June 25, 2013

Marilyn Tavenner, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Ave, SW
Washington, DC 20201

Re: Medicare Program: Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2014 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 2014 rates (CMS-1599-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. Refinement of MS-DRG Relative Weight Calculations for Implantable Devices and Cardiac Catheterization

AdvaMed commends CMS for its decision to move forward with using a new “Implantable Devices Charged to Patients” and the Cardiac Catheterization cost-to-charge ratios in the recalibration of MS-DRG weights for FY 2014. We have long supported the use of the new cost center as a solution to the problem of charge compression for implantable medical devices and cardiac catheterization in cost-based weights. In so doing, the agency will be addressing a longstanding bias in the weights due to “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 and cardiac catheterization. Notable independent researchers, including 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. AdvaMed is pleased that CMS has resolved data issues for implantable devices and cardiac catheterization and recommends that the agency finalize the proposal to use the
implantable devices and cardiac catheterization cost-to-charge ratios (CCRs) in calculating FY 2014 payments.

II. New Cost Centers for CT and MR

While AdvaMed supports the use of the Implantable Devices and the Cardiac Catheterization cost centers, CMS should not implement the proposed new cost-to-charge ratios for CT scans and MRs. AdvaMed continues to be concerned about the accuracy of data in the CT and MR cost centers. We asked our consultant, Direct Research LLC, to analyze CT and MR capital reporting for IPPS hospitals reporting CT, MR, and Other Radiology separately on the 2552-10 cost reports. The analysis found that many hospitals report little to no equipment capital cost for CT and MR.

We believe that using the data currently available from the new cost centers for CT and MR will ultimately lead to cost estimates that are inaccurate. Specifically, our consultant found that the estimated costs for CT and X-ray studies were roughly equal when computed with single claim OPPS data from hospitals that used separate CT and MR cost centers. For example, the estimated cost of a CT scan of the abdomen would be $95 while the estimated cost of an X-ray of the abdomen would be $93, and the cost of a CT scan of the head/brain would be $84 while the estimated cost of an x-ray of the skull would be $82. Such an outcome appears to be highly inaccurate, given that advanced imaging technologies require more substantial investments in equipment, have substantially larger service costs, require higher-skilled technologists, take longer to perform, have more diagnostic power, and yield results with greater clinical value.

Research conducted by the Research Triangle Institute, International (RTI) under contract with CMS to study the effects of charge compression anticipated the difficulty of establishing accurate cost-to-charge ratios for CT and MR services. According to the report, “[CT and MRI] services are very capital-intensive, and accurate cost ratios will depend on providers’ being able to assign actual equipment depreciation and lease costs directly to the cost centers, rather than the traditional method of allocating average capital costs based on square footage.” When RTI examined data from hospitals that reported costs for CT and MRI services on nonstandard lines, they found that “many facilities had very low cost ratios on these nonstandard lines, including many below 0.05.” RTI noted, “that this raises questions about the relative accuracy of [the hospitals’] cost finding.”

Another source of potential data error is the fact that hospitals are still familiarizing themselves with various aspects of the new cost report form. More specifically, the 2552-10 Medicare cost report form was effective for cost reporting periods beginning on or after May 1, 2010, and many hospitals began reporting separately for MR and CT cost centers during the first year of the new cost report form. Hospitals’ lack of familiarity

1 RTI 2007 at p. 65, fn. 20.
2 Id., at p. 65.
3 Id.
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with these components of the cost reporting process may also generate cost reporting errors.

CMS has also indicated its intent to extend use of data from separate CT and MR cost centers to Outpatient Prospective Payment System (OPPS) payment calculations beginning in CY 2014.\(^5\)

The payment rates for the Ambulatory Patient Classifications in the OPPS would be more dramatically impacted by the use of inaccurate CT and MR imaging cost centers than the CT and MR imaging procedures performed as part of a hospital admission. Moreover, implementation of these new imaging cost centers in the OPPS will impact the Physician Fee Schedule (PFS), as the Deficit Reduction Act limits PFS technical component payments to the level of corresponding OPPS payment for the same service.\(^6\)

AdvaMed urges CMS not to use the proposed CCRs for MRs and CT scans in the IPPS, OPPS, or the PFS until the effects on all three systems have been thoroughly analyzed.

