June 25, 2012

Marilyn Tavenner, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1588-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 Fiscal Year 2013 Rates

Dear Ms. Tavenner:

The Advanced Medical Technology Association (AdvaMed) is pleased to submit the following comments on proposed changes to the Medicare hospital inpatient prospective payment system and FY 2013 rates (CMS-1588-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. Charge Compression for Implantable Devices

Payment rates in Medicare’s hospital inpatient and outpatient payments have long been distorted by a problem known as “charge compression,” in which the billed charges and cost report data used to calculate Medicare payment rates for acute care hospitals significantly underestimate the resources associated with many procedures that include implantable medical devices. The problem exists because a single combined factor (known as a “cost to charge ratio”) is used to estimate costs for both implantable devices and other less complex medical supplies in the rate-setting process. Notable independent researchers at MedPAC and RTI International (under contract to CMS) confirmed that the problem of charge compression is real and significant and recommended solutions to address the problem.
CMS concurred with the independent analyses and in 2009 created a new separate cost center on the Medicare hospital cost report to identify and estimate the costs of services involving implantable devices more accurately. At the time of implementation, CMS anticipated that data from the new cost center would be available to set more accurate rates in the 2012 payment updates for the inpatient and outpatient systems.

Though a significant body of hospital cost reports employing the new cost center for implantable devices was available for the 2012 rate updates, CMS chose not to use the updated information and instead indicated that it preferred an even larger pool of hospital cost reports to begin using the new cost center for rate-setting purposes.

For 2013, the proposed rule notes that a sizeable number of hospitals in the FY 2010 HCRIS have reported data for implantable devices on their cost reports beginning during FY 2010. CMS, however, is able to access only those cost reports with fiscal year begin dates before May 1, 2010, rather than through September 30, 2010. CMS notes that this is because cost reports with fiscal year begin dates of May 1, 2010 through September 30, 2010, were filed on the new cost report Form 2552-10, and cost reports filed on the form 2552-10 are not currently accessible in HCRIS.

Compounding this problem is a second problem. Corresponding information regarding charges for implantable devices on hospital claims is not yet available from the MedPAR file. As a result of internal agency delays in preparing the data necessary for the adjustment, CMS is proposing to delay using the new cost center for calculating MS-DRG relative weights for FY 2013. CMS instead will continue computing the relative weights using a methodology that the agency, MedPAC, and independent researchers agree should be changed.

AdvaMed supported the agency’s decision to move from charge-based weights to cost-based weights, in concert with other improvements to the accuracy of weights based on estimated costs. AdvaMed therefore subsequently supported CMS’s proposal to address the problem of charge compression by establishing two separate cost centers in the Medicare cost reports, one for medical supplies and a second for implantable devices, and to define the cost centers based on the use of existing revenue codes and associated definitions.

AdvaMed is now extremely disappointed to learn of another delay in using the cost center for calculating MS-DRG relative weights. We are also concerned that the proposed rule signals the possibility that CMS may not have the necessary MedPAR data available to use for the relative weights in FY 2014.

We note that CMS could implement an accurate charge compression fix, with minimal effort in the FY 2013 final rule. CMS calculates the DRG relative weights from a summary of standardized charges by DRG and department (the 15 standard cost categories), and 15 national average cost-to-charge ratios. This final input to the DRG weight recalibration is essentially identical to the standardized charge fields in the After Outliers Removed (AOR) file distributed with the proposed rule. To implement the fix,
CMS needs a DRG-by-DRG estimate of the split of standardized supplies charges into implantable devices and routine supplies. Once supplier charges are apportioned in each DRG, separate national average cost-to-charge ratios for implantables and other supplies could be applied, based on the existing cost reports. At that point, the remainder of the DRG weight calculation would proceed (now with 16 charge categories), and decompression fix would be fully implemented.

The CY 2010 inpatient standard analytic file (SAF) has all the information required to calculate the DRG-level factors for apportioning the supplies charges. This file has information on charges by revenue center, allowing implantable devices to be split from routine supplies. It has information required for DRG assignment, and so could be run through the latest DRG grouper if DRG definition changes are an issue. Compared to the FY 2011 MedPAR, this file would be 9 months out-of-date, less out-of-date than the cost report information CMS will be using for this rule. This file can be queried using standard laptop computers, so processing burdens are minimal.

