their Pneumonia Readmission results that used dual eligible status as an indicator of low-income status. CMS plans to expand these confidential hospital-reports to five additional measures in the spring of 2020: acute myocardial infarction (AMI) readmission measure; coronary artery bypass surgery (CABG) readmission measure; chronic obstructive pulmonary disease (COPD) readmission measure; heart failure readmission measure; and total hip arthroplasty/total knee arthroplasty readmission measure. AdvaMed supports efforts to account for social risk factors in inpatient quality reporting programs and supports CMS’s proposal to provide hospitals with confidential data on potential disparities in readmission rates.

Consideration in Expanding and Updating Quality Measures—Proposed Adoption of Two Opioid-Related eCQMs

CMS is seeking comments regarding the possible addition of two new eQCM measures targeted at measuring opioid-related health events. While the measures target the safe use of opioids and efforts to prevent and/or limit adverse events linked to opioid use they stop short of evaluating the process used by hospital-based health providers in reaching the decision to initially prescribe opioids.

Opioid dependency is at an all-time high. For this reason, providers need to be sensitive to the potential of persons prescribed these substances to develop Opioid Use Disorder (OUD). We support both of the proposed opioid-related measures. In particular, we believe the Hospital Harm - Opioid-related Adverse Events eCQM is critical to improve patient safety. Identifying the rate at which naloxone is given in the hospital setting will provide further information on the frequency of Opioid Related Adverse Respiratory Events (ORAREs) and promote strategies to improve patient safety. These are necessary steps to reduce ORARE-associated morbidity and mortality for Medicare beneficiaries with inadequately managed pain.

While AdvaMed understands the value in tracking the progress of patients prescribed opioids we also strongly advocate for a comprehensive evaluation of the patient’s health, pain, psychological, and other physical needs which may indicate the need to use device-based alternative treatments in lieu of drug therapy (including opioids). A measure to track the safe prescribing of opioids, to include completion of a screening evaluation, is needed. AdvaMed also recommends that additional eQCM measures be developed which track the adoption of minimally invasive surgery in addition to device-based pain-relieving techniques and procedures which help reduce or alleviate the use of opioids. We encourage CMS to consider our recommendations which fall in line with the objectives of the IQR program by empowering patients with the tools needed to make decisions regarding their healthcare.
PPS-EXEMPT CANCER HOSPITAL QUALITY REPORTING (PCHQR) PROGRAM

Proposed Removal of the Web-Based Structural Measure: External Beam Radiotherapy (EBRT) for Bone Metastases from the PCHQR Program Beginning with the FY 2022 Program Year

CMS is soliciting comments on the removal of the External Beam Radiotherapy (EBRT) for Bone Metastases measure from the PCHQR program because of concerns related to the inability to effectively use the measure to track and capture data related to use of the technology in bone metastases patients. Use of the measure, since its inception, has been challenged by burdensome data reporting, appropriate CPT code use, and sampling concerns. These issues have created undue burden for inpatient and outpatient hospitals and contributed to loss of NQF endorsement and the measure steward. Considering the multitude of issues plaguing the ease of use of this measure and its ability to generate helpful data, AdvaMed is supportive of the recommendation to retire it from the PCHQR program beginning with FY2022.


The proposed IPPS rule solicits comments on ways to address pain management and post-treatment addiction in cancer patients. CMS is also seeking comments on measures and measure concepts for pain management that do not involve systemic opioid use.

AdvaMed member companies manufacture a range of technologies that can markedly reduce the need to prescribe opioids to patients experiencing chronic and acute pain. Our members also manufacture devices that can be used in treating opioid addiction. Many of the existing quality measures and measure concepts do not consider the role of device-based alternatives to systemic opioids in addressing pain and other issues that may result in opioid use disorder (OUD). It is imperative that these technologies be factored into quality measure decisions going forward. Device alternatives can be used in a variety of ways including drug delivery devices that can deliver non-systemic opioid analgesic medicines to surgical sites and non-systemic opioid interventions including minimally invasive surgery, and other invasive and non-invasive pain management modalities, such as spinal cord stimulators, implantable intraspinal drug infusion pumps, cooled and standard radiofrequency neuroablation, electromagnetic energy, digital therapeutics, vertebral augmentation, ultrasound-guided regional anesthesia, and portable continuous pain relief systems—including elastomeric pumps. Several of these devices may be suitable for use in addressing the acute and chronic pain needs of cancer patients. AdvaMed recommends that, as CMS works on the development of quality measures which address the pain management needs of cancer patients, that the agency work with clinicians and stakeholders to structure those measures in a way that accommodates the evaluation and use of device-based alternatives as an option to prescribing systemic opioids.
LONG-TERM CARE HOSPITAL QUALITY REPORTING PROGRAM (LTCH QRP)

