June 16, 2015

Via Electronic Mail

Andrew Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1632-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 Policy Changes and Fiscal year 2016 Rates

Dear Acting Administrator Slavitt:

On behalf of the Advanced Medical Technology Association (AdvaMed), I am pleased to offer comments on proposed changes to the Medicare hospital inpatient prospective payment system and FY 2016 rates published in the Federal Register April 30, 2015 (CMS-1632-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.

I. Solicitation of Public Comments on Expanding the Bundled Payments for Care Improvement (BPCI) Initiative

AdvaMed has been a strong supporter of delivery reform models since their inception in the Affordable Care Act. This support extends to models that would bundle inpatient, physician, and post-acute care services, and specifically the BPCI Initiative. We recognize the importance of the goals of delivery reform models as they seek to improve both the efficiency and quality of health care in this country and we believe that our members’ technologies can play a critical role in assisting providers to achieve these goals. Our member companies do so through advances in medical devices, diagnostics, and other advanced medical technologies. These products and services improve patient care quality and many improve efficiency by reducing the lengths of stay of patients in health care facilities, allowing procedures to be performed in less intensive and
less costly settings, providing early detection of disease and infections, and improving the ability of providers to monitor care, among other benefits.

A. Expansion of the Bundled Payments for Care Improvement (BPCI) Initiative

The proposed rule asks for comments on the potential expansion of the BPCI Initiative. First, AdvaMed disagrees with CMS’s assertion in the proposed rule that the existing expansion authority in Section 1115(A)(c) provides an option for the Secretary to require participation in the BPCI Initiative or any other delivery reform model tested by the Center. While we agree that the cited authority allows the Innovation Center to expand a payment or delivery reform model, including on a nationwide basis, we do not agree that this same provision in law authorizes the Secretary at any time upon expansion to require participation in the model. The suggestion of mandatory participation in BPCI must be related to change in the law.

Second, AdvaMed is pleased to see that CMS recognizes that further evaluation of the program is necessary before the agency would be prepared to move forward with expansion. Much more needs to be known about the impact of the program on beneficiary health outcomes, quality of care provided by awardees, and actual cost reduction and how cost reduction is achieved. The Year 1 Evaluation & Monitoring Annual Report for a limited number of awardees during the first months of participation in the program is a useful first step in providing the public information about implementation and impact of the program, but is very preliminary in providing any meaningful assessment of the program to date.

AdvaMed notes that few key details of how BPCI has been implemented and is being monitored are publicly available. For example, we know from the Innovation Center’s original Request for Applications (RFA) for BPCI that the Innovation Center expected that alignment of incentives among providers would be accompanied by care redesign and enhancements, such as reengineered care pathways using evidence-based medicine, standardized care using checklists, and care coordination. The RFA also indicates that gainsharing should support care redesign to achieve improved quality and patient experience and anticipated cost savings. Applicants must also discuss in detail how gainsharing will support care redesign. In addition, applicants must describe their methodology for sharing of gains between or among the hospital or other care settings and physicians and other non-physician practitioners. But we have been able to find very little about the nature of care redesign at the individual inpatient or post-acute care participating provider level. Additionally, nothing about gainsharing methodologies or levels of rewards at individual institutions has been released.

According to the RFA, overall quality of care for beneficiaries cared for by physicians and non-physician practitioners participating in gainsharing must meet minimum quality requirements and then remain constant or improve for the duration of the arrangement. Individual physicians and non-physician practitioners must meet quality thresholds and engage in quality improvement to be eligible to participate in gainsharing. Applicants must propose and have approved minimum quality thresholds and a process for monitoring quality and quality improvement. The RFA also indicated that a standardized set of quality measures would ultimately be required and agreed upon by CMS and the awardee for each of the Models 1-4 and would be based on
inpatient, outpatient, and physician quality reporting measures. But specific information about quality measures being used in programs is very limited.

Before significant expansion of the program, AdvaMed believes that the public should have much more information about the program or access to the information in order to assess the program’s impact on beneficiaries. This includes information obtained through future evaluations of the program, like the one released in February. But information should also be available independent of any future evaluations undertaken by CMS. This information will assist the public to assess for itself the impact of the program and to raise questions that should be investigated by CMS. For example, we argued in response to a CMS request for public comments on the potential release of Medicare physician payment information--specifically in the context of bundled payment and ACO programs—that patients have a great interest in knowing the financial incentives provided to their physicians through gainsharing or shared savings rewards. We stated then and continue to believe that physicians, knowing that the data will be made public, could be deterred from stinting on beneficiary care (e.g. withholding or not utilizing interventions known to be clinically effective) in order to benefit financially.

Incentives for reducing costs have the potential to lead to stinting on care, denying specialty referrals or higher cost tests and interventions, or selecting cheaper technologies, even when the specialty referrals or higher cost tests and interventions are the most appropriate treatment for the individual. Furthermore, the limited payment window used to evaluate costs and calculate shared savings in BPCI provides significant disincentives to treat patients with interventions that demonstrate long-term value. This may lead to focus on short-term cost savings even when this is not in the best long-term interest of the patient.

We continue to believe that such publicly available information about gainsharing rewards also would help CMS to target more effectively the agency’s program monitoring activities for assessing a program’s performance.

