June 16, 2015

Via http://www.regulations.gov

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1607–P
P.O. Box 8011
Baltimore, MD 21244–1850

RE: CMS–1607–P: 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; Quality Reporting Requirements for Specific Providers; Reasonable Compensation Equivalents for Physician Services in Excluded Teaching Hospitals; Provider Administrative Appeals and Judicial Review; Enforcement Provisions for Organ Transplant Centers; and Electronic Health Record (EHR) Incentive Program

Dear Mr. Slavitt,

The Society for Healthcare Epidemiology of America (SHEA) appreciates the opportunity to provide comments in response to the proposed rule for the Medicare Hospital Inpatient Prospective Payment Systems program for Acute Care Hospitals and Quality Reporting Requirements for Specific Providers.

SHEA represents more than 2,000 physicians, antibiotic stewardship experts, and other healthcare professionals globally with expertise in healthcare epidemiology and infection prevention. SHEA is dedicated to advancing the science and practice of healthcare epidemiology and preventing and controlling morbidity, mortality, and the cost of care linked to healthcare-associated infections (HAIs).

SHEA respectfully submits comments on the following sections of the proposed rule:

II. Proposed Changes to Medicare Severity Diagnosis-Related Group (MS-DRG) Classifications and Relative Weights

- F. Proposed Adjustment to MS–DRGs for Preventable Hospital-Acquired Conditions (HACs), Including Infections
- H.4.Solicitation of Public Comments on Expanding the Bundled Payments for Care Improvement (BPCI) Initiative
- H.5. FY 2016 Applications for New Technology Add-On Payments
  - c. Ceftazidime Avibactam (AVYCAZ)
  - e. CRESEMBA® (Isavuconazonium)

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IV. Other Decisions and Proposed Changes to the IPPS for Operating Costs and Indirect Medical Education (IME) Costs

- F. Hospital Value-Based Purchasing (VBP) Program: Proposed Policy Changes for the FY 2018 Program Year and Subsequent Years
  - 2.b.(1) Proposed Removal of Two Measures; Proposed Removal of IMM-2 Influenza Immunization Measure.
  - 2.c. Proposed New Measure for the FY 2018 Program Year: 3-Item Care Transition Measure
  - 2.e. NHSN Measures Standard Population Data.
  - 3. Previously Adopted and Newly Proposed Measures for the FY 2019, FY 2021, and Subsequent Program Years
  - 5.c. Proposed Baseline and Performance Periods for NHSN Measures and PC-01 in the Safety Domain for the FY 2018 Program Year.
  - 6.b. Proposed Baseline and Performance Periods for the PSI-90 Measure in the Safety Domain in the FY 2020 Program Year.
  - 7.c. c. Proposed Performance Standards for the FY 2018 Program Year.
- G. Proposed Changes to the Hospital-Acquired Condition (HAC) Reduction Program
  - 5.c. Proposed Domain 1 and Domain 2 Weights for the FY 2017 HAC Reduction Program.
  - 6. a. Proposal to Include Select Ward (Non-Intensive Care Unit (ICU)) Locations in Certain CDC NHSN Measures Beginning in the FY 2018 Program Year.

VIII. Proposed Quality Data Reporting Requirements for Specific Providers and Suppliers for FY 2016

- A.b.11. Proposed Modifications to the Existing Processes for Validation of Hospital IQR Program Data
- B.3.b. PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program; b. Summary of Proposed New Measures.
- C.9.c. Long-Term Care Hospital Quality Reporting Program (LTCH QRP); Proposed Revisions to Previously Adopted Data Submission Timelines Under the LTCH QRP for the FY 2017 and FY 2018 Payment Determinations and Subsequent Years and Proposed Data Collection and Data Submission Timelines for Quality Measures Proposed in This Proposed Rule.

SHEA thanks CMS for soliciting public comment on the Inpatient Prospective Payment System proposed rule. For future inquiries on this submission, please contact Lynne Batshon at 703-684-0761 or lbatshon@shea-online.org.