If CMS foresees further delays in the implementation of the cost centers, we believe it would be appropriate for CMS to institute the RTI and MedPAC recommended approach to the statistical disaggregation of CCRs in the medical supplies cost center. This would lead to an immediate correction for charge compression until data from the new cost centers become available.

If CMS does not adopt the options above, AdvaMed would recommend that CMS develop and discuss in the final IPPS rule an action plan for ensuring that FY 2011 HCRIS and MedPAR data will be available for allowing the implantable device cost center to be used for calculating MS-DRG relative weights for FY 2014.

II. New Cost Centers for CT and MRI

In the IPPS FY2011 final rule, CMS implemented new standard cost centers for CT and MRI. AdvaMed continues to be concerned about the accuracy of the data reported to the cost center in that it may not capture capital costs for CT and MRI equipment that have been allocated across the entire hospital, rather than to the radiology cost center. We encourage CMS to continue focusing on ensuring that hospitals accurately report operating and capital costs for these cost centers.

III. Proposed Adjustments for Documentation and Coding Changes

AdvaMed continues to recommend that CMS reconsider the methodology it has adopted for separating documentation and coding effects from case-mix change calculations in its retrospective and prospective adjustments required by law. AdvaMed recommends that
CMS test a range of regression models to estimate changes in documentation and coding. In addition, CMS should supplement claims data analysis with medical records analysis for distinguishing documentation and coding from real case-mix changes, in order to ensure accuracy in its estimates of both case-mix and documentation and coding changes.

The proposed rule notes that Medicare statute does not specify when CMS must apply the prospective adjustment for documentation and coding changes, only that CMS make an appropriate adjustment for these effects. The proposed rule adds that because the law is not prescriptive as to when the prospective adjustment must take place, CMS believes that it has some discretion as to the manner in which the agency applies the adjustment. For FY 2013, CMS proposes to capture the entire remaining prospective adjustment the agency has estimated to be necessary for recovering overpayments during 2008-2009 due to documentation and coding changes; this adjustment would reduce operating standardized amounts by 1.9 percentage points. CMS also proposes to apply an additional reduction of 0.8 percentage points for recovering documentation and coding overpayments during FY 2010. Together these two adjustments will result in a total reduction of 2.7 percentage points for operating standardized amounts for FY 2013. Not only is the amount excessive because of the methodology CMS has used to estimate documentation and coding effects that do not reflect real changes in case-mix, but it is also an excessive adjustment to make in one fiscal year.

If CMS does not change its methodology for estimating documentation and coding effects of MS-DRGs, AdvaMed recommends that CMS phase in the 2.7 percentage point prospective reduction over a three-year or longer period of time. If CMS were, for instance, to phase in the prospective reduction over a three-year period, the 2.7 percent FY 2013 reduction would become 0.9 percent, thereby increasing the proposed update to the national operating standardized amounts by the same amount. A longer phase-in is appropriate for a time when MedPAC projects negative Medicare margins of 7 percent for inpatient hospitals services in 2012. The longer phase-in is also critical because hospitals will receive a 2 percent reduction in their 2013 Medicare payments under the sequestration provisions of the Budget Control Act of 2011.

IV. New Technology Add-On Payments

The approval rate for applications for inpatient hospital new technology add-on payments over the past several years signals that the policy is not providing an effective program to ensure beneficiary access to new technologies. Overly restrictive criteria for considering and approving applications for add-on payments has resulted in few approvals in any one year, as shown in the table below. By our calculations, CMS has approved only 8 applications for new-tech add-on payments since 2005, and only 4 applications since 2007. The restrictive framework has had a chilling effect on the interest of the medical technology industry—one of this country’s most innovative industries—in submitting applications for consideration of approval.
### Applicants and Approvals for New Tech Add on Payments

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AdvaMed has long argued for the need for changes in existing new tech add-on policies. We continue to believe that these changes are critical for maintaining and improving access to innovative technologies. AdvaMed believes that the current new-technology payment methodology can be improved in two ways.

First, AdvaMed strongly supports increasing the add-on payment levels from 50 to 80 percent of the difference between the standard MS-DRG payment and the cost of the procedure with the new technology. Increasing the payment percentage is one improvement that would encourage more medical technology innovation and beneficiary access to that technology.

