June 30, 2014

Ms. Marilyn Tavenner, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1607-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: Medicare Program: Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2015 Rates

Dear Administrator 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 2015 rates (CMS-1607-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. New Technology Add-On Payments

AdvaMed has long argued for the need for changes in existing new tech add-on policies. 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. By our calculation, CMS has approved only 14 applications for new tech add-on payments since 2005, with the agency approving none or at most one application in several of those years. We believe 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—to even submit applications for a new-tech add-on in payment.

We continue to believe that two specific 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: (1) add-on payment levels should be increased from 50 to 80 percent of the difference between the standard MS-DRG payment and the cost of the procedure with the new technology, and (2) CMS should make the assignment of a new ICD code, FDA approval (or other necessary government agency approval), or when the technology is marketed in the U.S. and adequate data representing a minimum number of cases are available—whichever is later—the controlling date, for starting the eligibility window for a new technology payment.

This year’s proposed rule raises additional concerns about the restrictive policies CMS uses for approving new tech add-on payments. In particular, we are concerned about statements made by CMS in the proposed rule regarding the evidence presented by several applicants for new technology add-on payments to demonstrate compliance with the substantial clinical improvement criterion. In a number of instances, CMS is critical of certain study designs, particularly non-inferiority studies, which CMS states may prevent it from being able to determine whether substantial clinical improvement has been shown.

AdvaMed has previously commented on the use of a variety of study designs that are appropriate for use in research supporting medical technology innovation. A study may be designed to measure non-inferiority when compared to conventional treatment, but the results of the study may demonstrate superiority in terms of other measures, such as reduced pain, decreased recovery time or shorter hospitalizations. In addition, study data that provide information regarding patient outcomes may be more important than whether the study was designed as a superiority trial or a non-inferiority trial. For example, a non-inferiority safety trial that studied quality of life endpoints may be more useful to patients in determining their treatment options than a superiority trial that does not study any quality of life endpoints. Such studies can result in improvements over earlier generation devices, allowing for advancements in product performance, techniques, and treatment protocols that will optimize patient care as the health care system collectively learns.

Mandating superiority trial design adds significant costs for sponsors, and limits access for patients. Many medical devices and technologies are developed for relatively small populations. A medical device may be developed for use with a very limited number of patients with a given medical condition, for which it would be difficult to achieve a large sample size in a clinical study, particularly if the study required a superiority design. In large, cardiac-oriented studies, for example, superiority studies could raise sample size requirements significantly (i.e., 1,000 versus 8,000 patients) and add a tremendous burden.

AdvaMed believes that a policy to require superiority studies, or at least to question non-inferiority studies, could have negative results, including delaying patient access to innovative treatments, improved care outcomes, curtailing innovation, and discouraging competition. CMS should give great weight to the totality of the evidence, including non-inferiority studies and other methodological approaches, as it considers approval of applications for new tech add-on payments.
II. Two-Midnight Policy

AdvaMed is concerned that the two-midnight policy established in the FY 2014 final rule has focused undue attention on shorter stays and creates a false notion that such stays are not appropriate inpatient admissions. We believe that this policy conflicts with the Medicare Benefit Policy Manual, which states:

An inpatient is a person who has been admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services. Generally, a patient is considered an inpatient if formally admitted as inpatient with the expectation that he or she will remain at least overnight and occupy a bed even though it later develops that the patient can be discharged or transferred to another hospital and not actually use a hospital bed overnight.

The physician or other practitioner responsible for a patient's care at the hospital is also responsible for deciding whether the patient should be admitted as an inpatient. Physicians should use a 24-hour period as a benchmark, i.e., they should order admission for patients who are expected to need hospital care for 24 hours or more, and treat other patients on an outpatient basis. However, the decision to admit a patient is a complex medical judgment which can be made only after the physician has considered a number of factors, including the patient's medical history and current medical needs, the types of facilities available to inpatients and to outpatients, the hospital's by-laws and admissions policies, and the relative appropriateness of treatment in each setting. Factors to be considered when making the decision to admit include such things as:

- The severity of the signs and symptoms exhibited by the patient;
- The medical predictability of something adverse happening to the patient;
- The need for diagnostic studies that appropriately are outpatient services (i.e., their performance does not ordinarily require the patient to remain at the hospital for 24 hours or more) to assist in assessing whether the patient should be admitted; and
- The availability of diagnostic procedures at the time when and at the location where the patient presents.