Sincerely,

Anthony D. Harris, MD, MPH, FSHEA, FIDSA, President, SHEA

II. Proposed Changes to Medicare Severity Diagnosis-Related Group (MS-DRG) Classifications and Relative Weights

F. Proposed Adjustment to MS–DRGs for Preventable Hospital-Acquired Conditions (HACs), Including Infections

SHEA agrees with the proposal to continue similar 2-year time periods for calculation of Hospital-Acquired Conditions (HAC) reduction Program measure results. We note that HAC "descriptors" increase dramatically for FY 2016 requirements and the impact this will have on reporting or surveillance of HAC is unknown. Weighing certain HAC secondary infection diagnosis codes differently may impact reporting. The difference in the way HAC codes are used among hospital could merely represent differing underlying risk for infection by hospital based on the population served (e.g., rates of obesity), or documentation not adequately capturing HAC (for example, CAUTI events determined by claims data appear inaccurate; Ann Intern Med 2012; 157(5): 305–312). These variances may not be a reflection of patient safety problems. While SHEA does not hold specific concerns with the many new codes for existing HAC, the manner in which they will be utilized for reporting and reimbursement purposes is unknown.

H.4.Solicitation of Public Comments on Expanding the Bundled Payments for Care Improvement (BPCI) Initiative

The Bundled Payments for Care Improvement (BPCI) Initiative was developed on the premise that bundled payments for an episode of care (e.g., an inpatient hospital stay; post-acute care following an inpatient stay) will lead to higher quality and more coordinated care at lower cost to Medicare. Providers would receive a bundled payment and assume financial risk for any spending above the target that Medicare has established for the episode of care.

Payment for critical conditions (e.g., sepsis) must take into account the risks for infection associated with invasive care (e.g., CLABSI, VAP, CAUTI). **While we can strive for zero, we cannot eliminate the risk of these infections particularly in this relatively immunocompromised population. Payment should reflect hospitals' assumption of this risk and be reasonable enough to help fund ongoing hospital surveillance and prevention programs to mitigate this risk as much as possible.**

Payment for surgical procedures should take into account the relative SSI rates associated with the individual procedure. Some procedures (e.g., surgery for a ruptured appendix) are contaminated from the beginning and incur a high risk of infection, even despite maximum infection prevention precautions (e.g., broad-spectrum antibiotic therapy, clean closure procedures). Hospitals should not be penalized as they cannot prevent these infections altogether.

Payment should take into account the relative acuity of hospitals' patient population. There is a need to include a severity of illness risk adjustment when evaluating outcomes of patients related to the infections reported as HAC. For example many large tertiary academic hospitals receive the most complex cases, often with high risk of infection, and also serve as the safety net for underprivileged patient populations with limited healthcare access and potentially poor baseline health. Such hospitals should be measured against hospitals with similar attributes when it comes to determining a reasonable payment for an episode of care.

H.5. FY 2016 Applications for New Technology Add-On Payments

c. Ceftazidime Avibactam (AVYCAZ). CMS is inviting the public to comment on whether Ceftazidime Avibactam (AVYCAZ) meets the newness criterion for new technology add-on payments for FY 2016. CMS believes that AVYCAZ bears a substantial similarity to Ceftazidime and other currently available treatment options. **SHEA agrees with CMS's assessment that Ceftazidime Avibactam does not meet substantial clinical improvement to warrant new technology add on payments.**

e. CRESEMBA® (Isavuconazonium). CMS is concerned that CRESEMBA® may be substantially similar to other currently approved antifungal drugs. CMS is inviting the public to comment on if, and how, CRESEMBA® meets the newness, cost and efficacy criterion and its concerns regarding how it is substantially similar to other treatments for serious fungal infections. **SHEA agrees with CMS's assessment that *isavuconazonium* does not meet substantial clinical improvement to warrant new technology add on payments.**

IV. Other Decisions and Proposed Changes to the IPPS for Operating Costs and Indirect Medical Education (IME) Costs

F. Hospital Value-Based Purchasing (VBP) Program: Proposed Policy Changes for the FY 2018 Program Year and Subsequent Years

2. Proposed Retention, Removal, Expansion, and Updating of Quality Measures for the FY 2018 Program Year

b.(1) Proposed Removal of Two Measures; Proposed Removal of IMM-2 Influenza Immunization Measure. CMS is proposing to remove the IMM-2 Influenza Immunization Measure from the Hospital Value-Based Purchasing (VBP) Program effective for the FY 2018 program year, citing the measure as "topped out". **SHEA agrees and supports CMS's proposal to remove the IMM-2 Influenza Immunization Measure from the VBP Program.** Vaccination of hospitalized persons represents an important opportunity to enhance vaccination rates among the U.S. population, particularly among higher-risk populations. However if national performance on the IMM-2 measure has been "topped-out" and no longer serves as an indicator of higher level of performance, removal of this measure from the VBP Program is appropriate. We also agree with continuing to include this measure in the Hospital Inpatient Quality Reporting (IQR) program in order to ensure that proper attention to this important safety intervention continues through the Best Practices to Enable Healthy Living goal in the CMS Quality Strategy and priority of the same name in the National Quality Strategy.