Second, AdvaMed encourages CMS to make the assignment of a new ICD code or FDA approval—whichever is later—the controlling date, for starting the eligibility window for a new technology payment. Under the current policy, the 2 to 3-year period of "newness" for a technology or medical service 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 MedPAR data. With two-year lags in the MedPAR claims data and even longer lags in the final Medicare cost report data used to determine the payment rates, new technologies will not be fully recognized in the CMS data for several years after they are introduced, assigned an appropriate code, and identifiable in the data. Given these lags, it is even more important that the new technology add-on payment eligibility window is applied appropriately. In cases where an applicant can demonstrate a documented delay in market availability subsequent to FDA approval, CMS should delay the start of the newness period.

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

V. ICD-10

As CMS continues to refine the hospital payment system, AdvaMed reiterate our support for moving to the ICD-10 classification system. The use of ICD-10 would allow for 1) more specific and accurate representation of current and future medical procedures and diagnoses than is possible with the 30-year old ICD-9 system, and 2) more accurate and discrete data for health care billing, quality assurance, public health reporting, and health services research. By moving to the new system, CMS would keep pace with changes in medical practice and health care delivery. Continued delays will result in the need to duplicate resources in order to transition to the ICD-10 system. The Notice of Proposed Rulemaking regarding adoption of the ICD-10 coding systems was published in August, 2008, with an initial implementation date of October 2011. After several years of delay, it is time to move forward.

The FY 2013 Hospital Inpatient Prospective Payment System (IPPS) proposed rule proposes a modification of the ICD-9 freeze schedule to include an additional limited update to the ICD-9-CM code set on October 1, 2013 if ICD-10 implementation is delayed until October 2014. AdvaMed supports the recommendation which provides for limited updates to the ICD-9 code set in October 2012 and October 2013. However, we also recommend that CMS provide a limited update to the ICD-9 code set on October 1, 2014. These adjustments to the code freeze schedule will assure that the necessary ICD-9 codes are available for use until ICD-10 is implemented.

VI. Hospital Inpatient Quality Reporting (IQR) Program: Hospital Readmission Reduction Program

In the FY 2012 final rule, CMS identified three conditions, Acute Myocardial Infarction (AMI), Heart Failure (HF) and Pneumonia (PN) to be used for the Hospital Readmissions Reduction Program, under which payments to certain hospitals will be reduced to account for excess readmissions. In the FY 2012 IPPS Final Rule, CMS stated its intention to explore whether there are additional readmissions that could be excluded from the readmission measures that were finalized in that rule and noted that it likely would solicit public input on this issue in future rulemaking. CMS noted that these potential revisions would need to be NQF-endorsed.
AdvaMed wishes to reiterate some of the comments related to the exclusion criteria of the three CMS-adopted, NQF-endorsed, risk-standardized readmission measures that are currently in the hospital IQR program:

- Acute Myocardial Infarction (AMI) 30-day Risk Standardized Readmission Measure (NQF#0505)
- Heart Failure (HF) 30-day Risk Standardized Readmission Measure (NQF#0330); and
- Pneumonia (PN) 30-day Risk Standardized Readmission Measure (NQF#0506)

CMS adopted the measures and related methodologies as they were currently endorsed by NQF, concerned that if it modifies the endorsed measures, they would no longer be considered “endorsed”. This included the exclusions for unrelated admissions set forth in the existing NQF-endorsed measures. Although all three have been endorsed by the NQF, only one of these measures, AMI, contained some minimal exclusion criteria for readmission, namely exclusions for some planned readmissions related to percutaneous transluminal coronary angioplasty (PTCA) and coronary artery bypass graft procedures (CABG). The other two measures, dealing with heart failure and pneumonia, did not contain exclusion for diagnostic measures of readmission. Considerations of these exclusions are essential in developing a consistent and credible readmissions reduction program as many readmissions are clearly beyond a hospital’s control.