Admissions of particular patients are not covered or noncovered solely on the basis of the length of time the patient actually spends in the hospital. [Emphasis added]

Under original Medicare, the Quality Improvement Organization (QIO), for each hospital is responsible for deciding, during review of inpatient admissions on a case-by-case basis, whether the admission was medically necessary. Medicare law authorizes the QIO to make these judgments, and the judgments are binding for purposes of Medicare coverage. In making these judgments, however, QIOs consider only the medical evidence which was available to the physician at the time an admission decision had to be made. They do not take into account other information (e.g., test results) which became available only after admission, except in cases where
considering the post-admission information would support a finding that an admission was medically necessary.

Section 10, Chapter 1 of the Medicare Benefit Policy Manual (MBPM)

AdvaMed believes that the benefit policy manual continues to provide the best characterization of when inpatient care is appropriate.

We believe that the new policy is confusing for hospitals, physicians, and beneficiaries and is difficult to administer. It also contributes to an overuse of observation care services, which means higher out-of-pocket beneficiary expenses and impedes beneficiaries meeting the 3-day prior hospitalization requirement for skilled nursing facility (SNF) care.

In response to the questions posed in the FY 2015 IPPS proposed rule, AdvaMed does not have a position on a possible short-stay payment policy at the present time. We do, however, urge CMS to remove the presumption that inpatient stays lasting less than two midnights should be paid as outpatient cases. MACs and RACs should not deny inpatient admissions that are physician-ordered and properly documented. This correction should be made in the 2-midnight policy whether or not CMS establishes a short-stay policy. AdvaMed also recommends that CMS continue the moratorium on RAC enforcement until the 2-midnight policy is revised.

Furthermore, AdvaMed recommends that CMS convene, before moving forward with a specific short-stay policy, town hall meetings where stakeholders, including the device industry, can assist CMS in defining issues that must be addressed in a short stay policy and offer solutions for addressing these issues. The goal of any short stay policy should be to encourage hospitals and physicians to provide Medicare beneficiaries the most appropriate care in the most appropriate setting at the time the patient needs that care. An open and transparent process for stakeholders to offer their expertise and guidance and discuss appropriate options for a short-stay policy will help to achieve these goals.

III. Shoulder Replacement Procedures

The proposed rule would collapse MS-DRGs 483 and 484 into a single MS-DRG by deleting MS-DRG 484 and revising the title of MS-DRG 483 to read “Major Joint/Limb Reattachment Procedure of Upper Extremities”. Revision procedures would not be included in the collapsed MS-DRG 483. In addition, CMS notes that the MS-DRG does not meet all of the criteria for creating a CC and MCC subgroup.

AdvaMed supports this proposal to collapse MS-DRGs 483 and 484 into a single MS-DRG 483. The proposal will create a more clinically cohesive MS-DRG with similar complexity and resource consumption for procedures included in the MS-DRG and will ensure continued access to this important therapy for Medicare patients who can benefit from these procedures.
IV. Hospital Readmission Reduction Program

1. Proposed Addition of Coronary Artery Bypass Graft (CABG) to the Hospital Readmissions Reduction Program for FY 2017

AdvaMed supports the CMS proposal to add coronary artery bypass graft (CABG) surgery to the list of conditions in the readmissions reductions program for FY 2017. This addition recognizes that there is strong clinical evidence supporting various care protocols and medical technologies, such as negative pressure wound therapy (NPWT), that play a critical role in promoting wound healing and reducing the risk of deep sternal infections, which are particularly dangerous for these vulnerable patients.1,2,3

During the 2014 pre-rulemaking cycle, the NQF-MAP hospital workgroup conditionally supported this measure for use in the Hospital Readmissions Reduction Program. The condition for support was based on attainment of NQF endorsement. We are pleased that CMS subsequently submitted the Hospital-Level 30-Day All-Cause Unplanned Readmission Following Coronary Artery Bypass Graft (CABG) Surgery measure to NQF for endorsement on February 5, 2014 and we currently understand that NQF has recently recommended this measure for endorsement.