AdvaMed believes that CMS should provide a greater focus on educating hospitals about the importance of accurate cost reporting for MR and CT services. In addition, CMS should establish and communicate specific criteria for assessing the validity of data from the new CT and MR cost centers and only use data from those new cost centers if they meet those criteria. If a hospital’s data do not meet those criteria, CMS should continue to use the data from the original Radiology cost center to determine CCRs for CT and MR.

III. Policy Proposal on Admission and Medical Review Criteria for Hospital Inpatient Services

In the proposed FY 2014 IPPS rule, CMS proposes to reduce the update to the standardized MS-DRG payment amounts by 0.2% for new medical review criteria that would establish a presumption that hospital inpatient care is reasonable and necessary for beneficiaries who require more than one Medicare utilization day (defined as encounters crossing 2 midnights) after admission. AdvaMed is concerned with CMS’s proposal to make this budget neutral adjustment on the basis of its estimate that the new coverage policy will increase inpatient admissions and therefore Medicare spending. Neither Medicare law nor regulation requires CMS to make budget neutrality adjustments for changes in inpatient coverage decisions or the volume of services. AdvaMed is also concerned that the new policy would establish an unreasonable presumption that an inpatient stay of less than 2 midnights after admission is not reasonable and necessary and would result in burdensome medical reviews for hospitals when in certain cases an inpatient stay is required. For these reasons, AdvaMed recommends that CMS not finalize the update reduction proposed for the medical review criteria.

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\(^5\) Hospital Outpatient Prospective and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Electronic Reporting Pilot; Inpatient Rehabilitation Facilities Quality Reporting Program; Quality Improvement Organization Regulations, 77 Fed. Reg. 45061 (July 30, 2012).

IV. New Tech Add-On Payments

CMS has approved only 11 applications for new tech add-on payments since 2005, with CMS approving none or at most one application in several of those years. We were pleased that in 2012, CMS approved 3 applications. AdvaMed believes that the restrictive framework for approving applications 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.

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 will consider delaying the start of the newness period. However, AdvaMed recommends that the process be simplified for applicants from the outset by requiring CMS to use the later of either the assignment of a new code or FDA approval as the controlling date.

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. Hospital Readmission Reduction Program

1. NQF measure #1551 – Hospital-Level 30-Day All-Cause Risk-Standardized Readmissions Rate (RSRR) Following Elective Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA)

In the Proposed Rule, CMS proposes to expand the existing hospital readmissions reduction program measures to include a measure related to readmissions following elective hip and total knee replacements. Specifically, CMS proposes to include NQF measure #1551 – Hospital-Level 30-Day All-Cause Risk-Standardized Readmissions Rate (RSRR) Following Elective Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA). The agency proposes to include this measure, updated with the CMS planned readmission algorithm adapted for THA/TKA and excluding transfers, in the Hospital Readmissions Reduction Program beginning in FY 2015. AdvaMed supports the addition of this quality measure to the Hospital Readmissions Reduction Program. The number of hip and knee replacements performed on Medicare beneficiaries is increasing each year demonstrating the importance of these procedures in maintaining a high quality of life for Medicare beneficiaries. The inclusion of this quality measure will help ensure that Medicare beneficiaries are successfully transitioned from acute-care settings to post-acute care settings.

As an NQF-endorsed measure with broad support, this measure would focus attention on reducing undesirable readmissions to incentivize higher quality care. Various programs at center of excellence hospitals have made significant inroads in lowering readmissions for these major orthopedic procedures, and we expect that the adding this measure to emphasis the Readmissions Reduction Program will further encourage better care.

2. Planned Readmissions

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. The specific measures that were finalized in that rule were the following:

- 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 previously endorsed by NQF, concerned that if CMS modified 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 had 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 AMI exclusions were 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 suggested 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. AdvaMed also recommended that CMS 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.

AdvaMed is pleased that CMS is addressing both planned and unplanned readmissions for these, and other measures in the FY 2014 proposed rule. CMS notes in the proposed rule that, in response to numerous comments from the medical community, other stakeholders, and the general public encouraging the agency to identify and not count as readmissions a broader range of planned readmissions, CMS worked collaboratively to develop an expanded “planned readmission algorithm.” The algorithm is part of the CMS...
Planned Readmission Algorithm Version 2.1 Report that identifies planned readmissions across the readmission measures. As a result, for FY 2014, CMS specifically proposes to apply the algorithm to the AMI, HF, and PN measures. CMS sought NQF endorsement of the revised measures for the three current applicable conditions (AMI, HF and PN), as required by the statute. NQF endorsed the revised AMI (NQF #0505) and HF (NQF #0330) measures in January 2013 and the PN measure (NQF #0506) in March 2013. AdvaMed supports the efforts by CMS to address planned readmissions in these measures and propose these revisions after they had received NQF endorsement.