The current AMI exclusions are too limited in scope. In the case of heart failure, especially in patients with severe disease, several readmissions may be contemplated, for example placement of heart defibrillators, angioplasty, and surgeries such as bypass grafts or, in rare instances, heart transplants. For example, a patient being readmitted for heart transplant within 30 days and a patient returning for a planned implantation of a ventricular assist device (VAD) would not be excluded from heart failure readmission. The potential unintended consequence is that physicians may not release a patient home to prepare them for VAD implantation and would have to keep the patient unnecessarily hospitalized to avoid the readmission count. This is not practical and not cost effective. In the case of pneumonia -- depending upon the type, cause and underlying condition (e.g., coronary disease) -- there are several potentially planned readmissions circumstances which could be foreseen, including planned readmissions for contemplated treatment/surgery post resolution of the pneumonia.

AdvaMed strongly suggests that CMS review and re-evaluate the readmissions measures in detail and provide a comprehensive set of planned and unrelated readmissions conditions for each readmission measure sets. CMS should request that NQF then re-evaluate these measures and update them regarding the planned and unrelated admissions conditions. Patients with certain conditions which, by their very nature, necessitate potential readmissions such as trauma, cancer, end-stage diseases, and others should be excluded from readmission measures. CMS should consider including a modifier code on the hospital claims forms which specifically identifies a planned readmission to avoid unintended consequences of hospital performance. By providing a more comprehensive approach and including many of the suggestions above, CMS can
provide hospitals with the tools that they need to decrease readmissions while trying to improve quality of care for patients.

VII. Hospital Value-Based Purchasing Program

1. Efficiency Measure: Medicare Spending Per Beneficiary

CMS has proposed to add to the Hospital Value-Based Purchasing Program for the FY 2015 payment determination the Medicare Spending per Beneficiary measure, which was adopted for the Inpatient Quality Reporting (IQR) Program. The Measure Applications Partnership (MAP), in its final 2012 Pre-Rulemaking Report specifically could not support the inclusion of the Medicare Spending per Beneficiary measure in the VBP, due in-part to its lack of NQF-endorsement. Therefore,

*AdvaMed urges CMS to withdraw the proposed efficiency measure for the value-based purchasing program until such time that it is submitted and endorsed by NQF for use in this context.*

The proposed resource use measure conveys information about estimated costs of treatment and is devoid of any information concerning the quality of care provided as it relates to those costs. It is necessary to include appropriate quality data -- together with cost data -- so that the achievement of performance standards can be accurately displayed. AdvaMed is also concerned that application of such a cost measure could result in reduced provision of needed care and reduced access to appropriate care in an effort to limit costs, especially when applied in an incentive program. Well-designed quality measures can help to ensure that patients are receiving the right types of treatment to achieve desired health outcomes. AdvaMed encourages CMS to develop more appropriate efficiency measures that consider the costs in conjunction with quality across varied episodes of care.

2. Risk Adjustment Concerns For Both Readmissions and Spending Per Beneficiary Measures

AdvaMed recognizes the importance of considering risk adjustment factors in the development and implementation of the readmission measures and the proposed Spending per Beneficiary Efficiency measure. However, we are concerned regarding the risk-adjustment methodologies for both of these measures. Risk adjustment is a key element that must be valid, reproducible, sensitive and specific. Any flaws that may be present in the risk-adjustment methodology can potentially lead to flawed conclusions and therefore compromise the validity of the resultant conclusions. Thus it is important to consider as many relevant variables as possible in developing these models. Age, sex, race, severity of illness and clinical covariates, socioeconomic status, other concurrent treatments/interventions and their associated intensity/complexity and sources of co-morbidity should be considered factors in risk adjustors. The potential patient-specific side effects and adverse reactions associated with the different therapies and interventions
may also need to be considered. Notably absent from many discussions on determination of risk stratification factors are individual patient measures such as functional status or ability to ambulate/range of motion. AdvaMed strongly believes that these patient-specific factors should be included in the risk stratification for these measures, as they vary from patient to patient and can play a very significant role in contributing to outcome measurements, potential readmissions and estimated costs, especially in the post-surgical setting.

3. Proposed Efficiency Domain for FY 2015

CMS is proposing to add the Efficiency domain to the Hospital VBP program beginning with the FY 2015 program. Consequently, CMS is proposing the following domain weights for the FY 2015 program for hospitals that receive a score on all four proposed domains: clinical process of care--20%; patient experience of care--30%; outcome--30%; and efficiency--20%. CMS states that “this domain weighting appropriately reflects our priorities for quality improvement in the inpatient hospital setting and aligns with the National Quality Strategy’s priorities.” CMS also notes that the proposed weighting scheme “places the strongest relative emphasis on outcomes and patient experience,” while incorporating a measure of efficiency for the first time. CMS, however, does not detail how it determined the resulting weighting scheme or provide any background as to the determination of weighting for the efficiency domain. For example, CMS does not describe if any evidence base was used to support the development of the scheme.