Given the devastating toll that sternal wound infections can play in relationship to CABG surgery, we believe the addition of this quality measure to the readmissions reduction program will encourage hospitals to consider all medical and technological approaches to reduce the risk of this dangerous complication.

V. Hospital Value-Based Purchasing Program (HVBP)

1. Proposed Addition of Total Joint Arthroplasty (TJA) Complications to HVBP Program

AdvaMed supports CMS’ proposal to add the NQF-endorsed quality measure of “Hospital-level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA)” (NQF #1550) to the HVBP program.

The addition of this measure to the VBP will further drive hospitals to boost their quality of care initiatives around this high-volume procedure that reduces pain and increases mobility for hundreds of thousands of Medicare beneficiaries each year. In addition, many quality measurement organizations, including the Measure Applications Partnership, have recommended that this measure be added to the VBP program.

References:
This measure is particularly significant because it captures multiple complications and adverse events at various post-op time intervals, and would give hospitals a common benchmark around which to organize their quality improvement efforts. As a major orthopedic procedure, a complication measure for total joint arthroplasty will result in considerable gains in patient outcomes and will provide hospitals additional incentives to strive for the best possible patient outcomes on this key quality measure. This measure will serve to enhance the multiple orthopedic reconstruction programs that use integrated clinical pathway programs to lower — or in some cases eliminate — adverse events surrounding TJA, and the addition of this measure will further boost these efforts.

Because of the importance of this quality measure in the VBP program, we ask that CMS consider flexible approaches in determining the baseline and performance periods, so as to allow this measure to be implemented sooner than FY 2019, perhaps by using slightly truncated baseline and performance periods. We are also pleased that CMS plans to add this measure to the Clinical Care-Outcomes domain, and encourage CMS to expand the portfolio of outcome-based quality measures in the HVBP program to cover more medical conditions, beyond the current PSI-90, CLABSI, CAUTI, SSI and mortality measures.

2. FY 2017 Efficiency Domain Weighting

In the FY 2015 rule, CMS is proposing a continuation of the increased weight of the efficiency domain at 25% for FY 2017. The efficiency domain currently only includes a single measure — the Medicare Spending per Beneficiary (MSPB) measure — which makes up 25% of the total performance score. The effect is that MSPB represents the most significantly weighted VBP measure.

As part of the Hospital VBP program, the MSPB assesses Medicare Part A and Part B payments for services provided to a Medicare beneficiary during a spending-per-beneficiary episode that spans from three days prior to an inpatient hospital admission through 30 days after discharge. The MSBP calculates a ratio based on a hospital’s average spending compared to a national median. There are currently few outcome measures that assess the quality of care or clinical outcomes that are factored into these assessments. However, the MSPB measure is solely a cost-based assessment.

AdvaMed supports the goal of improving efficiency within the healthcare system, which aims to achieve better outcomes at lower total health costs. However, the DRG system currently provides hospitals with strong efficiency incentives, and the VBP is intended to ensure that DRG payments are better targeted to care that is likely to achieve good outcomes. AdvaMed is concerned that basing 25% of the total performance score on a measure of cost comparison — with no quality component — will encourage hospitals to take steps to reduce Medicare expenditures with uncertain checks on the corresponding impacts on quality.

Using an efficiency measure without a quality component would be inconsistent with the goal of improving quality and outcomes, which underlies the intent of the VBP. AdvaMed encourages CMS to place more emphasis on the development of patient care outcomes measures, establishing proven clinical processes for care, and improving patient experience.
believes that measures aimed at improving efficiency should be well-grounded in current best evidence, and balance improved clinical outcomes concurrently with cost reduction. Therefore, AdvaMed continues to recommend that CMS reduce, not increase, representation of the efficiency domain until it has included efficiency measures that truly balance cost and quality within this domain.

3. Possible Episode-Based Measures for Inclusion in the Efficiency and Cost Reduction Domain in Future Years

CMS proposes to expand the efficiency domain to include six episode-based payment measures applying the Medicare Spending per Beneficiary model. These include three medical condition measures: 1) kidney/urinary tract infection; 2) cellulitis; and 3) gastrointestinal hemorrhage. They also include three surgical conditions: 1) hip replacement/revision; 2) knee replacement/revision; and 3) lumbar spine fusion/refusion.