In addition to the expanded list of planned readmissions through use of the algorithm, CMS is proposing that if the first readmission is planned, it will not count as a readmission, nor will any subsequent unplanned readmission within 30 days of the index readmission count as a readmission. As a result, unplanned readmissions that occur after a planned readmission and fall within the 30-day post discharge timeframe would no longer be counted as outcomes for the index admission. Although CMS states that this proposed change would affect a very small percentage of readmissions (approximately 0.3 percent of index admissions nationally for AMI, 0.2 percent for HF, and less than 0.1 percent for PN), we believe that these modifications are very important. AdvaMed supports this proposal, as this reflects a more realistic approach to more accurately address outcomes following planned readmissions in these circumstances. Additionally, AdvaMed wishes to reiterate that CMS should also consider including a modifier code on the hospital claims forms which specifically identify a planned readmission to avoid unintended consequences of hospital performance.

VI. Hospital Value-Based Purchasing Program

1. Value-Based Purchasing Measures Proposed for FY 2016

The Proposed Rule discusses several new measures CMS proposes to include in the FY 2016 Hospital Value-Based Purchasing (VBP) program. Specifically, CMS proposes to add a new outcomes measure – SSI for colon and abdominal hysterectomy procedures. AdvaMed strongly supports the addition of this new quality measure to the VBP program. Endorsed by the NQF and recommended by the Measure Applications Partnership (MAP) in February 2013 for inclusion in the IQR program, this measure has significant stakeholder support and would capture important information about the quality of care provided to Medicare beneficiaries while encouraging better care protocols aimed at reducing SSI risk.

2. Future VBP Measure for Complication Rate Following Hip & Knee Replacement

AdvaMed suggests that CMS add the NQF-endorsed quality outcome measure, “Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip
arthroplasty (THA) and total knee arthroplasty (TKA)” to the VBP program. This would be consistent with the MAP’s February 2013 recommendation to HHS. As this measure is currently scheduled for use in the IQR program for FY 2015 payment determination, hospitals will already be preparing to have their complication rate for these procedures reported on Hospital Compare.

It would encourage the development of multidisciplinary teams (surgical specialists, infectious disease consultants, and nurses, among others) within hospitals, thus leading to improved care. We are also aware of orthopedic surgeons that have made significant strides in reducing complications after joint arthroplasty, and we believe the addition of this measure will lead to further quality efforts in this area.

3. **Proposed VBP Measures for Radiation Dose Tracking**

In light of the widespread use of imaging technologies, CMS is adding five radiation dose optimization quality metrics to the Physician Quality Reporting System (PQRS), effective January 1, 2014. In addition to supporting the PQRS metrics, AdvaMed urges the agency to incorporate radiation dose optimization measures into the hospital inpatient VBP program so as to align quality metrics across both physician and hospital quality reporting systems.

4. **Proposed Efficiency Domain Weighting Change for FY 2016**

CMS proposes to modify the domain weights used to calculate a hospital’s total performance score so that clinical process of care measures would receive less weight (10% compared with 20% in FY 2015) and HCAHPS would receive less weight (25% v. 30%), while more weight would be given to the outcomes (40% v 30%) and efficiency (25% v 20%) domains. 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 whether any evidence base was used to support the development of the proposal.

As proposed, the efficiency domain currently only includes one finalized measure -- Medicare Spending per Beneficiary. This sole measure is currently assigned a 20% weight of the total score, making the performance score on that single measure quite substantial. A single calculation of Medicare spending per Beneficiary is insufficient to measure efficiency. In many cases, an intervention may increase costs within a limited window, but provide greater value over a longer period of time. AdvaMed strongly recommends that CMS reduce, not increase, representation of the efficiency domain until such time that CMS has a significant number of new NQF-endorsed and MAP supported efficiency and corresponding outcome measures available for implementation. Without such changes, CMS would continually over-weight this domain when viewed in the context of the other domains and their contents. It would also further highlight the

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markedly unbalanced nature of this proposal and does not provide for adequate representation of the remaining domains.

