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June 30, 2014

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

Re: CMS-1607-P: Medicare Program; Hospital Inpatient Prospective Payment System for Acute Care Hospitals and Long-Term Care Hospital Prospective Payment System for FY 2015, proposed rule

Dear Ms. Tavenner:

The Society for Healthcare Epidemiology of America (SHEA) wishes to thank the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide input into its proposed FY 2015 Hospital Inpatient Prospective Payment System (IPPS) changes. We are pleased that CMS continues to demonstrate its commitment to improving the quality of patient care and believe that CMS is moving in the right direction. The following comments address issues raised by CMS related specifically to SHEA's area of expertise: Healthcare-Associated Infections (HAIs). SHEA's specific recommendations are in *italized font*.

Proposed Changes to Medicare Severity Diagnosis-Related Group (MS-DRG) Classifications and Relative Weights Proposal Regarding Current HACs and Previously Considered Candidate HACs

SHEA supports the inclusion of the following measures as proposed: SSI following colon surgery (FY 2016), SSI following abdominal hysterectomy (FY 2016), MRSA bacteremia (FY 2017), and C. difficile (FY 2017). We note that some Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) definitions may be undergoing changes in the coming years. We agree

with CMS that definitional changes be subject to adequate notice and comment. *In addition, we recommend that any definitional changes be accompanied by a ‘wash-in’ period whereby there would be time for facilities to learn how to implement the new definition and perform internal validation, and for the CDC to collect an adequate amount of baseline data from which standardized infection ratios (SIRs) would be calculated.*

Hospital Value-Based Purchasing (VBP) Program Measures for the FY 2017 Hospital VBP Program

For the FY 2017 Hospital VBP Program measure set, CMS indicates that it is proposing to remove PN-6, SCIP-Inf-2, SCIP-Inf-3, and SCIP-Inf-9 as they are now “topped-out.” *SHEA agrees and supports removal of these measures.* We believe that only areas in need of improvement should be included in the program. Removal of these measures will reduce the reporting burden on participating hospitals and ensure that only measures that allow valid statistical comparisons will be included.

CMS is also proposing to adopt several new measures into the VBP program including: Methicillin-resistant *Staphylococcus aureus* (MRSA) bacteremia (NQF #1716) and *Clostridium difficile* (*C. difficile*) Infection (NQF #1717). Both will be reported via NHSN.

SHEA agrees that these measures represent important components of quality improvement in the acute inpatient hospital setting. Regarding Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia (NQF #1716), SHEA agrees and supports the addition of this measure to the Hospital VBP Program. However, we note that CDC has nationwide data indicating progress on mitigation of invasive MRSA infections. Infections caused by this pathogen vary widely geographically. Also, there has been a significant shift to community associated MRSA skin/soft tissue infections, many of which are likely best treated with direct interventions at the site of infection which do not involve use of antibiotics. NHSN’s lab ID MRSA Bloodstream Infection (BSI), hospital onset, is a useful metric to monitoring the epidemiology of this infection. However as the proportion of community associated strains become predominant there will be less ability on the part of acute care settings, i.e. hospitals, to effect any appreciable impact on their frequency. While SHEA believes it makes sense to include this measure for now, we recommend that it be monitored closely going forward.

Clostridium difficile Infection (NQF #1717) is a risk-adjusted outcome measure monitoring hospital onset of *C. difficile* infection events using a SIR (i.e. *C. difficile* SIR) among all inpatients in the facility, and is reported via CDC’s NHSN. *SHEA agrees and supports inclusion of this measure in the Hospital VBP Program, however, we urge caution to be sure that it tracks to Hospital Onset-C. difficile SIR.* A lot of CDI emerge in the community and we have less ability to impact this during the acute care stay of patients.

CMS also proposes adoption of the current CLABSI Measure (NQF #0139) for the FY 2017 Hospital VBP Program. *SHEA agrees and supports addition of this measure. We need more description of reliability adjusted modifications from NHSN.*

SHEA notes that CMS proposes to add six episode-based standardized Medicare payment measures for future inclusion and expansion into the VBP under the Efficiency domain. Three of the measures under consideration address medical episodes, which would be triggered by an inpatient claim with a specified MS-DRG: (1) kidney/urinary tract infection; (2) cellulitis; and (3) gastrointestinal hemorrhage. The other three address surgical episodes: (1) hip replacement/revision; (2) knee replacement/revision; and (3) lumbar spine fusion/refusion. Medicare payments for services provided during an episode beginning three days prior to admission through 30 days after discharge would be attributed to the hospital at which the index admission occurred. ***SHEA does not support inclusion of the episode-based standardized measures into VBP at this time.*** Given that VBP already includes an efficiency measure for all Medicare MS-DRGs (Medicare spending per beneficiary), there is no need to break these out separately and thus penalize or reward hospitals twice. We feel that these measures need further clarity and discussion with stakeholders before they can be included in the VBP Program.