B. Use of Health Information

To respond to CMS’s question on health information our comments will focus on telehealth and remote monitoring as forms of health information technology that “can be used and encouraged in coordinating care across care settings, including postacute care.” Telehealth and remote patient monitoring technologies are generally recognized as fundamental tools for improving the efficiency and quality of health care. The BPCI Initiative with its emphasis on care coordination and collaboration among providers is an ideal delivery model for realizing the benefits telehealth and related technologies can bring to improving the efficiency and quality of care.

To the extent that payments to BPCI model participants are based on Medicare fee-for-service rules, however, providers participating in the Initiative will be challenged to realize the full benefits of telehealth technologies because Medicare’s fee-for-service program limits the type of technologies that may be covered, the site of service where beneficiaries may receive care and the geographic area where they must reside. A similar problem exists for remote monitoring services, with only limited reimbursement for these services, such as for cardiac trans-telephonic
monitoring of pacemakers, or remote monitoring of patient physiological data as part of new billable chronic care management services for beneficiaries with multiple chronic conditions. To the extent telehealth services are not covered by Medicare, the upfront investment and ongoing implementation costs of telehealth create a disincentive to use these technologies at a time when cost pressures and restricted budgets limit the ability of BPCI participants to do so.

AdvaMed recommends that the Innovation Center use its waiver authority during the demonstration phase to expand the availability of telehealth and remote monitoring services for BPCI participants to enhance their ability to coordinate care, especially for care provided in postacute care settings (including the home) following discharge from the hospital. Studies have found that a large portion of the variation in spending across many of the 48 clinical conditions can be attributed to postacute care spending. Incentives for BPCI participants to provide expanded telehealth and remote monitoring technologies would enable providers to deliver postacute services with higher levels of efficiency and quality, thereby helping them to meet program spending reduction and quality improvement goals.

C. Quality Measurement and Payment for Value

The proposed rule asks for comments on the nature of quality measures to be incorporated in the future for the BPCI initiative. Specifically, CMS asks whether they should apply the same quality measures to all episodes or develop episode-specific quality measures.

Historically, CMS has proposed and implemented episode-based measures which are condition specific. Currently, the Inpatient Quality Reporting (IQR) Program contains several episode of care based measures, all of which are specific for clinical conditions such as acute myocardial infarction (AMI), heart failure and pneumonia. In addition, CMS is proposing the following additional episode of care measures for the FY 2018 IQR program, all of which are also condition-specific:

- THA/TKA payment per episode of care;
- Kidney/UTI clinical episode based payment;
- Lumbar Spine fusion/re-fusion episode based payment;
- Cellulitis clinical episode based payment; and
- Gastrointestinal hemorrhage clinical episode based payment

AdvaMed supports the development of episode-specific quality measures for use in the BPCI program. Applying the same quality measures to all episodes would not take into account any detailed examination of individual clinical conditions during the measure development and vetting stages and could ultimately lead to one or more unintended consequences.
D. Rebas ing Spending Targets for BPCI Participants

AdvaMed supports approaches that recognize that continual savings from one year to the next and especially from one agreement period to another will be difficult after initial savings are achieved. CMS should take steps to account for previous years’ savings such that providers do not have a disincentive to continue in BPCI after early successes in the program. AdvaMed recommends that the Innovation Center consider adopting one of the following rebasing methodologies for BPCI participants:

1. Incorporate positive net payment reconciliation amounts realized during the initial performance period into the target of the subsequent performance period; or
2. Set the target price at the higher of the provider-specific or regional average episode payment amount.

In this way, the high-performers will always have an incentive to improve even when Medicare spending for their bundle falls as a result of better care, fewer infections, or reductions in readmissions.

E. Beneficiary Access to All Appropriate Treatment Options and Innovative Technologies under BPCI

While we strongly support delivery reforms, we are also concerned that the financial incentives in delivery reform models, including BPCI, can have the inadvertent effect of discouraging providers from (1) considering the full array of treatment options, especially if they may increase costs above “benchmark” thresholds—we refer to this as stinting, or (2) using innovative treatments, technologies, and diagnostics that may bring value to the health care system over the longer term, but are more costly in the short run. The potential negative impact of the financial incentives of these models is magnified by the short payment windows used in BPCI—30, 60, or 90 days—to compare actual spending against benchmarks in order to determine the level of savings that may be shared among providers. Many medical devices and technologies provide benefits over a long period of time spanning multiple years.

We want to start by thanking the Innovation Center for its decision earlier this year in acknowledging the impact a higher cost innovative technology can have on providers’ ability or interest in using that technology in patient care when they participate in delivery reform models, specifically in BPCI. In this instance, the Innovation Center decided to remove New Technology Add-On Payments (NTAP) approved by CMS for extra payment during a 2-3 year period, from a provider’s actual spending total for an episode of care. This policy will go a long way in removing disincentives providers would face in using the technology awarded NTAP status while at the same time ensuring that Medicare beneficiaries will have access to new technologies and treatments appropriate for their conditions. It is a good example of how the cost reduction incentives in certain delivery reform models can have an enormous impact on whether beneficiaries have access to the best that American medicine has to offer.
AdvaMed believes that additional innovative technologies, beyond NTAPs, should qualify for a similar adjustment as that being made for NTAP approvals, and that CMS should establish a review process for these technologies to determine whether their cost should be removed from actual spending totals for participating BPCI providers. We elaborate on our recommendation below.