VII. Hospital Inpatient Quality Reporting (IQR) Program:

1. Additional Hospital IQR Measures for the FY 2016 Payment Determination and Subsequent Years

CMS proposes to add five new measures to the Hospital IQR Program measure set for the FY 2016 payment determination and subsequent years. The proposed new measures are:

- Hospital 30-day All-Cause Risk Standardized Readmission Rate following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1891)
- Hospital 30-day All-Cause Risk Standardized Mortality Rate following COPD Hospitalization risk (NQF #1893)
- Hospital 30-day All-Cause Risk Standardized Rate of Readmission Following Acute Ischemic Stroke
- Hospital 30-day All-Cause Risk Standardized Rate of Mortality Following an Admission for Acute Ischemic Stroke
- Hospital Risk-Standardized Payment Associated with a 30-Day Episode of Care for Acute Myocardial Infarction (AMI)

The proposed readmission and mortality measures for Chronic Obstructive Pulmonary Disease are NQF-endorsed measures that were supported for addition to the IQR program by the MAP. In the proposed rule, CMS notes the high incidence of COPD, which has been identified by AHRQ as an ambulatory-care-sensitive condition for which hospitalization can potentially be prevented. CMS also believes that data on variation in hospital mortality rates for these patients suggest opportunities for improving care. AdvaMed supports the addition of these NQF-endorsed and MAP recommended COPD measures to address this serious issue.

Regarding the proposed readmission and mortality measures for acute ischemic stroke, CMS acknowledges that these measures are not NQF endorsed or supported for inclusion by the MAP. Nevertheless, in the proposed rule CMS notes that adoption of the measure is imperative because it aims to address a prevalent and costly health problem, and because it aligns with priority quality improvement objectives. AdvaMed agrees that this is a serious health concern, but strongly urges CMS to work with the MAP and NQF to refine these readmissions and mortality measures -- or develop/consider alternate measures -- that can be supported by the MAP and meet the standards for NQF endorsement.

Likewise, the proposed measure of risk-adjusted payment per episode of care for AMI patients is not NQF endorsed, and MAP support was made contingent on NQF endorsement. In the proposed rule, CMS however notes that this measure would provide valuable information on the substantial variation in the cost of care for AMI patients and
would be paired with the current 30-day AMI mortality and readmission measures. AdvaMed strongly recommends that CMS accepts MAP’s recommendation and submit the measure for NQF-endorsement, as MAP’s support was contingent on successful passage through the NQF endorsement process.

2. Proposed Refinements to Hospital IQR Program Measures

   a. Proposed Expansion of CLABSI and CAUTI Measures

AdvaMed supports the proposal by CMS to expand the CLABSI and CAUTI measures to select non-ICU locations beginning with infections occurring on or after January 1, 2014, to medical, surgical, and medical/surgical wards. As the prevalence of the use of urinary and central venous line catheters outside the setting of the ICU is significant, this would allow hospitals that do not have ICU locations to use these tools and resources for quality improvement and public reporting efforts.8,9,10

   b. Proposed Refinement of SCIP-INF-4: Cardiac Surgery Patients with Controlled 6 AM Postoperative Serum Glucose in the Hospital IQR Program

AdvaMed recognizes the importance of measuring and controlling postoperative serum glucose and supports the continued inclusion of this care process and outcome in the IQR program. Potential for cost savings exist if patient outcomes are improved and the length of stay is reduced as a result of glycemic control. AdvaMed supports the proposal to adopt changes to SCIP INF-4: “Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose in the Hospital IQR Program,” beginning with January 1, 2014 discharges. As CMS noted in the proposed rule, the National Quality Forum (NQF) Steering Committee voted to change the measure from controlled glucose at 6AM to a more comprehensive controlled glucose 18-24 hours post-surgery for cardiac surgery patients. The specifications also require corrective action to be documented if a post-operative glucose is over 180 mg/dl.

In our comments on the FY 2013 IPPS proposed rule, AdvaMed suggested that CMS revise the proposed measure “Cardiac surgery patients with controlled 6AM 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.”11 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 recommended that CMS revise this measure to align with the updated NQF-endorsed version.

AdvaMed suggests that additional recommendations -- which are noted in “The Society of Thoracic Surgeons Practice Guideline Series: Blood Glucose Management during adult Cardiac Surgery”, the Society of Thoracic Surgeons (STS) -- be considered for inclusion in future changes to SCIP INF-4. They include: 1) requiring corrective action to be documented in cases of hypoglycemia and glycemic variability, 2) providing additional incentives to hospitals that provide more frequent measurement of blood glucose levels to ensure that episodes of hypoglycemia (<70mg/dL) or glycemic variability do not go undetected, and 3) extending the period of post-operative glucose monitoring and management for patients with diabetes undergoing cardiac surgery from 24 to 72 hours.