Measures for the FY 2019 Hospital VBP Program

In the FY 2014 IPPS/LTCH PPS final rule, CMS declined to finalize the PSI-90 measure for the FY 2019 Hospital VBP Program in order to adopt a more recent baseline period than would have been possible at that time. In order to clarify the measure's status under the Hospital VBP Program and ensure that there is no confusion about its intent, CMS is proposing to readopt the PSI-90 measure for FY 2019 Hospital VBP Program and subsequent years.

SHEA continues to have concern about the reliability and reproducibility of this claims-based composite measure because of generally poor agreement between these and NHSN-based surveillance criteria. We do acknowledge that surgical site infection (SSI) is the one exception to this observation. We encourage the Agency for Healthcare Research and Quality (AHRQ) and other independent researchers to examine value, validity, reliability, and reproducibility of PSI-90 by comparing it to epidemiologic measures within NHSN's domain. For example, how well does the claim of central venous catheter-related BSI correlate with CLABSI surveillance by provider across the U.S? If relatively good, would episodes of bloodstream infection involving a central venous catheter be counted twice in PSI-90 and NHSN-based surveillance in assessing performance of a provider?

SHEA is aware that claims-based codes do have moderate sensitivity and high specificity for identifying surgical site infection (SSI). [M, et. al. Accuracy of administrative code data for the surveillance of healthcare-associated infections: a systematic review and

meta-analysis. Clin Infect Dis 2014;58:668-96]. This element therefore may be reliable. SHEA, however, recommends these be studied further, both as independent variables, how these correlate with SSI and NSHN-based surveillance criteria.

Previously Adopted and Proposed Performance Periods and Baseline Periods for the FY 2017 Hospital VBP Program

For the FY 2017 NHSN measures in the Safety domain (including the proposed CLABSI, C. difficile infection and MRSA bacteremia measures), CMS is proposing to adopt a performance period of CY 2015 (January 1, 2015 through December 31, 2015), and a corresponding baseline period of CY 2013 (January 1, 2013 through December 31, 2013) for purposes of calculating improvement points and calculating performance standards.

SHEA agrees with this approach, however, we recommend collaboration with NHSN on limitations of SIR analysis – especially for smaller size facilities or those with lower volumes of use of devices such as central lines, urinary catheters, and surgical procedures. For some providers a SIR may not calculate even for a 12-month block of time. Is there a statistical solution for these instances or alternative analytical approach?

Proposed Additional Performance Standards for the FY 2017 Hospital VBP Program *Proposed Changes to the Hospital-Acquired Condition (HAC) Reduction Program*

Benchmarks listed in the table at the bottom of P. 28127 of the *Federal Register* indicate = 0.0000. While elimination of these involving HAIs remains the goal, shouldn't these targets align with the HHS HAI Elimination Plan 2020 Targets? For many others, e.g. cleanliness/quietness of room there are intermediate levels – not such an absolute. Why would this same logic not apply to HAIs? Others have investigated and found as efficacy of prevention progresses, we may reach an irreducible point that despite consistent and reliable use of evidence-based HAI prevention strategies, HAIs still occur.

CMS notes that the predicted number of events is calculated using the national HAI rate and the denominator counts (that is, number of device days, procedure days, or patient days depending on the HAI). In the event an SIR cannot be calculated because the facility has <1 predicted infection, Domain 1 scores exclusively will be used to calculate a HAC score. In other words, CMS will exclude from the overall HAC score calculation any measure for which an SIR cannot be calculated for the reason set out above.

SHEA believes that for situations applied to providers described above, sole reliance on Domain 1 is not prudent. SHEA encourages collaboration with NHSN to address these as there may be other analytical approaches that do not rely completely on claims-based composite measures.

CMS is proposing pooling the abdominal hysterectomy SSI SIR and colonic procedure SSI SIR as this would provide a single SSI SIR, which is consistent with reporting a single SSI SIR as meant by design of the NQF endorsed measure (NQF #0753), and would allow a risk-adjusted weighting of the surgical volume among the two procedures.