For similar reasons, AdvaMed is also concerned that quality standards used for BPCI providers could discourage early adoption of new and better alternative treatments simply because the quality measures do not reflect breakthrough and innovative treatments. If a new approach to care is developed that may be superior to standard practice, and no special exception is provided for the new alternative treatment, physicians or hospitals may avoid adopting it because it will lower the provider’s quality score and, in turn, reduce shared savings.

We have learned recently from the Innovation Center of a very specific and concrete example of how quality measures in a delivery reform model can affect beneficiary access to innovation in medical technologies. The example comes out of experience in Pioneer ACOs, but is relevant to BPCI. Physicians in Pioneer ACOs had asked to be able to use a new and more effective pneumococcal pneumonia vaccine instead of an older version of the vaccine that is specified in a process quality measure used for both MSSP and Pioneer programs. The problem that physicians in these ACOs face is a reduction in their quality scores if they prefer to use the new vaccine, simply because this particular measure does not yet reflect a new standard of care and because no special exception is allowed for physicians to use the innovation. Patients may not be harmed by the older vaccine but they are not, at the same time, provided the benefits of the new product. This is another good example of how a technical adjustment in ACO— and bundled payment— programs can provide Medicare beneficiaries the benefits of innovation in health care without undermining the overarching goals of the program.

Our specific recommendations for payment and quality score adjustments follow:

**AdvaMed Recommendations for Addressing Patient Access to Innovative Care through Payment and Quality Score Adjustments**

Our recommendations would provide adjustments for a limited number of innovative treatments or diagnostics that are first reviewed and approved by CMS after meeting certain criteria. These adjustments would be used for a limited period of time to allow time for these treatments and diagnostics to be reflected in new benchmarks or incorporated in quality measurement to the extent they become the standard of care. For purposes of payment for innovative treatments, the cost of approved innovative treatments would be removed from the calculation of benchmarks and Medicare expenditures when calculating savings or losses. Where the barrier to adoption is a quality standard, quality measurement would exclude the case with the new treatment from the provider or physician quality score. With these adjustments, the disincentives to use an innovative treatment or diagnostic would be neutralized and BPCI providers would make decisions purely on medical grounds.
CMS Review of New Treatments and Process: AdvaMed urges CMS to establish a process for manufacturers or developers to identify breakthrough technologies/treatments meeting the criteria below. This process would be similar to the one now used by CMS for New Technology Add-On Payments. Manufacturers and developers would provide CMS the estimated incremental increase in spending that would result from each use of an approved treatment. They would also provide CMS the data and methodology for such estimates as part of the application process to assist CMS in determining whether a treatment or technology warrants special accommodation and what adjustments would be made. If approved by CMS, the adjustments would apply to use of the technology across BPCI providers, and other relevant delivery reform models.

CMS would also allow individual bundled payment and other delivery reform awardees to request an adjustment if they were to adopt breakthrough/high cost treatments in advance of other providers. The adjustment could be applied to the individual awardee or all awardees using the treatment.

Recommended Eligibility Criteria for Payment Adjustments: CMS would establish the following criteria to authorize adjustments to benchmarks and calculations of Medicare expenditures:

- New technologies/treatments/diagnostics that offer clinical improvements for all or certain types of patients and represent a higher cost to the awardee than use of current therapies; or
- Existing treatments or diagnostics that offer significant therapeutic advances for new populations or conditions and that represent a higher cost to the awardee(s) than existing treatments for those populations.

Recommended Eligibility Criteria for Quality Measurement Adjustments: CMS would establish the following criteria to authorize adjustments to calculations of Medicare’s individual quality scores:

- The new treatment, service, or diagnostic test is potentially a superior clinical substitute for the current treatment, service, or diagnostic test used for quality measurement; or
- The treatment, service or diagnostic test is clinically equivalent to existing treatment, service, or diagnostic test but provides advantages for patients or providers, such as ease of administration or reduced discomfort.

Length of Adjustment Period: At the time of qualification, CMS would determine the length of a payment and/or quality adjustment period based on a reasonable assumption of the time needed for the product to be reflected in benchmarks. Generally, this would be a period of three to five years from the time of designation. In the case of an alternative quality measure, the adjustment
period would end if a consensus quality standard body determined that a new quality measure should be developed or the new treatment or diagnosis should replace the existing one.

II. New Technology Add-On Payments (NTAP)

AdvaMed has long argued for changes in new-tech add-on policies to ensure that the original intent of the law establishing the add-on policy is met for ensuring Medicare beneficiaries access to innovative treatments. We point to a February Health Affairs study, “US Hospital Payment Adjustments for Innovative Technology Lag Behind Those in Germany, France, and Japan”. This study found that Medicare approved considerably fewer innovative technologies for add-on payments, compared to similar payment mechanisms in Germany, France, and Japan. We are concerned that an overly restrictive Medicare new-tech add-on policy is compromising beneficiary access to the best that American medicine has to offer.

AdvaMed believes that the current new-technology payment methodology can be improved in several ways:

1. CMS should use the most recently available cost data and information available (including data from surveys of providers of services and suppliers conducted by the Secretary, private payers, health plans, physician specialty societies or manufacturers as well as commercial price data and data from manufacturer invoices) for assigning new technology procedures to appropriate MS-DRGs.