As proposed, the efficiency domain currently only includes one measure -- Medicare Spending per Beneficiary. As a result, this sole measure is assigned a 20% weight of the total score, making the performance score on that single measure quite substantial. Thus, we believe that the efficiency domain, at this stage, is disproportionately weighted and represented, when viewed in the context of the other domains and their contents. AdvaMed believes that ample emphasis should be placed on achieving outcomes, providing quality clinical processes, and improving patient experience. AdvaMed suggests that CMS reduce the proposed weight for the efficiency domain from 20% to 10%, which would result in a weighting scheme that provides a more balanced and adequate representation of the remaining domains.

VIII. “Cardiac Surgery Patients with Controlled 6 AM Postoperative Glucose” Measure and Proposed Measures to Assess Adequate Glucose Control

AdvaMed suggests that CMS revise the proposed measure “Cardiac surgery patients with controlled 6 AM postoperative serum glucose” to be consistent with the recently updated NQF-endorsed measure “Cardiac surgery patients with controlled postoperative blood glucose (less than or equal to 180 mg/dl) in the timeframe of 18 – 24 hours after anesthesia end time.”¹ As part of its measure maintenance process, NQF updated this measure with the revised measure endorsed in January 2012. The measure was revised to

coincide with updated clinical guidance and responses from the NQF Steering Committee during the measure endorsement maintenance process. Specifically, the revisions to the measure centered on the timing of postoperative blood glucose measurement. The NQF Steering Committee recommended changing the measure from the 6 AM time frame to the currently endorsed timeframe of 18 to 24 hours. The CMS Surgical Care Improvement Project - SCIP Technical Expert Panel agreed with the recommendation. The resulting measure change was incorporated into the measure through the NQF endorsement process. Additional evidence-based support for changes to the measure stemmed from The Society of Thoracic Surgeons (STS) published Class I Recommendations which indicate that patients -- with and without diabetes -- with persistently elevated serum glucose (>180 mg/dL), should receive IV insulin infusions to maintain serum glucose <180 mg/dL for the duration of their ICU care. STS recommends that a target blood glucose level <180 mg/dL should be achieved in the peak postprandial state for patients in step down units and on the floor. For these reasons, AdvaMed recommends that CMS revise this measure to align with the updated NQF-endorsed version.

IX. Hospital-Acquired Conditions (“HAC”)

1. Classification of AKI as a HAC

AdvaMed continues to support CMS’s proposal to delay action on classifying Contrast-Induced Acute Kidney Injury (“AKI”) as a Hospital-Acquired Condition (“HAC”) until improved coding is available. CMS’s efforts to reduce the incidence of HACs are commendable. However, HAC status can result in significant financial penalties for hospitals, and CMS should ensure that only appropriate, preventable conditions are selected as HACs.

Additionally, AdvaMed continues to have concerns about the ability of providers to prevent AKI through the application of current evidence-based guidelines. While additional guidelines have been released since the 2012 Final Rule was published, there remains considerable uncertainty about the pathogenesis of AKI and the ability of providers to prevent the condition. Therefore, if CMS classifies AKI as a HAC before clear prevention guidelines exist, hospitals could be inappropriately and unfairly penalized for a condition that was not reasonably preventable. Accordingly, AdvaMed supports CMS’s proposal to delay action on the AKI determination until coding is improved to allow for proper identification of AKI as a HAC and clear prevention guidelines are more fully developed.