SHEA agrees and supports this proposal; however we encourage collaboration with NHSN leadership and professional organizations representing surgeons to develop a profile of surgical procedures that are high volume and frequency across the spectrum of acute care hospitals that might be added to colonic procedure and abdominal hysterectomy. We suspect an expansion of the number of NHSN procedure groups for any one provider may increase the likelihood that an overall SIR for say 4-10 procedure groups will reliably calculate an overall SIR. This may address and mitigate the need to drop domain 2 or make other adjustments.

CMS states its intention for the future direction of electronic quality measure reporting to significantly enhance the tracking of Healthcare Acquired Conditions (HAC) under the HAC Reduction Program. Moreover, CMS will continue to work with measure stewards and developers to develop new measure concepts, and conduct pilot, reliability and validity testing as part of efforts to promote the adoption of Certified Electronic Health Record Technology in hospitals.

SHEA agrees with this direction. NHSN's lab ID metrics are aligned with this approach and offer a useful model to follow. There are also Software as a Service (SaaS) applications that can extract metrics that might serve an e-measure(s) goal that is efficient and resonate with clinicians as meaningful. We recommend that you also consider e-measures related to antimicrobial stewardship; this may be very amenable as it relates to consumption of antimicrobials from medication administration records. In addition, NHSN is close to releasing its antibiotic stewardship module broadly. Further experience with the NHSN module may be needed in order to garner experience before adding this measure. SHEA is happy to assist with development of same.

Updates on AHRQ PSI-90, and CDC/NHSN CLABSI and CAUTI Measures

The PSI-90 composite includes PSI-7 (Central venous catheter-related bloodstream infections rate) that is based on ICD-9 administrative claims data and is not as well validated as NHSN CLABSI. SHEA is concerned that when the transition to ICD-10 is complete (and many hospitals will start exclusively reporting ICD-10 at end of 2014, even if mandatory implementation has been pushed back to 2015) we will not have sufficient validation of the new PSI-7 in terms of reliability. Furthermore, as it currently exists, some vascular catheter related infections may be "double counted" once under the CDC CLABSI measure, and then again as part of PSI-90. We recommend that PSI-7 be removed from the HAC calculation.

SHEA is concerned about the approach of using composite measure scores for eight separate component indicators in the AHRQ PSI-90, for the measures do not identify specific areas that can be targeted for improvement efforts. However, SHEA appreciates that CMS recognizes this measure is currently undergoing maintenance review by the National Quality Forum (NQF), along with the NHSN Catheter-Associated Urinary Tract Infection (CAUTI) and Central Line-Associated Blood Stream Infection (CLABSI) measures. *SHEA supports the stance by CMS that if changes to the measure are made, a notice would be issued to allow for comments prior to requiring reporting of the updated measure.*

Criteria for Applicable Hospitals and Performance Scoring Policy

SHEA supports the continued use of a scoring methodology that aligns with the achievement methodology that is used under the hospital VBP program and agrees that aligning the scoring methodologies reduces confusion.

SHEA notes that for FY 2016, CMS is proposing to adjust the scoring methodology of Domain 2 and the weighting of Domains 1 and 2 due to the addition of CDC's NHSN Surgical Site Infection (SSI) measure. *SHEA agrees with the pooling approach to combining the standardized infection ratio (SIR) of the two SSI measures reported to NHSN as these SIRs will incorporate risk adjusted weighting of the surgical volume between the two measures.*

Yet, while SHEA supports the use of CDC/NHSN data in Domain 2, we believe that adding this new pooled SSI SIR to the existing CAUTI and CLABSI SIRs could lead to obtaining an average ratio or score of the three that lacks specificity in determining a hospital's true HAI scores. Additionally, adding the MRSA bacteremia and *C. difficile* SIR to the average for FY 2017 has the potential to further dilute this measure, much as the current Domain 1 composite AHRQ PSI-90 is now. *At this time, we recommend that CMS assign each of the CDC/NHSN measures a separate percentage to total the Domain weight. Having each of the CDC/NHSN measures weighted individually will provide more specificity in determining a hospital's HAI score, and will guide specific areas for performance improvement.*

For FY 2016, CMS is also proposing to decrease the weight of Domain 1 from 35% to 25% and increase the weight of Domain 2 from 65% to 75%. *SHEA strongly supports the proposed change to the weighting of Domains as this gives more weight to epidemiologically-based HAI criteria using standard definitions from CDC/NHSN rather than measures that are obtained from claims-based data.*

Proposed changes to the Hospital-Acquired condition (HAC) Reduction Program Future considerations for the Use of Electronically Specified Measures

SHEA supports the inclusion of a validated electronic measure of all-cause harm, as we believe that electronic measures are less prone to inter-rater reliability problems compared to manually-derived subjective measures. We recommend that HAI e-measures be reported to CDC's NHSN, consistent with other HAI measures.