AdvaMed commends CMS for identifying 6 specific clinical areas of interest and requesting comments, even before proceeding to propose these for reporting requirements. AdvaMed supports healthcare transformation moving toward better quality of care, patient outcomes, and lowering healthcare costs. Episode-based payment models have the potential to support such transformation if they are appropriately designed.

In the proposed rule, CMS indicates the criteria they used in selecting these six measures and which they will be using to select other types of episodes in the future. These criteria are the following:

1. The condition constitutes a significant share of Medicare payments for hospitalized patients during and surrounding the hospital stay;
2. The degree to which clinical experts consulted for this project agree that standardized Medicare payments for services provided during the episode can be linked to the care provided during the hospitalization;
3. Episodes of care for the condition are comprised of a substantial proportion of payments for post-acute care, indicating episode payment differences are driven by utilization outside of the MS-DRG payment;
4. Episodes of care for the condition reflect high variation in post-discharge payments, enabling differentiation between hospitals; and,
5. The medical condition is managed by general medicine physicians or hospitalists and the surgical conditions are managed by surgical subspecialists, enabling comparison between similar practitioner types within each episode measure.

AdvaMed is greatly disappointed that the concept of quality is totally absent from any of the criteria, listed above. AdvaMed believes that the “existence of appropriate quality measures” should be the first criterion in CMS’ evaluation of whether to develop and test episode-based models. AdvaMed requests that CMS provide more detail in these episodic measures relating to the quality of care relative to the costs measured. We believe that it is essential that episode-based payment models should only be considered for procedures or medical conditions for which quality measures exist to monitor key relevant outcomes.
AdvaMed is also concerned about episode-based measures that do not take into account all the complex factors that contribute to the cost of care. Not considering these factors may have the unintended consequence of putting providers at risk solely based on their selection of patients. The development of episode-based risk adjustments is a critical — but largely untested — requirement to a successful episode-based model.

Payment models also must be sufficiently flexible to ensure that they do not interfere with the most appropriate treatments. As diagnostic advancements allow clinicians to determine more accurately the most effective treatments for individual patients, patients within the same episode may receive very different treatments based on numerous factors such as their anatomy, comorbidities, lifestyle and/or symptomology, requiring sufficient payment model flexibility.

In addition, payment models must not interfere with a provider’s selection of the appropriate device to use for a given patient. For example, some implanted medical devices may vary depending on their useful life expectancy. In the case of a pseudoarthrosis outcome following lumbar interbody fusion procedures, it is not apparent until many months to years following the procedure that most cases would require subsequent reoperation. The incentives to minimize costs under an episode measure may lead practitioners to choose cheaper, less durable devices. Because device failure and complications would occur outside the episode period there is no negative financial impact on the practitioner, although the patient faces future procedures.

AdvaMed also recommends that CMS look to the existing Bundled Payment for Care Improvement (BCPI) Program for instruction prior to proceeding with similarly structured episode-based measures. Specifically, we believe that the existing hip/knee pilot programs could provide useful insights, including the appropriate length for episode evaluation and information regarding quality measures which can be integrated in order to create a more robust efficiency measure that balance both cost and quality. It is likely that as data are collected and analyzed over the evaluation of the BCPI, CMS will be able to assess better whether particular procedures are appropriate for inclusion in an episode-based payment model.

If designed properly, AdvaMed could support these types of measures, including those for hip/knee replacement/revision as appropriate candidates for consideration. For example, we understand that Yale’s Center for Outcomes Research & Evaluation (CORE), in conjunction with CMS, is currently developing patient-reported functional status outcomes following total hip/knee arthroplasty which may become part of a bundled episode-based payment system. Because of the significant cost variation that exists within the episode of care surrounding a total joint arthroplasty (TJA) hospitalization, particularly in the post-acute care period, there are opportunities for hospitals and physicians to work together more efficiently in advancing high quality patient care. These measures could also encourage providers to develop post-acute clinical pathways that are customized for each patient’s needs, and utilize all care protocols and technologies that hasten rehabilitation and recovery.