c. Proposed New Measure for the FY 2018 Program Year: 3-Item Care Transition Measure (CTM–3) (NQF #0228). The 3-Item Care Transition Measure (CTM–3) is an NQF-endorsed measure. CMS is proposing this measure for the VBP Program based on the Measure Application Partnership (MAP) recommendation, the adoption of the measure in the Hospital IQR Program and posting of measure data on Hospital Compare for at least one year before the beginning of the performance period for the measure. **SHEA agrees and supports CMS's proposal.**

e. NHSN Measures Standard Population Data. Beginning in 2015, the Centers for Disease Control and Prevention (CDC) will collect data in order to update the standard population data for all CY 2015 National Healthcare Safety Network (NHSN) healthcare associated-infection new standard population measures, i.e. new standard population data. CMS has determined that it cannot equally compare CDC's new standard population data with current standard population

data presently used to calculate improvement points in the Hospital VBP Program. CMS proposes to use current standard population data to calculate and report performance measure scores until the FY 2019 program year. For the FY 2019 and subsequent years, CMS will use new standard population data to calculate and report performance measure scores.

SHEA agrees and supports the need for CMS to develop a plan to address the CDC's updated standard population data. This recalibration will reflect significant progress towards elimination of HAIs – especially so for CLABSI, but for others sites as well. Additionally this will help reset base performance for CAUTI which has been more challenging based on the most recent NHSN HAI report (CDC. National and State HAIs Progress Report. January 2015).

Although SHEA agrees with this approach, using the current standard population data to calculate report measure scores for FY 2018, which are based on CY 2016 data, may be confusing for hospitals. They will be generating SIR data using the new standard population data. While this seems to be necessary because the baseline period for FY2018 is CY 2014 for which the current standard population data will be used, the differences in the data that hospitals will receive from NHSN and the data CMS will be using to calculate performance scores will need to be clearly and widely publicized to avoid confusion at the hospital level.

3. Previously Adopted and Newly Proposed Measures for the FY 2019, FY 2021, and Subsequent Program Years

CMS intends to include additional data in certain NHSN measures beginning with the FY 2019 program year under Hospital VBP Program, specifically the Central Line Associated Blood Stream Infection (CLABSI) and Catheter-Associated Urinary Tract Infection (CAUTI) measures. These measures have been based on data collection from adult, pediatric and neonatal ICUs. CMS plans to expand this data collection to selected ward (non-ICU) locations beginning with the FY 2019 program year. CMS plans to propose a baseline period of CY 2015 and a performance period of CY 2017 for that initial year. CMS previously modified IQR Program requirements to include reporting on the expanded locations beginning January 1, 2015.

SHEA supports expanding the scope of data collection for NHSN measures to include selected non-ICU locations beginning in FY 2019. CAUTI and CLABSI are important patient safety concerns in non-ICU areas and, in many hospitals, the majority of these infections occur outside of the ICU. Inclusion of these areas in the CAUTI and CLABSI measures would provide further incentive for hospitals to optimize preventive measures in non-ICU areas and would allow the data to more accurately reflect overall hospital performance. **SHEA also supports the increased weight for safety domain from 15% for FY 2016 to 20% for FY 2017 to 25% for FY 2018 onwards.**

SHEA recommends CMS provide additional detail on how the SIR metric for both CAUTI and CLABSI in ICUs and selected non-ICU areas will be used for quality and safety improvement and public reporting. There has been little, if any, experience or use of this to date. SHEA recommends CMS work with NHSN subject matter experts to better understand impact of the expanded scope prior to adoption.

SHEA recommends CMS improve risk adjustment (e.g. case mix index) for measures (CLABSI, CAUTI, CDI) where the exclusive use of the SIR is known not to sufficiently distinguish between high and low risk patient populations (e.g. bone marrow transplant, solid organ transplant, HIV infected vs. a healthy labor and delivery patient in the risk of CDI or CLABSI). Certain hospitals, such as major teaching institutions that do not have dedicated wards

for these high risk patient populations, are at risk of being penalized because of the failure to properly adjust for patient acuity. This is a disincentive for these hospitals to take care of the sickest patients. By further risk adjusting (e.g., with a case mix index, not available to the CDC/NHSN), this bias could be partially corrected.