We note that despite the advantages of less subjectivity, e-measures suffer from other threats to reliability: namely, e-measures still require capable electronic medical record systems across all US hospitals, and there needs to be external validation that e-measures are implemented identically at all sites.

Hospital Inpatient Quality (IQR) Program

Removal and Suspension of Hospital IQR Program Measures

CMS is proposing to remove five measures from the Hospital IQR Program for the FY 2017 payment determination and subsequent years, which begins in the CY 2015 reporting period: (1) AMI-1 Aspirin at arrival (NQF #0132); (2) AMI-3 ACEI/ARB for left ventricular systolic dysfunction (NQF #0137); (3) AMI-5 Beta-blocker prescribed at discharge (NQF #0160); (4) SCIP INF-6 Appropriate Hair Removal; and (5) Participation in a systematic database for cardiac surgery (NQF #0113). *SHEA agrees and supports this proposal.*

In the proposed rule, CMS notes it is recommending a change to the criteria for determining when a measure is “topped-out”. Specifically, CMS notes that it will be applying two criteria that were already adopted as part of the Hospital Inpatient VBP. As it pertains to HAI measures and infection prevention measures, *SHEA agrees with the proposal to align the definition of “topped-out” with the Hospital VBP Program to reduce confusion and promote consistency.* Explicit criteria to determine “topped out” status of measures are critical to ensuring consistency within the IQR program across measures and over time. The application of criteria that have been previously adopted by the Hospital VBP Program aligns the approach to determining “topped out” status among programs. The retention of some “topped out” measures as voluntary, electronically reported measures will allow ongoing vigilance to ensure that hospitals continue to maintain a high level of performance.

SHEA supports removal of the following for FY 2017 payment determination:

- SCIP -Inf-1: Prophylactic antibiotic received within one hour prior to surgical incision
- SCIP-Inf-2: Prophylactic antibiotic selection for surgical patient
- SCIP-Inf-3: Prophylactic antibiotics discontinued within 24 hours after surgery end time (48 hours for cardiac surgery)
- SCIP-Inf-4: Cardiac surgery patients with controlled postoperative blood glucose
- SCIP-Inf-6: Surgery patients with appropriate hair removal (previously suspended)
- SCIP- Inf-9: Urinary catheter removed on Postoperative Day 1 (POD1) or Postoperative Day 2 (POD 2).

SHEA supports transition of SCIP-Inf-1, SCIP-Inf-2, and SCIP-Inf-9 to the voluntary electronic reporting list.

SHEA does note however, that since CMS is proposing to continue to move toward including more clinical outcome measures, the loss of some of the current criteria, such as “availability of alternative measures with a stronger relationship to patient outcomes”, or “a measure that does not align with current clinical guidelines or practice”, be done cautiously and with ample opportunity for public comment. These may be problematic if not tested and validated prior to adoption.

This vetting is important as SHEA believes there needs to be sufficient lead-in time for implementation of changes to measures, especially in regard to those measures impacting information technology requirements. The latter will likely require dedicated resources and testing.

Influenza Vaccination Coverage among Healthcare Personnel (HCP)

CMS clarifies in the proposed rule that beginning with the 2014-2015 influenza season, facilities should collect and report a single vaccination count for each healthcare facility by CMS Certification Number (CCN). *SHEA agrees and supports this proposal as a way to reduce the burden of data collection, instead of separating and reporting data by inpatient and outpatient setting.*

Proposed Refinement of Total Hip Arthroplasty and Total Knee Arthroplasty (THA/TKA) 30 Day Complication and Readmission Measures

In the proposed rule, CMS notes, it will refine the measure to exclude those patients who have a hip fracture coded as either a principal or secondary diagnosis during the index admission. *SHEA believes the hospital-level risk-standardized complication rate following elective primary THA and TKA appears reasonable. SHEA agrees with exclusion of those patients who have a hip fracture coded as either a principal or secondary diagnosis during the index admission* as it will avoid inclusion of patients whose reason for admission was hip fracture that the care team later deemed as needing a total hip arthroplasty.