2. New technology add-on payments should be increased from 50 to 80% of the difference between the standard MS-DRG payment and the cost of the procedure with the new technology. The study cited above found that from 2002 through 2013 CMS had projected NTAP spending would amount to $598 million, but analysis of MedPAR data showed that hospitals received only $201.7 million over the entire 12-year period. Additionally a subsequent analysis by Avalere Health shows that many cases receiving NTAPs also receive outlier payment—often in excess of the NTAP amount. The fact that so many NTAP cases also qualify for outlier payments highlights the inadequate level of NTAP amounts to cover the cost of these new technologies. **We urge CMS to address this chronic underfunding problem.**

3. Criteria applied in making substantial improvement determinations. In order to be eligible for add-on payments, a new technology must represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. In making this determination, the Secretary should consider whether the new technology or medical service meets one or more of the following criteria: (a) provides more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions; (b) no approved alternatives exist; (c) offers significant advantages over existing approved alternatives (d) results in reduced costs over an episode of care; (e) improves patient quality of life; (f) creates long-term clinical efficiencies in treatment; (g) addresses patient-centered objectives as defined by the Secretary; or (h) meets such other criterial as the Secretary may specify.

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

In addition to our recommendations above for improving the methodology for approving add-on payments for new technologies, AdvaMed wishes to respond to the proposed rule’s request for comments contained in discussions of applications for NTAPs in FY 2016. AdvaMed is concerned that the review process and standards imposed are constantly changing and impose hurdles that make approval increasingly difficult. We wish to comment on two issues raised in the proposed rule: the standards used to evaluate substantial clinical improvement and evaluation of the “newness” criterion.

**Substantial clinical improvement criterion**

To satisfy the substantial clinical improvement criterion, a new technology must represent a substantial clinical improvement in the available treatment options for the relevant patient conditions. As such, it might be an improvement compared to existing treatments for the same patient population and condition or it might offer treatment to patients/conditions for which there is no existing treatment.

AdvaMed is highly concerned about the constantly changing standards applied by CMS in determining substantial clinical improvement, the inability for an applicant to know how CMS will evaluate its technology, and the standards that will be used. CMS continues to raise the bar for what it wants to see in the design methodology. AdvaMed appreciates the rigor that CMS uses for the evaluation of substantial clinical improvement but we often see a disconnect between what CMS considers to be acceptable evidence and what others—e.g., peer-reviewed literature—consider to be outstanding clinical design studies (meeting randomized, blinded clinical trial requirements) with appropriate Medicare representation.

For the WATCHMAN® system, CMS suggests that demonstrating substantial clinical improvement for this technology should be based on a clinical trial with a superiority design rather than the non-inferiority trial design that was used. The applicant disagrees, noting that due to WATCHMAN’s target population, it was only necessary to show efficacy similar to warfarin. Also, in its review of the WATCHMAN® system, CMS states that the studies met their safety endpoints, yet the agency surprisingly raises safety questions seemingly to draw a tentative conclusion that WATCHMAN is not a substantial clinical improvement.

AdvaMed appreciates the need for CMS to require clinical studies and to focus on clinical effectiveness and safety, but we strongly believe that it is not appropriate for CMS to continue to add requirements or to impose standards that exceed realistic requirements for clinical trials.
“Newness” criterion

To satisfy the cost criterion, the cost of using a new technology must exceed the threshold published in Table 10 of the final rule for the applicable fiscal year. Table 10 released with the FY 2015 IPPS/LTCH PPS final rule contains the final thresholds that are used to evaluate applications for new technology add-on payments for FY 2016. In discussing the NTAP application for the WATCHMAN® System, however, CMS solicits public comments on the use of supplemental threshold values when the coding to identify a new technology is reassigned to a new MS-DRG that does not have a threshold value in Table 10.

For the WATCHMAN® System, the applicant based its analysis on the current MS-DRG assignment of the relevant procedure code and concluded that the technology meets the cost criterion. In the FY 2016 proposed rule, CMS proposes to identify procedures performed within the heart chamber using intracardiac techniques, including those identified by ICD-9-CM procedure code 37.90 (the relevant procedure code for the WATCHMAN® System) to two new proposed MS-DRGs (MS-DRGs 273 and 274). According to the proposed rule, the proposed DRG changes could have implications for determining whether the WATCHMAN® System meets the cost criterion.

CMS notes in the proposed rule that previous situations occurred where the coding associated with a new application is included in a proposal to change one or more MS-DRGs and refers the reader to the FY 2013 IPPS final rule discussion about Zenith® Fenestrated Abdominal Aortic Aneurysm Endovascular Graft (77 FR 55360). In that example, CMS notes that thresholds that were 75 percent of one standard deviation beyond the geometric mean standardized charge for the proposed new MS-DRGs were used for the cost criterion. CMS notes that it “could be” appropriate for the applicant to demonstrate that the average case-weighted standardized charge per case exceeds the supplemental thresholds for MS-DRG 273 and 274. CMS intends to calculate supplemental threshold values for the proposed new MS-DRGs (MS-DRGs 273 and 274) using the data which had been used to generate the FY 2015 IPPS Table 10 and plans to post these supplemental threshold values for public consideration on the web site at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html.

CMS invites public comment on whether the WATCHMAN® System meets the cost criterion and on whether considering these supplemental threshold values as part of the cost criterion evaluation for this application is appropriate as well as how to address similar future situations in a broader policy context should they occur.