5. Previously Adopted and Newly Proposed Baseline and Performance Periods for FY 2018 Program Year

c. Proposed Baseline and Performance Periods for NHSN Measures and PC-01 in the Safety Domain for the FY 2018 Program Year. **SHEA agrees with the continued use of 12-month baseline periods.** As noted in a previous comment on IV.F.2.e. , however, the discrepancy between the standard population data that will be used by the NHSN system to calculate hospital-generated SIR data for 2016 data (i.e., new standard population data) and that which will be used to calculate performance standards and report measure scores (i.e., current standard population data) for the 2016 performance period may generate confusion for hospitals when different values are obtained from the two systems. The expectation of this discrepancy may also be important for hospitals to recognize as they establish their internal quality goals. Thus, hospitals should be provided with advanced notification and explanation of this data analysis plan.

6. Proposed Measure Refinements for the FY 2018 HAC Reduction Program

b. Proposed Baseline and Performance Periods for the PSI-90 Measure in the Safety Domain in the FY 2020 Program Year. Given the proposal to add to the Hospital VBP program non-ICU CAUTI and CLABSI data, SHEA recommends no longer using ICD coding or claims data to measure CLABSI and CAUTI. We recommend excluding PSI-07 and PSI-13 from the calculation of PSI-90 because these infections are already captured in the NHSN survey data used for both HAC and Hospital VBP programs. Studies comparing the correlation of NHSN surveillance to claims based diagnoses found significant discordance and claims data did not identify any additional data (Teherani et al. Infect Control Hosp Epidemiol 2013;34(2):176-183).

7. Maintenance of Technical Specifications for Quality Measures

c. Proposed Performance Standards for the FY 2018 Program Year. **SHEA believes the proposed standards are appropriate based on the previously established methodology, recognizing that the numerical values for the performance standards presented in this proposed rule are estimates based on currently available data and that the numerical values will be updated in the final rule.**

G. Proposed Changes to the Hospital-Acquired Condition (HAC) Reduction Program

5. Proposed Changes for Implementation of the HAC Reduction Program for FY 2017.

c. Proposed Domain 1 and Domain 2 Weights for the FY 2017 HAC Reduction Program. CMS is seeking public comment on its proposal to decrease the Domain 1 weight from 25 percent to 15 percent and increase the Domain 2 weight from 75 percent to 85 percent for FY 2017. **SHEA agrees with the proposal to increase the weighting of Domain 2 (CDC NHSN measures), as we believe the new weighting reflects the importance of hospital acquired infections and we agree that NHSN measures are more reliable than claims-based measures.**

6. Proposed Measure Refinements for the FY 2018 HAC Reduction Program

a. Proposal to Include Select Ward (Non-Intensive Care Unit (ICU)) Locations in Certain CDC NHSN Measures Beginning in the FY 2018 Program Year. CMS is inviting public comment on a proposal to include data from pediatric and adult medical ward, surgical ward and medical/surgical ward locations in addition to data from adult and pediatric ICU locations for the CDC NHSN CLABSI and CAUTI measures beginning with the FY 2018 HAC Reduction program. **SHEA supports the inclusion of ward locations for NHSN CLABSI and CAUTI measures beginning with FY 2018, as this change appropriately recognizes the importance of controlling hospital acquired infections outside of the ICU.**

The use of CYs 2015 and 2016 is preferred over CY 2014 and 2015 for performance period given all of the changes in CAUTI criteria that were enacted in CY 2015 by NHSN. We do recommend, as stated previously, that CMS, in collaboration with CDC, determine how the SIR for CAUTI and CLABSI for these two location types, critical care and ward, will be calculated and displayed. SIR tends to vary significantly between ICU and ward locations, especially for CAUTI. It may be best if there be separate strata for ICU and ward locations rather than an overall SIR that collapses these location types.

SHEA recommends CMS consider providing additional details about the NHSN locations that are included and excluded from this planned scope of work. There may be an assumption that the expansion includes Ward locations facility wide. However SHEA believes that is not the intent of this proposal. Confusion in this regard may be related to facility-wide scope that is part of lab ID MRSA bacteremia and C. *difficile* NHSN modules, which does capture data across a facility.