As CMS continues to examine use of these measures, AdvaMed urges CMS to rely on a transparent consultative process that allows for full review and comment on all aspects of the model. Relevant expertise exists across many different interested parties and it will be important
to receive full input from all stakeholders on the details of any model before proceeding.

4. Proposal to Add the Care Transition Measure from HCAHPS Survey to the Patient and Caregiver Centered Experience of Care/Care Coordination (PEC/CC) Domain of the Hospital VBP Program beginning in FY 2018

CMS is “considering proposing to add the Care Transition Measure from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey to the Patient and Caregiver Centered Experience of Care/Care Coordination (PEC/CC) domain of the FY 2018 Hospital VBP Program.” AdvaMed believes that incentivizing hospitals to coordinate patient transitions to outpatient care settings will significantly aid in decreasing readmissions and potentially mortality among the Medicare population. Therefore, AdvaMed supports this proposal and urges CMS to finalize it.

VI. Hospital Inpatient Quality Reporting (IQR) Program

1. Removal of SCIP Inf-4: Cardiac Surgery Patients with Controlled 6AM Postoperative Blood Glucose (NQF #0300) from the Hospital IQR Program

AdvaMed has concerns concerning the removal of the SCIP Inf-4 measure (Cardiac Surgery Patients with Controlled 6AM Postoperative Blood Glucose (NQF #0300) from the Hospital IQR program. AdvaMed appreciates the underlying principle for the removal of “topped out” measures from the Hospital IQR program as a means of alleviating the reporting burden for measures with exceedingly high performance, however, we believe that the SCIP Inf-4 measure is an exception to this general rule. The SCIP Inf-4 measure currently represents the only performance measure implemented for the control of postoperative serum glucose. While performance on this measure stands at 97 percent nationally, AdvaMed is concerned that future measure performance may decline without further reporting. Therefore, AdvaMed supports retention of the SCIP Inf-4 measure in the Hospital IQR Program.

Hyperglycemia, which occurs during coronary artery bypass grafting and cardiac surgery, increases perioperative morbidity and mortality and results in decreased long-term survival and recurrent ischemic events. Maintaining serum glucose at optimal levels with continuous insulin infusions — in patients with and without diabetes mellitus — reduces morbidity and mortality, lowers the incidence of sternal wound infections, reduces hospital length of stay (LOS), and enhances long-term survival. Accordingly, there is a greater need for not only more monitoring of blood glucose levels in these patients, but more frequent monitoring. It has been well established that blood glucose variability also is a driver of mortality complications and increased costs and less variability through tighter blood glucose control and monitoring will lead to more favorable results.

Furthermore, not only is measurement at 6 a.m. postoperative days 1 and 2 important, but the Society of Thoracic Surgeons recommends hourly glucose monitoring and measurement during intravenous (IV) insulin infusions to avoid fluctuations in glucose levels and to minimize the risk of hypoglycemia. As continuous glucose 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 keep patients’ blood sugar levels within specific ranges. These advancements have the potential for significant improvements in cost if patient outcomes are improved and the LOS is reduced as a result of glycemic control. Therefore, it is important to both patient care and system resources to retain the SCIP Inf-4 measure in the Hospital IQR program to ensure continued quality performance in the space.

2. Proposed addition of Severe Sepsis and Septic Shock: Management Bundle (NQF #0500) (chart-abstracted) to the IQR program for the FY 2017 payment determination and subsequent years.

AdvaMed commends CMS for taking action to address severe sepsis and septic shock patients in using the “Severe Sepsis/Septic Shock: Management Bundle” (NQF #0500). This measure aligns well with the goals of the National Quality Strategy and fills an important measure gap. The significant clinical and economic impact of sepsis in terms of related morbidity, mortality, and costs in the hospital setting are well documented. There are an estimated 1.14 million cases of sepsis or septicemia in the US every year, and mortality rates are estimated to be in excess of 28 percent, with a recent study indicating that sepsis contributed to 1 in every 2 to 3 hospital deaths, with most of these patients having sepsis at admission. Thousands of patients are negatively impacted each year with hospitalization costs related to sepsis that exceed $19 billion annually in the U.S. In addition to being NQF endorsed, this sepsis quality measure has also been analyzed, debated, utilized, and evaluated in the Surviving Sepsis Campaign (SSC), with proven improvements in 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.