AdvaMed recommendation: AdvaMed strongly believes that NTAP applications should be evaluated based solely on the Table 10 thresholds published in each year’s final rule. The primary purpose of the final rule to establish the processes and values that will be used during the next fiscal year: the FY 2014 IPPS final rule for FY 2015; the FY 2015 IPPS final rule for FY 2016, etc. NTAP applications are due in December of the year prior to the start of the fiscal year in which the NTAP would take effect. Thus, NTAP applications for FY 2016 were due in December 2014. These applications and the pertinent cost analyses were prepared based on the MS-DRGs and associated NTAP cost thresholds which were published in Table 10 of the FY
The CMS review should be conducted based on these same MS-DRGs and associated NTAP cost thresholds and these should be the basis of CMS’ determination whether the applicant satisfies the NTAP cost threshold criteria.

For approved NTAP applications affected by proposed MS-DRG changes, CMS can move the procedures to the new MS-DRGs after the NTAP decision is made. This is the same manner of treatment as CMS applies when it shifts existing procedures with an NTAP to different MS-DRGs due to changes in the MS-DRGs.


Effective October 1, 2015, CMS will assign codes for new technologies and services that are not usually captured by coders or that lack the desired level of specificity within the structure of ICD-10-PCS to section X. Section X codes are being developed with the intent of establishing a mechanism to better track and analyze use of new services and technologies. Codes included in section X of ICD-10-PCS will be referred to the coordination and maintenance committee for deletions or revisions.

There are many unanswered questions regarding the impact of the use of these new codes on reimbursement for their associated technologies. Devices that receive new technology add-on payment (NTAP) status are FDA-approved new technologies that demonstrate substantial clinical improvement in the patient population with which they are used while also meeting specific cost criteria. Payment for these codes is currently set using a standardized approach. Traditionally, codes with the new technology designation are placed in a DRG following expiration of NTAP status based on claims data collected during the 2-3 year period in which the add-on payment was in effect.

AdvaMed is concerned that placement of NTAP eligible device codes in ICD-10-PCS section X could result in negative treatment of the codes by payers for purposes of coverage and payment—similar to the encounters of many Category III CPT code users. For this reason it is imperative that the process established for payment of services and technologies coded with the section X codes be clarified for all interested stakeholders and that CMS explicitly state that the services and technologies in section X are neither experimental nor unproven. AdvaMed also recommends that Medicare contractors be instructed to continue covering and paying NTAP eligible procedures in the same manner which has been historically directed by CMS.

The proposed rule states that codes placed in ICD-10-PCS section X will have to go through the Coordination and Maintenance Committee meeting process prior to being revised or deleted. This could potentially result in coverage and payment gaps for NTAP procedures that are ready to transition to MS-DRG placement. There should be no gap in coverage and payment during the
transition from NTAP status to permanent MS-DRG placement. CMS should clarify the process for transitioning NTAP codes in ICD-10-PCS section X into a DRG following expiration of their NTAP status. AdvaMed encourages CMS to provide continued coverage and payment for section X services and technologies with NTAP status at the expiration of the 2-3 year add-on payment period. CMS should ensure that these services and technologies are eligible for placement in an appropriate MS-DRG immediately following expiration of their NTAP status and that any process to delete the section X code previously associated with the technology is coordinated in a way that avoids any disruption in coverage or payment.

AdvaMed encourages CMS to closely monitor implementation and use of the new section X codes. This is a critical step in determining their effectiveness.

IV. MS-DRGs 273 and 274

The proposed rule would create two new MS–DRGs to classify percutaneous intracardiac procedures:

- MS–DRG 273, entitled “Percutaneous Intracardiac Procedures with MCC,”
- MS–DRG 274, entitled “Percutaneous Intracardiac Procedures without MCC.”

CMS proposes to assign procedures performed within the heart chambers using intracardiac techniques to the two proposed new MS–DRGs. Existing percutaneous intracoronary procedures with and without stents would continue to be assigned to the current MS–DRGs (MS-DRGs 246-251) to reflect that those procedures are performed within the coronary vessels.

AdvaMed supports CMS’s proposal to establish MS-DRGs 273 and 274. This proposal would better recognize clinical homogeneity and resource requirements for a range of heart chamber procedures that tend to be longer and more technology-intensive than percutaneous coronary intervention procedures for cardiovascular disease.

V. MS-DRGs 268 and 269

The proposed rule would create two new MS–DRGs primarily focused on selected Aortic procedures:

- MS–DRG 268, entitled “Aortic and Heart Assist Procedures with MCC,”
- MS–DRG 269, entitled “Aortic and Heart Assist Procedures without MCC.”

CMS proposes to reclassify 12 complex, invasive and costly surgical procedures involving the aorta, selected abdominal visceral vessels, and selected extra-cardiac structures.

AdvaMed supports CMS’s proposal to establish MS-DRGs 268/269. This proposal improves clinical homogeneity and alignment of resource intensity for these procedures as compared to current classification in MS DRG 237/238.
However, the proposed names of the new MS-DRGs have already created confusion in the provider community and broader public that interacts with providers. Heart assist insertion procedures currently exist in multiple DRGs with higher incidence and resourcing than the less common removal and repair codes 37.49 (Other repair of heart and pericardium), 37.55 (Removal of internal biventricular heart replacement system), and 37.64 (Removal of external heart assist system(s) or device(s) included in proposed MS-DRG 268-269.

We therefore recommend CMS consider a different nomenclature for the proposed DRGs to specify “Aortic procedures” separate from “heart assist removal or repair”. Reference to Pulsation Balloon insertion could also eliminated entirely with this edit, or added to MS-DRG 270, 271, 272 to be inclusive instead of exclusive.