The changes proposed to the HAC program are similar to those for Hospital VBP Program, but the performance periods and inclusion of data on HAC program CLABSI and CAUTI for wards are out of sync with the Hospital VBP Program. The HAC program will apply to CLABSI and CAUTI in wards beginning FY2018 (performance period CY2015 and CY2016), one year earlier than Hospital VBP Program. The HAC Program will continue to use two years' data unlike the Hospital VBP Program. The HAC Program will use new NHSN standard population as baseline beginning FY2018, one year earlier than the Hospital VBP Program. Since the HAC Program reduction adjustment is made after Hospital VBP Program adjustment is made, **SHEA recommends CMS synchronize the performance periods for HAI and the types of HAI and locations (ICUs/Wards) for both the Hospital VBP Program and the HAC Program. We further recommend using 12-month performance reporting periods for both HAC and VBP programs.**

VIII. Proposed Quality Data Reporting Requirements for Specific Providers and Suppliers for FY 2016

A. Hospital Inpatient Quality Reporting (IQR) Program

11. Proposed Modifications to the Existing Processes for Validation of Hospital IQR Program Data

b. Proposed Modifications to the Existing Processes for Validation of Chart-Abstracted Hospital IQR Program Data. CMS is seeking comments on its proposal to remove the immunization measure validation stratum, to move the Influenza Immunization (NQF #1659) measure to the clinical process of care validation stratum, and to reweight the topic areas for validation beginning with the FY 2018 payment determination and for subsequent years. SHEA strongly

supports the concept and process of auditing to improve the validity of data for the CMS VBP and IQR programs**. In view of removal of the influenza vaccination (IMM-2) measure from VBP but continuation of this measure in the IQR program in the set of clinical measures that are chart-abstracted, SHEA agrees with the proposed changes in the validation process.** Specifically, we agree with including the influenza immunization measure validation in the Clinical Process of Care stratum along with other measures.

Although influenza vaccination appears to have been "topped-out", it was recently reported that even in the presence of high compliance with the measure, the percentage of hospitalized patients that actually receive influenza vaccination remains low, because the measure excludes those that "refuse" the vaccine.[1] Therefore, in addition to maintaining this as a chart-abstracted IQR measure that undergoes validation, we encourage CMS to abstract the prevalence of influenza vaccine refusal among vaccination-eligible patients, as that potentially represents an area for improvement in the quality of care.

SHEA agrees with the proposed weighting of the validation of chart-abstracted measures in the hospital IQR program. We also agree with delaying the public reporting of electronic clinical quality measure data submitted by hospitals for CY 2016/FY 2018 payment determination in order to allow CMS time to evaluate the accuracy and effectiveness of electronically reported clinical quality measure data.

Lastly, SHEA strongly recommends including the NHSN measures in the CMS validation program. As reported in the most recent CDC Healthcare-associated Infections (HAI) Progress Report (available at http://www.cdc.gov/HAI/pdfs/progress-report/hai-progress-report.pdf), as of 2013, audits to verify the accuracy of data reported to the NHSN were being performed by only a handful of states. Given the high weighting assigned to NHSN measures in these programs, validation of these data is as important as for the other clinical measures.

B. PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

3. Proposed New Quality Measures Beginning With the FY 2018 Program

b. Summary of Proposed New Measures. CMS is proposing adoption of three new NQF-endorsed quality measures for the FY 2018 PCHQR Program. The measures are:

- Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717) (CDC NHSN CDI Measure)
- CDC NHSN Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure (NQF #1716) (CDC NHSN MRSA Measure)
- CDC NHSN Influenza Vaccination Coverage Among Healthcare Personnel (HCP) Measure (NQF #0431) (CDC NHSN HCP Measure)

[1] Masnick M, Leekha S. Frequency and Predictors of Seasonal Influenza Vaccination and Reasons for Refusal Among Patients at a Large Tertiary Referral Hospital. Infect Control Hosp Epidemiol. 2015 Mar 16:1-3. [Epub ahead of print]

SHEA supports the addition of all three new measures beginning with the FY 2018 program. SHEA encourages CMS to monitor future novel diagnostic strategies for *Clostridium difficile* testing and better adjustment based on the test used.

C. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

9. Form, Manner, and Timing of Quality Data Submission for the FY 2016 Payment Determination and Subsequent Years

c. Proposed Revisions to Previously Adopted Data Submission Timelines Under the LTCH QRP for the FY 2017 and FY 2018 Payment Determinations and Subsequent Years and Proposed Data Collection and Data Submission Timelines for Quality Measures Proposed in This Proposed Rule. SHEA supports the modification to the data submission and correction deadlines to align with other quality reporting programs (e.g. the IRF QRP and Hospital IQR Program). SHEA also supports the display of the NHSN Outcome measures, the use of the SIR, and the extension of the data submission timeline.