Request for Information on LTCH QRP Quality Measures, Measure Concepts and Standardized Patient Assessment Data Elements under Consideration for Future Years

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. AdvaMed recommends that CMS adopt a malnutrition-related quality measure in the LTCH QRP as soon as feasible.

Standardized Patient Assessment Data Reporting Beginning with FY 2022

AdvaMed supports CMS’s proposal to include the nutritional approach data elements for the Standardized Patient Assessment Data Reporting (i.e., Parenteral/Intravenous Feeding, Feeding Tube, Mechanically Altered-Diet, and Therapeutic Diet). 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.

MEDICARE AND MEDICAID PROMOTING INTEROPERABILITY PROGRAM

Urge CMS to Develop Opioid Measures for Non-pharmacologic Alternatives to Opioids

The proposed rule solicits comments on including new measures for OUD prevention and treatment in the Promoting Interoperability Program. The opioid crisis has had a major adverse impact on the health and welfare of many patients including Medicare beneficiaries. Significant attention has been dedicated to questions related to prescribing opioids and other drugs to patients. Unfortunately, that same level of attention has not been dedicated to exploring the role that device-based alternatives can play in minimizing and/or alleviating the need to prescribe systemic opioids and in managing OUD. AdvaMed member companies manufacture a range of technologies that can markedly reduce the need to prescribe opioids to patients experiencing chronic and acute pain. Our members also manufacture devices that can be used in treating opioid addiction. Given the link between opioid abuse and chronic and acute pain, we believe CMS can and should actively support methods to alleviate pain without systemic opioids by implementing appropriate coverage, coding, and reimbursement policies. Many of the existing quality measures and measure concepts do not consider the role of device alternatives to systemic opioids in addressing pain and other issues that may result in OUD. It is imperative that these technologies be factored into quality measure decisions going forward.
Device alternatives can be used in a variety of ways including drug delivery devices that can deliver non-systemic opioid analgesic medicines to surgical sites and non-systemic opioid interventions including minimally invasive surgery, and other invasive and non-invasive pain management modalities, such as spinal cord stimulators, implantable intraspinal drug infusion pumps, cooled and standard radiofrequency neuroablation, electromagnetic energy, digital therapeutics, vertebral augmentation, ultrasound-guided regional anesthesia, and portable continuous pain relief systems—including elastomeric pumps.

It is critically important that patients have access to alternatives at a time that suits their individual needs—which can vary depending upon family and personal history or other physical and psychological conditions—to avoid the prescription and use of opioids and the potential development of OUD.

AdvaMed recommends that CMS consider developing measures that capture consideration of use, time to access, and overall effectiveness of device alternatives to systemic opioids in all health settings. These measures could include the deployment of device-based alternative technologies in acute care settings (i.e. the utilization of technologies and procedures to reduce and eliminate post-surgical pain without the need for systemic opioids) and could measure long term impacts on reduced prescribing of systemic opioids. We believe that development and use of these types of measures could be implemented in a way that does not create additional work on the part of providers but does prompt necessary discussion regarding available options including avoidance of and/or reduced prescribing (i.e, “weaning”) of systemic opioids. This is especially important in treating patients who may require immediate access to device alternatives, in lieu of initial step-wise treatment that may involve drug therapy, due to a variety of personal and social factors.

AdvaMed appreciates the opportunity to comment on the proposed rule. If you have any questions, please contact Chien-Wei Lan at clan@advamed.org or Richard Price at rprice@advamed.org.

Sincerely,

Donald May
Executive Vice President,
Payment and Health Care Delivery