Proposed Additional Hospital IQR Program Measures for FY 2017 Payment Determination and Subsequent Years

While CMS notes in the proposed rule that it may require measures that have not been endorsed, *SHEA would like to express our continued support for the use of NQF-endorsed measures, as opposed to those not endorsed by NQF.* The process of appropriately developing, vetting, and maintaining measures is important to the validity and reliability of measures that are being used for reimbursement strategies as well as monitoring of adverse patient outcomes.

Regarding the Proposed Severe Sepsis and Septic Shock: Management Bundle Measure (NQF # 0500), SHEA appreciates CMS' attention on sepsis and septic shock as it clearly causes considerable morbidity and mortality across the U.S. Consistent with the efficacy of the CLABSI prevention bundle¹, there has been notable success in lessening mortality associated with a similar bundle of prompt management interventions aimed at the patient with sepsis and/or septic shock.^{2,3} Most recently however there has been conflicting evidence on efficacy of this sepsis bundle.⁴ Further, NQF Patient Safety Measures Standing Committee has recently obtained comments and are working on modifications to No. 0500. *Therefore SHEA recommends completion of this maintenance work by NQF prior to adoption of this by CMS.*

SHEA is aware that some regional sepsis campaigns (e.g., New York state public health requirements for evidence-based protocols for the early recognition and treatment of patients with severe sepsis and septic shock) do not explicitly require central venous pressure (CVP) measurement that is called for those with septic shock. Thus, if CMS were to adopt the current measure some hospitals could be compliant with local/state requirements and yet be non-compliant with the proposed CMS measure.

Public Reporting of Electronic Clinical Quality Measures

For electronic clinical quality measure data submitted for FY 2016 payment determination, CMS is proposing that the data would be publicly reported as previously finalized. However, CMS notes that with the FY 2017 payment determination, hospitals that voluntarily report one year of electronic clinical quality measure data would have an option to have their data reported on Hospital Compare with a preview period prior to reporting. *SHEA supports giving hospitals the ability to preview any data, especially electronically submitted data, before the data are released to the public's attention. We also support adding a footnote next to voluntarily reported data that will identify it as such.*

Possible New Quality Measures and Topics for Future Years

While CMS notes that Electronic Health Record (EHR) technology is continuing to improve and moving towards electronic quality measure reporting may reduce administrative burden on hospitals, *SHEA is concerned with the proposal to require reporting of electronic clinical quality measures for the Hospital IQR Program beginning for the CY 2016 reporting period or FY 2018 payment determination.* HAI surveillance measures are not included in Meaningful Use until Stage 3, which is now scheduled to begin in 2017. Therefore, minimal IT support is currently available in many facilities for HAI-related measures. In addition, with many of the measures within the IQR program undergoing review and updating, any electronic reporting must take into account the time needed to develop and implement the appropriate electronic adaptations for such changes. *We caution CMS about the timeframe for required electronic reporting of HAI*

data and encourage collaboration with CDC/NHSN and EHR vendors to determine this timeframe.

CMS also indicates it is considering the addition of Hepatitis B Vaccine Coverage Among all Live Newborn Infants Prior to Hospital or Birthing Facility Discharge (NQF #0475) as an electronic clinical quality measure starting October 1, 2016. SHEA recognizes this measure is an important part of public health safety and supports the addition of this measure for reporting.

Form, Manner, and Timing of Quality Data Submission

CMS notes that for the FY 2016 payment determination and subsequent years, it wishes to clarify that all patient-level required data collected by CDC will be shared with CMS for Hospital IQR Program and Hospital VBP Program administration, monitoring and evaluation activities, including validation, appeals review, program impact evaluation, and development of quality measure specifications. CMS also proposes to receive access from CDC to voluntarily submitted name and race identifying information with respect to Hospital IQR Program required measures, and that this data will also be used for program administration, monitoring and evaluation activities, including validation, appeals review, program impact evaluation, and development of quality measure specifications.