Example:

MS-DRG 268 Aortic Procedures and Heart Assist Removal or Repair with MCC
MS-DRG 269 Aortic Procedures and Heart Assist Removal or Repair without MCC
MS-DRG 270 Pulsation Balloon and Other major Cardiovascular procedures with MCC
MS-DRG 271 Pulsation Balloon and Other major Cardiovascular procedures with CC
MS-DRG 272 Pulsation Balloon and Other major Cardiovascular procedures without CC/MCC.

VI. Hospital Acquired Condition (HAC) Reduction Program – Proposed Refinements to FY 2018 Measures

AdvaMed supports the expansion of the measure populations for the CDC/NHSN Central Line Associated Blood Stream Infection (CLABSI) and Catheter Associated Urinary Tract Infection (CAUTI) measures to include patients in select non-Intensive Care Unit (non-ICU) locations (adult and pediatric patients in medical, surgical, and medical/surgical wards), in addition to adult and pediatric ICU locations, beginning in FY 2018. AdvaMed agrees that by expanding the settings for collection of these measures, hospitals that do not have ICUs will be able to participate and thus benefit from the resources provided by the NHSN for public reporting and quality improvement.

VII. Hospital Inpatient Quality Reporting (IQR) Program – Proposed Refinements to Existing Measures

AdvaMed commends CMS’s proposal and associated rationale for incorporating the refinements to the patient populations for the pneumonia mortality and readmission measures, both of which were previously adopted in the Hospital IQR Program; the latter were also adopted into the Hospital Readmissions Reduction Program (HRRP). These refinements – which arose out of the National Quality Forum (NQF) Measure Applications Partnership – address concerns about variation in coding of pneumonia as a principal diagnosis in order to avoid patients being captured by the pneumonia readmission and mortality measures.
AdvaMed supports CMS’s proposal to refine the measure cohorts for the Hospital 30-Day, All-cause, Risk-Standardized Mortality Rate (RSMR) following Pneumonia Hospitalization and the Hospital 30-Day, All-cause, Risk-Standardized Readmission Rate following Pneumonia Hospitalization measures to include patients with a principal discharge diagnosis of aspiration pneumonia and patients with a principal discharge diagnosis of sepsis or respiratory failure who also have a secondary diagnosis of pneumonia present on admission. For each measure, CMS estimates that the refinements would substantially expand the cohort of included patients (by about 40 percent in both cases) and would also increase the number of hospitals meeting the minimum requirement of 25 cases for public reporting of a measure score (86 hospitals for the mortality measure and 67 hospitals for the readmission measure).

We agree with CMS that this proposal will address stakeholder concerns that the current specifications may result in variation in the number of pneumonia cases captured due to differences in hospital coding; refining the population for these measures will ensure better collection of more complete and comparable data across hospitals.

**Removal of Measures for the FY 2018 Payment Determination and Subsequent Years**

AdvaMed supports the removal of Surgical Care Improvement Project (SCIP) Inf-4: Cardiac Surgery Patients with Controlled Postoperative Blood Glucose from the Hospital IQR Program. AdvaMed appreciates CMS’s rationale for removal of this measure given the significant burden on hospitals to report the measure and ensure adherence to the requirements of the measure specifications. As the Society of Thoracic Surgeons is currently updating guidelines related to glucose control for cardiac surgery patients, AdvaMed agrees that awaiting this guidance before incorporating metrics of postoperative glucose control in cardiac surgery patients into the Hospital IQR program is logical.

We do, however, believe that glycemic control is important in this patient population in particular, and it is important to note that the SCIP Inf-4 measure represents the only performance measure for the control of postoperative blood glucose in the Hospital IQR program. The development of hyperglycemia in the postoperative period for coronary artery bypass grafting, acute coronary syndrome, acute myocardial infarction, coronary artery surgery and cardiac surgery has been shown to result in increased perioperative morbidity and mortality, decreased long-term survival, and recurrent ischemic events.¹₂

AdvaMed understands that evidence indicate that a one-time blood glucose test in the postoperative period is not shown to improve patient outcomes; however, as continuous glucose

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monitoring devices continue to be available for use in the operating room/ICU setting, there will be significant opportunities to improve patient care by extending the timeframe for monitoring trends in blood glucose levels and initiating timely actions to correct any derangements. These advancements have the potential for significant improvements in patient outcomes, consequently reducing cost and the patient length of stay (LOS) as a result of improved glycemic control.\(^3\)\(^4\)

AdvaMed would like to encourage CMS to focus on the creation of a better measure that could capture glucose control over time for cardiac surgery patients. We believe that there is the opportunity to evaluate new measures that may more effectively tie performance to improved outcomes, especially as monitoring technologies advance to facilitate improved patient care.

**Hospital Value-Based Purchasing Program (HVBP)**

A. **Possible Measure Topics for Future Years:**

   1. General Considerations When Including Additional Measures to Expand the Efficiency and Cost Reduction Domain for the Value-based Purchasing Program

CMS proposes to add seven episode-based measures for future inclusion and expansion into the VBP program under the Efficiency domain. AdvaMed supports healthcare transformation moving toward better quality of care, patient outcomes, and lowering healthcare costs. Episode-based efficiency measures have the potential to support such transformation if they are appropriately designed.