While outcomes measures that address sepsis have been adopted in CMS programs, this measure would further drive improvement by encouraging implementation of practices to improve management of sepsis and septic patients. This measure can have meaningful impact on improving patients’ lives and reducing healthcare costs. Therefore, AdvaMed supports CMS’ addition of Severe Sepsis and Septic Shock: Management Bundle (NQF #0500) (chart-abstracted) to the IQR program for the FY 2017 payment determination and subsequent years.

VII. Long Term Care Hospital Quality Reporting (LTCHQR) Program

1. Ventilator-Related Quality Measures Proposed for Inclusion in the LTCHQR Program for the FY 2018 Payment Year and Beyond

AdvaMed strongly supports CMS’ proposal to include the following two new ventilator-related quality measures in the LTCHQR Program beginning in FY 2018, pending NQF-endorsement:

- Functional Outcome Measure: Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support
- National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure
A. Functional Outcome Measure: Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support

This functional outcome measure relies on functional assessment items originally developed and tested as part of the Post-Acute Care Payment Reform Demonstration Version of the Continuity Assessment Record and Evaluation (CARE) Item Set, which was designed to standardize assessment of patient status across acute and post-acute settings, including LTCHs, inpatient rehabilitation facilities, skilled nursing facilities and home health agencies.

The creation of a mobility-related measure for inpatients requiring ventilator support is newly required by law. Evidence suggests that mobility in mechanically ventilated patients leads to improved physical and mental functioning and the potential to facilitate ventilator weaning. New technologies are available to assess, remind and alert facility staff to prescribed mobility requirements.

Given the importance of functional improvement for this patient population and the demonstrated ability of LTC hospitals to ensure functional improvement of these patients through therapy services as well as via enhanced technologies, this measure will provide invaluable information to Medicare beneficiaries and their families who need LTC hospital services. Moreover, the measure will create clear accountability for LTC hospitals to ensure ventilator patients are achieving expected functional improvements related to mobility during their stay.

We agree with the Measure Application Partnership (MAP) recommendations in their January 2014 Pre-Rulemaking Report suggesting further modifications and development concerning the initial measure specifications. We are pleased that CMS has subsequently taken steps to further improve the measure based on feedback from the MAP, CMS’ technical experts, and from public comments received on the draft measure. AdvaMed strongly supports the intention stated by CMS to submit this measure for future NQF endorsement.

B. National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure

AdvaMed also fully supports the addition of the Ventilator-Associated Event (VAE) Outcome Measure to the LTCHQR Program, pending NQF endorsement. Earlier this year, the MAP supported addition of this measure to the LTCHQR in its January 2014 pre-rulemaking report despite the lack of NQF endorsement, noting the value of the measure in helping facilities monitor ventilator use and identifying improvements for preventing complications. It is our understanding that this measure was submitted to NQF for endorsement in 2013. However, the data demonstrating that the measure is reliable and valid were not available at the time of review.

The measure developer noted that they are currently working on these analyses and that additional information would be available in the next one to two years. AdvaMed strongly supports the intention stated by CMS to submit this measure for future NQF endorsement.

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4 Section 1886(m)(5)(D)(iv) of the Affordable Care Act, as added by section 1206 (c) of the Pathway for SGR Reform Act of 2013, provides for the establishment, no later than October 1, 2015, of a functional status quality measure under the LTCHQR Program for change in mobility among inpatients requiring ventilator support.
encourages the measure developer to submit the measure for NQF endorsement when this additional information becomes available.

This measure algorithm was constructed to detect the broad range of conditions or complications occurring in mechanically-ventilated adult patients. It is well established that the longer patients are mechanically ventilated, such as those on long-term mechanical ventilation in LTC hospitals, the more likelihood that VAEs may occur. This reporting measure provides a prudent mechanism for providers of long term mechanical ventilation to understand the burden of morbid complications associated with mechanical ventilation and an objective means to measure the impact of care improvement initiatives.