SHEA has significant concerns and does not support the proposed release of all submitted patient-level data from NHSN as is set forth in this proposed rule. Although the intention to use the patient-level data for case-matching during the validation process is understood, SHEA suggests that CMS evaluate the outcome and consequences of obtaining Medicare patient-level data via the newly submitted Medicare beneficiary number process before it requests the submission of all patient-level data in general. This proposal for patient-specific protected health information (PHI) also, in our estimation, goes well beyond CMS' current need related to quality measure reporting and validation. CMS already receives specific information from CDC for cases selected during the validation process. This proposal to receive all patient PHI, including beneficiaries of non-CMS payers, opens the opportunity for data mining of highly sensitive patient information.

Further, NHSN users are assured in writing that the "information that is shared in this surveillance system that would permit identification of an individual ...will be held in strict confidence....and not disclosed without consent of the individual... in accordance with Section 304,306 and 308(d) of the Public Health Service Act." Providing all patient level data from NHSN to CMS that goes beyond CMS's current use for validation of quality reporting without specific explanation of usage would also potentially alter a hospital's willingness to report this information. Moreover, some of the patient identifier information is already voluntary for hospitals to submit (e.g. name, race, ethnicity) and CMS would only receive partial information from many of these cases.

CMS also proposed that this information be used for quality measure specifications. However, because CDC is the measure steward for all the NHSN measures that are used for IQR and VBP, there is no need for CMS to request this confidential patient identifier information. *SHEA is concerned about this CMS proposal and we do not feel this should proceed without engaging CDC's NHSN team and key stakeholders representing SHEA and APIC.*

SHEA notes that this precedent-setting action of releasing patient-level data, without appropriate testing and vetting of process, has the potential to open itself to patient-level data being requested at other levels. Unintended consequences from use of that data in validation programs that may not be “mature” could result in poor quality monitoring and possible breaches in patient confidentiality. In addition, out of concern for the retrieval of this data, facilities may begin choosing not to submit the voluntary data to CDC/NHSN. *SHEA requests that CMS delay implementation of the proposal until it is able to provide clarification on how the data may be used and protected. In addition, SHEA encourages CMS to collaborate with CDC/NHSN and other organizations on the retrieval and analysis of this data.*

Proposed Modifications to the Existing Processes for Validation of Chart-abstracted Hospital IQR Program Data

CMS is proposing to change the timing of when the sample for validation of the HAI data is selected. Due to the proposal to change the timing of the validation itself, the sample selection timing must also change. *SHEA supports this proposal and agrees with CMS that this change will give facilities more time to complete the HAI validation template requirements.*

CMS also notes that for FY 2017 payment determination and subsequent years, it will require hospitals to submit a mix of 40 charts to validate HAI measures and 32 charts to support clinical process-of-care measures (a total of 72 charts per year). This proposal is reflective of the greater impact the HAI measures will have on both the Hospital VBP and HAC Reduction programs. SHEA supports the direction of this proposal.

Finally, we note that CMS is proposing to expand the options for secure transmission of electronic versions of patient medical record reporting, specifically allowing hospitals to submit digital images (PDFs) of patient charts via the Quality Net website. *SHEA fully supports this proposal as we believe it will streamline the validation process and the burden of work for hospitals, which is an important factor in healthcare cost efficiencies.*

PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

CMS is proposing to delay public reporting of NHSN Catheter-Associated Urinary Tract Infections (CAUTI) and Central Line-Associated Bloodstream Infection (CLABSI) data until

2017 for PPS-exempt cancer hospitals. CMS recognizes that a low volume of data is being produced and reported by facilities and CDC is unable to calculate reasonable and reliable baseline estimates or expected rates. SHEA supports this delayed approach, and also urges CMS to be mindful of the same potential experience with the Harmonized Procedure Specific Surgical Site Infection (SSI) measure as well. We agree a minimum volume must be reported before meaningful analyses can be performed.

In addition, SHEA recommends study of method(s) and need to adjust when assessing performance of cancer hospitals to exclude patients in this setting who are discharged to hospice or admitted/transferred to palliative care service. Otherwise, cancer hospitals with a higher proportion of patients discharged to hospice or admitted to palliative care service might be at a disadvantage. Specifically these hospitals may have higher incidence of HAI (CLABSI, CAUTI or SSI) and/or mortality that reflects a higher case mix of those on hospice or palliative care.

Quality Data Reporting Requirements for Specific Providers and Suppliers
Long-Term Care Hospital Quality Reporting (LTCHQR) Program

CMS adopted two new quality measures for the LTCHQR Program for the FY 2016 payment determination and subsequent years, in addition to the three previously adopted measures (the CAUTI measure, CLABSI measure, and Pressure Ulcer measure): (1) Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680); and (2) Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) (77 FR 53624 through 53636).