When CMS considers including these episode-based measures into the Efficiency and Cost Reduction domain, the existence of appropriate quality measures should be the first criterion in CMS’s evaluation of whether to use episode-based efficiency measures.

AdvaMed is concerned that episode-based measures may not take into consideration all the complex factors that contribute to the cost of care. This could put providers at risk solely based on the selection of their patients. Efficiency measures must be sufficiently flexible to ensure that they do not interfere with the most appropriate treatments. Patients within the same episode may receive very different treatments based on their anatomy, comorbidities, lifestyle, personal preferences and/or symptomology, requiring sufficient payment model flexibility.

AdvaMed encourages CMS to make sure the existence of appropriate quality measures is the first criterion in CMS’s evaluation of whether to use episode-based efficiency measures. In addition, as CMS continues to look at these measures, we urge CMS to rely on an open


consultative process that allows for full review and comments. Relevant expertise exists among many interested stakeholders whose input on the details of any model should be considered before proceeding.

2. Specific Consideration When Including Lumbar Spine Fusion/Refusion Clinical Episode-Based Payment Efficiency Measure In Efficiency and Cost Reduction Domain

AdvaMed appreciates CMS’s goal to measure the efficiency of care within a set of homogeneous conditions and procedures for Lumbar Spine/Refusion procedures; however, we have concerns regarding how CMS will adjust for hospitals with high volumes of certain types of patient populations constituting an episode condition or surgery.

It appears that the proposed procedure-specific measure for lumbar fusion/refusion is subject to significant variation in patient subgroup characteristics that cannot be ascertained using the current methodology. For example, the measure would include all fusions involving the lumbar spine, without consideration of the clinical circumstances necessitating fusion. This is a critical issue. Hospitals providing spinal fusion surgery may specialize in the treatment of specific pathologies, such as spinal deformity, tumor, or trauma. In addition, some hospitals may perform a substantial number of complicated revision surgeries after an initial lumbar fusion. Differences between these subgroups within the proposed lumbar fusion episode condition may be stark in terms of payment amounts, care trajectories, and/or the risk for complications. The methodology documentation does not describe how these important subgroup differences would be addressed in a fashion that will be equitable across hospitals with distinct patient populations. Since this measure will be used along with CMS’s existing measure that focuses on cost and efficiency – the Medicare Spending Per Beneficiary (MSPB) measure – it is possible that certain hospitals may be penalized twice if the hospitals have both high Lumbar Spine Fusion/Refusion procedure cost and high MSPB. It is important for CMS to ensure that hospitals with a high volume of patients – especially those with complex patients for an episode condition or surgery – are not inappropriately penalized, rewarded, or otherwise scrutinized as a result of performance on overlapping measures.

In addition, the measure methodology document makes reference to clinical logic for ascribing services to the episode window, including the identification of relevant diagnoses or procedures on a given claim, but importantly, does not describe how clinical relevance is to be defined at the individual claim level. It is possible, for example, for a diagnosis code relevant to an episode window (e.g., arthrodesis status or low back pain) to appear on a Part B claim concurrently with unrelated diagnoses or procedure codes. Transparency into how the payment amounts for this type of claim would be allocated would provide important insight into the validity of the decision rule for defining related services, and provide greater clarity to CMS’s overall proposal.
In summary, AdvaMed believes that it is important for CMS to ensure that hospitals with high volumes of patient populations for lumbar procedures or certain subpopulation of lumbar spine fusion/refusion are not disproportionately penalized. In addition, CMS should specify the combination of diagnosis codes and procedures needed to define clinically relevant services for this episode-based efficiency measure.

**B. Identification of Future Measure Gap Areas**

1. **Malnutrition**

AdvaMed appreciates the opportunity to provide comments on future measure topics and recommends that CMS include malnutrition measures and/or measure set(s) in future Inpatient Quality Reporting and Hospital Value-Based Purchasing Programs. Importantly, measuring malnutrition care in hospitalized patients: (1) aligns with all six national quality priorities; (2) addresses a gap where there is variation in clinical practice\(^5\); and (3) provides an opportunity to address measure gaps across care settings in future programs.\(^6\)\(^,\)\(^7\)\(^,\)\(^8\)

Malnutrition is an independent predictor of mortality, length of stay, unplanned readmissions and hospital costs.\(^9\) Malnutrition is associated with a number of negative outcomes for patients: higher infection and complication rates,\(^10\) increased muscle loss,\(^11\) impaired wound healing,\(^12\) longer length of hospital stay,\(^13\) and increased morbidity and mortality.\(^14\) Additionally, studies have demonstrated a link between malnutrition and increased readmission rates.\(^15\) Malnutrition can either be a contributing cause or a consequence of many disease conditions, acute conditions or illnesses. Disease-Associated Malnutrition (DAM) affects between 30% and 50% of patients admitted to hospitals. Significantly the morbidity, mortality, and direct medical costs associated with Disease-Associated Malnutrition for age 65 years+ in the U.S. are estimated to be $51.3 billion.\(^16\)

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\(^6\) Avalere Health, May 2014, Dialogue Proceedings: Measuring the Quality of Malnutrition Care.
\(^11\) Id.
Despite significant negative impact on patient outcomes and costs\textsuperscript{17}, malnutrition is an area that has largely remained unaddressed and has opportunity for improved performance.\textsuperscript{18} Implementation of patient-driven and team-based malnutrition care plans, and care coordination between providers, patients, and community-based services are critical for improving outcomes for malnourished and at-risk patients.\textsuperscript{19,20} Evidence demonstrates that early nutrition intervention for hospitalized patients can lower costs by decreasing preventable readmissions, complications, length of hospital stay (LOS), and mortality.\textsuperscript{21,22}

As recovery, rehabilitation time and functional independence may be significantly improved by preventing and treating malnutrition, we believe that malnutrition is a “measure that matters” for hospitalized patients and their families.