Furthermore, this reporting measure will raise awareness to the medical detriment of extended time on mechanical ventilation and will encourage facilities to implement strategies to reduce time on mechanical ventilation, including weaning strategies, appropriate analgesia and sedation, daily interruption of sedation and early mobilization.

Finally, the foundational clinical elements for VAE definition (including PEEP, FiO2, temperature and WBC) are readily available, objective, rational and reportable. Measurement and reporting of VAE — along with tracking of care improvement initiatives — can help to quantify the extent to which VAE are preventable.

VIII. Recommendations for Future Measures

AdvaMed recommends that a malnutrition care quality measure be prioritized for implementation in the Inpatient Quality Reporting Program and the Hospital Value-Based Purchasing Program as soon as feasible.

Despite research that demonstrates malnutrition impacts patient outcomes, resource use, and costs, there are currently no quality measures to address gaps in management of malnutrition through screening, assessment, nutritional intervention, execution of nutritional care (treatment) plan, and care coordination.

Malnutrition is both a patient-safety risk and an underlying risk factor for multiple other CMS priorities. Malnutrition is a leading cause of morbidity and mortality, especially among the elderly. Increasing the risk of malnutrition in older patients is the presence of comorbidities, including high-impact Medicare conditions such as cardiovascular disease, stroke, cancer, COPD, renal disease, depression, and dementia. Malnutrition is linked to increased rates of hospital morbidity, increased incidence of hospital-acquired pressure ulcers and infections, delayed wound healing, decreased respiratory and cardiac function, poorer outcomes of chronic lung diseases, increased risk of cardiovascular and gastrointestinal disorders, reduced physical

function, development of nosocomial infections,9 and impairment of non-specific and cell-mediated immunity.10

Early nutrition intervention can lower costs by decreasing preventable readmissions, complications, length of hospital stay, and mortality. Clinical consensus recommendations underscore that early and systematic nutrition care coupled with interdisciplinary clinician collaboration is critical in remediating malnutrition in both the hospital and in the post-acute care setting. This includes identifying and diagnosing patients, rapidly implementing interventions, and executing a nutrition care plan from admission through discharge.11 Studies have demonstrated that implementation of a comprehensive nutrition pathway from inpatient admission to post-discharge improved identification of high-risk patients, decreased time to nutrition consult, and decreased length of stay and 30-day readmission rates.12,13

In 2013, AdvaMed — as part of a group of key stakeholders — participated in a dialogue around measuring the quality of malnutrition care in the hospitalized patient.14 While participants focused on measures that address hospital care, priority was given to measures that could be applied across multiple settings. Measure areas prioritized by stakeholders for future measure development included implementation and execution of patient-centered nutrition care plans, health information technology infrastructure to support nutritional care, and establishment of malnutrition as a “never event” to prevent decline in the health of elderly patients during hospitalizations. Further stakeholder input and research was recommended to advance efforts around the prioritized areas.

In addition, addressing malnutrition directly aligns with National Quality Strategy aims and priorities related to patient safety, care coordination, patient- and family-centered care, population health, and affordability. Also, as a member of the MAP Coordinating Committee, AdvaMed has previously highlighted the need to emphasize malnutrition as a priority gap area for future quality measure development. Because malnutrition impacts patient care in multiple care settings, there also is an opportunity to extend a malnutrition care measure outside of the hospital to post-acute care settings, such as nursing homes and home health, and align incentives for providers.

We commend CMS for the actions the agency has taken to date to promote identifying, preventing and treating disease-related malnutrition in a timely manner. Action in this area would build on important policies adopted by CMS during the last year. These policies include providing hospitals with additional flexibility to privilege qualified nutrition professionals to order therapeutic diets for patients15 and integrating nutrition consultation and services in the

11 Tappenden, K, et. al. J Academy of Nutr and Dietetics 2013; 113:9; 1219-1237
15 79 Federal Register 27106; Medicare and Medicaid Programs; Regulatory Provisions to Promote Program
Discharge Planning Guidance in the Conditions of Participation. We urge CMS to take the next step in improving outcomes by prioritizing malnutrition care as a future quality measure.

We thank you for the opportunity to submit these comments. If you have any questions, please contact Richard Price (rprice@advamed.org) or Steven Brotman (sbrotman@advamed.org).

Sincerely yours,

Don May