AdvaMed also recommends that the proposed adopted measure for the IQR program be updated in the Hospital Value-Based Purchasing Program for future reporting years. As noted in the proposed rule, the SCIP INF-4 measure has been finalized for FY 2014 and FY 2015 and proposed for FY 2016. AdvaMed encourages CMS to adopt the updated measure description for the Hospital Value-Based Purchasing program to reflect the more comprehensive controlled glucose 18 – 24 hours post-surgery to be in alignment with the NQF recommendations and the IQR program.

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

12 Id.
14 Id.
of hyperglycemia has become an emerging standard of care, especially among critically ill patients.\textsuperscript{15} In the future, as continuous glucose monitoring devices become available for use in the OR/ICU setting, there will be significant opportunities to improve patient care by increasing the timeframe of glucose monitoring postoperatively, increasing the frequency of blood glucose measurements and putting measures in place to monitor and track hypoglycemic events and glycemic variability.

VIII. Hospital-Acquired Conditions (“HAC”) Payment Reduction Program

1. Proposed Domain Approach to Determine the Total HAC Score

CMS proposes to adopt eight measures for the FY 2015 HAC Payment Reduction Program grouped into two domains. Proposed Domain 1 includes six Agency for Healthcare Research and Quality (AHRQ) Patient Safety Indicator (PSI) measures, which are claims-based measures calculated by AHRQ. Proposed Domain 2 includes two Centers for Disease Control and Prevention (CDC) healthcare associated infection (HAI) measures. Hospitals report on these measures through CDC’s National Healthcare Safety Network (NHSN).

While CMS believes that proposed Domain 1 would be simpler to interpret, it seeks comment on an alternative approach which, instead of the proposed six AHRQ Patient Safety Indicators, the AHRQ measure PSI 90, a composite of eight component AHRQ PSI indicators would be used. The eight components overlap partly but not completely with the proposed six measures. PSI-90 is included in the IQR program and is part of the VBP program measure set beginning with the FY 2015 payment determination.

AdvaMed appreciates CMS’ discussion of alternative Domain 1 measures in proposing its specific measure scoring methodology for the HAC Reduction Program. While not CMS’ preferred choice, the alternative approach also supports CMS’ efforts to identify and monitor adverse events and inform hospitals about patient safety performance. Given the severe burden and impact of sepsis on patients, hospitals, and the overall health system, AdvaMed recommends using PSI-90 as it includes an indicator related to sepsis management, “PSI-13 Postoperative sepsis rate” and wound dehiscence, “PSI-14 Wound dehiscence rate,” both of which can be improved with proper peri-operative treatment of patients at risk of post-operative complications. Moving toward outcomes-based measures such as the PSI-13 ensures overall improved care and enhancements in the health status of the patient.

2. New HAC Category for SSIs Following Caesarean-Section Births

Although Medicare serves mostly older patients, a substantial number of Medicare beneficiaries are of child bearing age. In fact, Medicare paid for roughly 14,000 births in

Almost a third of all babies in the U.S. are delivered via C-section,\(^{17}\) with certain patients, such as those with diabetes and other co-morbidities at particular risk for post-op SSI.\(^{18}\) To that end, AdvaMed urges CMS to create a new HAC category for SSI following caesarean-section births. This would encourage quality improvement and cost savings that result from treating C-section patients with all appropriate preventive approaches.

According to one study, adoption of a comprehensive clinical prevention program lowered post-operative SSI by 96% for C-section patients over a five-year period.\(^{19}\) This new measure would also be consistent with CMS’ proposal to add SSI following abdominal hysterectomy to the HAC Reduction and Value-Based Purchasing (VBP) programs. Enhanced SSI prevention protocols not only increase quality outcomes for patients, but also reduce health care expenditures through shorter hospital stays and avoided readmissions.

### IX. Possible New Quality Measures for Future Years

#### 1. Malnutrition Measures

AdvaMed commends CMS for its ongoing work to address nutritional needs for Medicare beneficiaries through updates to MS-DRG malnutrition severity levels (CMS-1588-F), proposal to grant hospitals the flexibility to allow qualified dietitians to order patient diets (CMS–3267–P), and recent discharge planning guidance revisions that require evaluation to consider the patient’s likelihood of needing post-hospital services including nutritional consultation and meal services (CoP at 42 CFR 482.43). These are all positive steps towards improving patient access to timely nutrition assessment and interventions.