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2 ibid.
X. Possible New Quality Measures for Future Years

1. Malnutrition Measures

AdvaMed believes that malnutrition evaluation measures, if endorsed in the future by NQF, should be added to the IQR.\(^4\) The Department of Health and Human Services’ (HHS) National Quality Strategy and the Measures Application Partnership (MAP) convened by the National Quality Forum (NQF) have prioritized patient safety and care coordination measures for federal quality programs. In a report submitted to HHS in February 2012, the MAP listed Hospital Program Priority Measure Gaps that were identified by the MAP and/or the public, including malnutrition. The report also listed malnutrition for consideration in post-acute care/long-term care performance measurement programs.\(^9\)

Malnourished hospitalized patients experience significantly higher incidence of total complications when compared to well-nourished patients, such as increased risk of nosocomial infections,\(^10\) pressure ulcers,\(^11\)-12 and pneumonia.\(^13\) Inclusion of malnutrition measures in the IQR would provide an opportunity to address both patient safety and care coordination, since malnutrition contributes to increased mortality and morbidity, longer hospitalizations, and the increased likelihood that patients will be readmitted to a health care facility or require ongoing services. Malnutrition and loss of lean body mass in patients with chronic disease must be identified and addressed early in the hospital, long-term care, and ambulatory care settings or they can lead to poor health outcomes and hospital readmissions.\(^14\)-15

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\(^6\)Braunschweig C, Gomez S, Sheean PM. Impact of declines in nutritional status on outcomes in adult patients hospitalized for more than 7 days. *J Am Diet Assoc.* 2000;100:1316-1322.
\(^7\)Mechanick, JI. Practical aspects of nutritional support for wound-healing patients. *Am J Surg.* 2004;188:52S-56S.
Screening patients for malnutrition/risk of malnutrition, nutrition assessment and timely interventions (e.g., dietary counseling, the use of appropriate oral supplements, and tube feeding or parenteral nutrition when indicated) can improve patients’ health status and reduce costs, complications, and readmissions. We urge CMS to explore the adoption of a malnutrition quality measure to encourage such screenings, assessments, and interventions as soon as feasible.

2. **Quality Measures That Encourage the Use of Technology to Improve Care and Prevent Hospital-Acquired Conditions (HACs).**

In the IPPS FY2013 proposed rule, CMS proposes to designate iatrogenic pneumothorax with venous catheterization as a HAC for Medicare payment purposes. AHRQ’s 2001 published report “Making Health Care Safer: A Critical Analysis of Patient Safety Practices” (AHRQ Publication No. 01-EO85), recommends the use of ultrasound for the placement of all central venous catheters. Iatrogenic pneumothorax with venous catheterization is highly preventable with the use of ultrasound guidance. Using this method, fewer complications from needle placement result in improved patient outcomes and greater clinician efficiency. Accordingly, we agree that CMS should include this among the conditions subject to Medicare’s HAC policies.

3. **Future Measures Addressing Sepsis in the IQR Reporting Program**

AdvaMed recommends that CMS consider an additional measure area for the IQR program to address a condition that is high-impact and high-burden: addressing the importance of timely treatment of sepsis and septic shock. Sepsis is a devastating condition that has considerable impact to patients, hospitals and the overall health system, with a severe impact on the Medicare system as the third most expensive condition billed to Medicaid and most expensive billed to Medicare. There are an estimated 1.14 million cases of sepsis or septicemia in the U.S. every year. With mortality rates in excess of 28%, sepsis is a leading cause of death. AdvaMed recommends that in future rulemaking cycles, CMS consider including additional quality measures related to sepsis management and treatment in the IQR program, for example, the NQF-endorsed measure: Severe Sepsis and Septic Shock: Management Bundle (NQF #0500): Initial steps in the management of the patient presenting with infection (severe sepsis or septic shock). In addition to being NQF-endorsed, this sepsis quality measure has also been used and tested in The Surviving Sepsis Campaign (SSC), which established guidelines for sepsis management. This, and additional management of sepsis measures, should be vetted via the MAP in the near future for pre-rulemaking recommendations back to HHS and potential inclusion in subsequent rulemaking.

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4. Future Additional Measures to Assess Adequate Glucose Control

AdvaMed recognizes the importance of measuring and controlling postoperative serum glucose and its role in reducing morbidity and improving patient outcomes. AdvaMed encourages CMS to consider including additional measures related to glycemic control in future rulemaking cycles which may encompass a broader population beyond those in the post-op cardiac setting. Optimized glycemic control via close monitoring and treatment of hyperglycemia has become an emerging standard of care, especially among critically ill patients.¹⁹

If you have any questions or comments please contact Richard Price at (202) 434-7227 or rprice@advamed.org.

Sincerely,

[Signature]

Ann-Marie Lynch