SHEA agrees and supports this proposal. Long-term care hospitals (LTCH) provide an essential service to support patient's needs across the range of care settings. These metrics listed above are consistent with acute care and are applicable to LTCH. We feel the influenza vaccination – especially for personnel in LTCH – is an essential patient safety intervention and CMS' focus on this will facilitate increasing the proportion of personnel receiving annual influenza vaccine. Patients will benefit but as we have seen in the traditional skilled nursing home setting, there is lower return on investment on immunization of residents compared to personnel. *SHEA supports alignment of reporting proportion of patients and personnel receiving influenza vaccine with reporting period for other measures submitted to LTCH CARE data set starting in FY 2016 as it reflects the influenza season and will reduce the data entry time for LTCH personnel.*

CMS is also proposing three new LTCHQR program measures for the FY 2018 and subsequent years' payment determinations: 1) Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function; 2) Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support; and 3) National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure. Improved functional status and improved, early mobility by those patients who are ventilated reduces the likelihood of

infection, and significantly improves morbidity, mortality, cost, and quality of life in this vulnerable population and *SHEA therefore supports these proposed additions as long as there are sufficient resources to support collection of this to improve patient care and reporting requirements. SHEA does not support inclusion of VAE measure at this time.* Instead SHEA urges further study of this quality measure before proceeding with adoption. While CDC recognizes the importance of LTCH for surveillance, VAE is a relatively recent measure that is in active use in some acute care hospitals but has not yet been endorsed by NQF. The studies cited in this proposed rule refer to acute care facilities, but we are unaware of published investigations using VAE in the LTCH. As a result, we believe further experience is necessary with VAE surveillance in LTCH before moving forward adopting this as a quality measure. One example requiring clarification is whether the epidemiology of VAE differs in a LTCH setting where tracheostomies are largely predominant.

Because NHSN does support VAE reporting in the LTCH setting, we encourage CMS to wait for more experience with this in collaboration with NHSN. We anticipate the total number of LTCHs currently using this is modest in number and therefore limits establishment of a baseline level of performance. We do agree validation and accountability are important parameters for quality measures and reporting; at such time as there is more experience with VAE in LTCH setting along with NQF endorsement this measure can be revisited.

Previously Adopted Quality Measures for the FY 2017 and FY 2018 Payment Determinations and Subsequent Years

We agree and support the expansion to include Hospital Onset MRSA-BSI and Hospital Onset CDI SIRs for LTCH. This population carries a high burden of exposure to antibiotics as they arrive at LTCH with several weeks of therapy for infections that are difficult to treat. This results in selection for multidrug-resistant organisms (MDROs) so it is logical to include MRSA. We recommend studies to investigate measures that relate to antimicrobial stewardship for this setting as there is a global crisis involving emergence of MDROs. Often LTCHs are at the epicenter of clusters and outbreaks of cross transmission of MDROs. We recommend therefore collaboration with SHEA, Association for Professionals in Infection Control and Epidemiology (APIC), CDC, Society for Hospital Medicine (SHM) and clinicians who provide patient care in this setting to develop measures that promote stewardship and mitigate cross transmission. A great deal more is needed in this regard as this is a public health crisis that has already arrived.

LTCHQR Program Quality Measures and Concepts under Consideration for Future Years

We recommend that you consider development and pilot testing of measure(s) related to antimicrobial stewardship. This may fall under the topic of poly-pharmacy but we

feel more precise focus on this is important given the trends with MDROs in the U.S. and ongoing outbreaks of these amongst and between points of care delivery.

In conclusion, SHEA appreciates the opportunity to comment on the proposed measures and applauds CMS' continued commitment to improving quality and promoting patient safety. SHEA believes the current CMS-CDC interagency collaboration using NHSN as the foundation for HAI surveillance, prevention, control, quality improvement and value-based purchasing is critical and we commend CMS for its efforts to move away from administrative data and towards more accurate NHSN surveillance data for its HAI-related data sources. We encourage CMS to involve SHEA, APIC and CSTE as well as CDC in your efforts to further refine definitions, measures and validation processes. SHEA stands ready to assist in this important work.

Sincerely,

A handwritten signature in black ink, appearing to read "Daniel Diekema". The signature is fluid and cursive, with a large initial "D".

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