Nevertheless, malnutrition continues to be a serious health issue for hospitalized patients, despite ongoing work in this area. One in three patients enters the hospital malnourished\(^{20,21,22}\) and more become malnourished during their stay.\(^{23}\) Existing hospital quality measures are limited as they only address individual metrics that may predict risk or identify a subset of malnourished or at-risk patients, e.g., Dehydration, and Pressure Ulcers. CMS has acknowledged the impact of under-nutrition (and obesity) on patient outcomes in ambulatory care settings with the implementation of a body mass index quality measure in the Medicare Shared Savings Program and in the Physician Quality

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16 August 31, 2012 Medicare Inpatient Prospective Payment System Final Rule, Page 53528.
19 Using a multi-faceted active change process and infection prevention to reduce post-op C-section infections. Jeanette Harris MS, MSM, BS, MT/CLSI(ASCP), CIC MHS Infection Prevention; Evelyn Hickson, RN, MSN, CNS, WCC Perinatal Clinical Nurse Specialist, Poster presented at SAWC Spring 2013.
Reporting System. Hospitalized patients, regardless of body mass, can suffer from undernutrition because of their propensity for reduced food intake which could be the result of poor appetite from illnesses, gastrointestinal symptoms, or reduced ability to chew or swallow. We believe that there continues to be a measure gap with nutritional screening, assessment, and intervention for malnourished and at-risk patients in the acute care setting.

Malnutrition in the hospital setting is common and costly -- both in terms of increased health care expenses and poorer patient health outcomes. The malnourished patients are two times more likely to develop a pressure ulcer; malnutrition/weight loss are risk factors for hospital-acquired infections and postoperative complications; patients with malnutrition or weight loss have 2.5 times the risk for surgical site infection; and 45 percent of patients who fall in the hospital are malnourished.

Nutrition can play a critical role in improving hospital patient outcomes and decreasing costs by reducing complications, unplanned readmissions, and length of stay. Studies have shown that nutrition intervention leads to significant improvements in patient outcomes with:

- 25% reduction in pressure ulcer incidence;
- 28% decrease in avoidable readmissions;
- 14% fewer overall complications;
- Average length of stay is reduced by approximately 2 days;
- Decreased mortality; and
- Improved quality of life.

Screening hospital patients for malnutrition/risk of malnutrition, assessment, and timely interventions (e.g., dietary counseling, use of appropriate oral supplements, and tube feeding or parenteral nutrition when indicated) improves patients’ health status and reduces costs, complications, and preventable readmissions. AdvaMed urges CMS to explore adoption of a malnutrition quality measure to help ensure that all malnourished and at-risk patients receive timely nutritional care upon admission and prior to discharge. AdvaMed believes that a hospital malnutrition quality measure also would complement current CMS efforts to improve patient care, including achieving Partnership for Patients goals and National Quality Strategy priorities, such as improved patient safety, prevention, care coordination, patient experience, and efficiency.


In the proposed rule, CMS emphasized its interest in moving to electronic reporting for all chart-abstracted and HAI measures in the IQR program, and indicates its intention to propose several measures that would be collected via EHRs for addition to the IQR program in future rulemaking including the Severe Sepsis and Septic Shock Management Bundle (NQF #0500).

AdvaMed supports CMS’ proposal for hospitals to report additional electronic measures to reduce the burden associated with chart abstracted measures. AdvaMed specifically supports the addition of the “Severe Sepsis and Septic Shock Management Bundle” measure to be collected via EHRs in the future. As CMS notes in the proposed rule, this measure has been recommended the Measures Application Partnership for inclusion in to the IQR program, thus is deemed as a high-burden, high-impact condition.

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 the 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. 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.

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This measure has proven success in improving outcomes among 165 hospitals around the world that voluntarily collected data to demonstrate the beneficial effects of the bundle as part of the SSC efforts.

AdvaMed believes that sepsis is an essential condition for CMS to address as part of the increased attention on infections and other hospital-acquired conditions. AdvaMed supports CMS’ efforts to reduce the burden associated with reporting chart abstracted measures by collecting this measure via EHR.

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

Sincerely,

/s/

Ann-Marie Lynch
Executive Vice President,
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