AdvaMed urges CMS to address this measure gap by implementing malnutrition measures and/or measure set(s) in future IQR and Hospital VBP programs that include the use of a validated screening tool. Studies have investigated various methods for screening and assessing malnutrition and have shown several tools to be simple and accurate.\textsuperscript{23} Despite advances in medical, surgical, nursing, and nutrition support, malnutrition remains a debilitating and highly prevalent condition in the acute hospital setting, with studies reporting prevalence rates upwards of approximately 40%.\textsuperscript{24} Early identification and treatment of malnutrition helps optimize the patient’s chances of ameliorating the adverse outcomes associated with malnutrition. Given the high prevalence of malnutrition for older adults, it is critical to identify patients who are at-risk for malnutrition upon admission, implement a team-based care plan, intervene as appropriate, and provide continuity of care prior to discharge with patient education, diet orders, and services as needed. The impact on care can be substantial – for example, one study found that patients who receive high quality nutritional care (defined as early intervention plus frequent use of nutrition services) averaged a 2.2 day shorter period of hospitalization than those who received medium quality nutritional care (defined as early intervention or frequent use of nutrition services).\textsuperscript{25}

\textsuperscript{17} Corkins, et al, \textit{JPEN J Parenter Enteral Nutr} 2014 38: 186.
\textsuperscript{18} Avalere Health, November 2014, Dialogue Proceedings: Launching the Malnutrition Quality Improvement Initiative.
\textsuperscript{19} Tappenden, \textit{Science Magazine Supplement} December 2014.
\textsuperscript{20} Tappenden et al, \textit{JPEN J Parenter Enteral Nutr} 2013 37: 482.
Because malnutrition also impacts patient care across the care continuum, AdvaMed also recommends that CMS encourage coordination and shared accountability by including malnutrition related measures in all settings where patients receive care (including ambulatory, acute, and post-acute settings).  

2. Acute Kidney Injury (AKI)

In recent years, experts repeatedly called for action to address Acute Kidney Injury (AKI) – a major cause of mortality among both adults and children, with mortality rates of 23.9% in adults and 13.8% in children.  

In addition to the adverse health consequences associated with AKI, there are economic implications as well. Short-term economic implications stemming from AKI include more investigations, higher intensity of monitoring, unplanned or longer ICU stay, longer or failed weaning from mechanical ventilation, longer hospitalization, and higher risk of early re-hospitalization. The long-term economic implications of AKI include new or accelerated chronic kidney disease (CKD), end stage kidney disease (ESKD), re-hospitalization, increase in the use of health services, increase in risk of sepsis, cardiovascular events, fractures, malignancy, tuberculosis reactivation, and possibly an increase in costs to society stemming from a decrease in the quality of life.

Because of AKI’s prevalence and the associated high mortality rate, prevention or amelioration of AKI would prevent a large number of deaths and substantially reduce complications and their associated costs. AKI presents a tremendous opportunity for improving care through proactive approaches. According to one comprehensive review of the care of patients who died in hospital with a primary diagnosis of AKI, up to 30% of cases of AKI may be preventable, 45% of cases had an unacceptable delay in recognizing AKI diagnosis, 13% of cases had complications of AKI, and 29% had inadequacies in clinical management of AKI.  

Moreover, recent data clearly indicate that post-discharge coordination of care of AKI patients can be improved substantially. AKI has clear gaps in the quality of care, which should be addressed through a thorough process beginning with an inter-disciplinary stakeholder engagement, and proceeding to identification of key priorities across the spectrum of AKI and renal replacement therapy (RRT) care, scanning of literature for existing quality management of AKI/RRT care, development/evaluation of

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novel/innovative evidence-based quality measures for NQF endorsement, and development of implementation/sustainability strategies.

Earlier this year, on February 16, Continuous Renal Replacement Therapies (CRRT) held a roundtable in which inter-disciplinary stakeholders (nurses, pharmacists, researchers, policymakers, and industry) discussed AKI as a quality paradigm. The objective of the roundtable was to evaluate elements of AKI as quality measures, derive consensus on selected quality measures, and develop benchmarks for evaluating care delivery, including RRTs for patients with AKI. The roundtable explored (1) the current status and gaps in knowledge; (2) defining, measuring, and targeting patient safety and quality in AKI; and (3) ensuring patient safety and quality for RRT in AKI. The output of this roundtable is forthcoming.

While the discussion from the CRRT roundtable was helpful in framing the issue, CMS has the ultimate authority to ensure that the quality measures are eventually implemented in the Medicare program. AdvaMed urges CMS to address this important measure gap area by taking the steps to implement measures regarding AKI in future IQR and Hospital VBP Programs.

We thank you again for this opportunity to comment on the proposed rule for the MSSP program. If you have questions, please contact Richard Price at rprice@advamed.org or 202-434-7227.

Sincerely,

/S/

Don May
Executive Vice President,
Payment and Health Care Delivery