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June 18, 2010

Ms. Marilyn Tavenner, Acting Administrator
Centers for Medicare & Medicaid
Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445G
Washington, DC 20201

RE: CMS-1498-P, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2011 Rates; Effective Date of Provider Agreements and Supplier Approvals; and Hospital Conditions of Participation for Rehabilitation and Respiratory Care Services Medicaid Program: Accreditation Requirements for Providers of Inpatient Psychiatric Services for Individuals Under Age 21

Dear Ms. Tavenner:

The Society for Healthcare Epidemiology of America (SHEA) writes to address several issues raised by the Centers for Medicare & Medicaid Services (CMS) Inpatient Prospective Payment System (IPPS) Proposed Rule for Fiscal Year 2011.

SHEA was founded in 1980 to advance the application of the science of healthcare epidemiology and prevent healthcare-associated infections. The Society works to maintain the utmost quality of patient care and healthcare worker safety in all healthcare settings. SHEA is a growing organization, strengthened by its diverse membership with expertise in medicine, public health, and healthcare epidemiology.

We would first like to acknowledge and thank CMS for responding to our suggestions from prior years to focus on healthcare-associated infection (HAI) prevention and support our request to measure HAI reduction using rate-based, risk-adjusted measures developed from evidence-based guidelines and definitions. The proposal by CMS to utilize the standardized Centers for Disease Control and Prevention's (CDC) definitions and submission of data from CDC's National Healthcare Safety Network (NHSN) is welcomed by SHEA and our partners in infection prevention.

The emphasis on NHSN along with developing various electronic data

transfer systems is an encouraging approach since the current surveillance labor intensity needed for data collection is high. Data collection involves not only patient assessment and chart review, but frequently accessing the data manually in most facilities at this point in time.

SHEA supports value based purchasing programs (VBP), and we constantly seek a balance in the time needed for our primary mission, the prevention of HAIs (focusing on interventions related to HAI reduction) as well as documentation and data validation so essential in measuring improvements in as efficient and transparent a manner as possible. Secretary Sebelius has publicly acknowledged the remarkable success current interventions are having on dramatically reducing HAIs across the country.

As we comment on these proposals, we hope it is clear that we strongly support NHSN since it provides the most meaningful and standardized data to measure improvement and continue to work closely with our partners—including CDC, CMS and HHS to achieve our common objectives. CDC is developing electronic methodologies that will take advantage of the current capabilities of NHSN and reduce surveillance time and labor. NHSN does provide the necessary risk adjusted standardized data of value to CMS and the public as well as to our efforts to measure true HAI rates as we strive to eliminate HAIs. We simply seek a more deliberately time-sequenced approach to HAI data collection to meet CMS goals as well as our mutually desired outcome — the prevention of HAIs.

Quality Measure Reporting and Healthcare Quality Reporting (HAC)

Current status

This year, CMS is not proposing to add or remove any hospital-acquired conditions (HACs). Rather, the agency stated it is focused on evaluating the impact to date of the HAC policy. We note that CMS had provided analysis of nine months of present on admission (POA) coding and we find the data to be focused on cost impact of POA codes. We would encourage CMS to consider the implications of the POA assignments as well as the use of administrative data. For instance, the high proportion of the catheter-associated urinary tract infection (CAUTI) category showing nearly 83% coded as POA may reflect either outpatient processes or issues with the POA coding algorithm. The appended article by Meddings et al. may be useful in this analysis. (Meddings et al. *Infect Control Hosp Epidemiol* 2010; 31(6):627-633).

- **SHEA supports the CMS evaluation of the HAC policy and believes a robust program evaluation must continue to be conducted before CMS considers adding any *additional* categories of HACs.**
- **SHEA suggests POA data point to the need for sufficient training on new codes used in claims reporting and believe these results demonstrate the need for sufficient time for training on *any* new electronic media.**

SHEA appreciates that CMS laid out its vision for the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program for FYs 2012, 2013 and 2014 in the proposed rule as suggested by SHEA in previous years. Specifically, CMS proposes to retire one measure

for FY 2011, add 10 measures in FY 2012, add three measures in FY 2013 as well as require participation in one of four registries, and add four measures in FY 2014. However, the plan as outlined lacks sufficient detail to provide well informed comments. For example, although CMS lists eight possible HAC “measures” for FY 2012 there are no details on how the measures would be constructed. Moreover, CMS neither puts the RHQDAPU plan in the context of Meaningful Use of EHRs, nor outlines the relationship between the two programs going forward. We urge CMS to follow a methodical framework to prioritize and integrate measures into one program in order to reduce the burden on hospitals. The long-term goal should be to transition from RHQDAPU to incorporation of the program and quality measures into Meaningful Use measures.

- **SHEA urges CMS to reduce the burden on hospitals and to not grow both programs and measures at the same time. The long-term goal should be to transition from RHQDAPU to Meaningful Use measures.**

Measures for FY 2011

SHEA supports the retirement of the Agency for Healthcare Research and Quality (AHRQ) mortality measure for Selected Surgical Procedures Composite for FY2011. AHRQ itself noted in a June 2009 report that the measure is not appropriate for comparing hospitals’ performance.

- **SHEA agrees that the AHRQ mortality measure for Selected Surgical Procedures Composite be retired.**

Measures for FY 2012

CMS proposes eight hospital-acquired condition (HAC) measures:

- Foreign Object Retained After Surgery,
- Air Embolism,
- Blood Incompatibility,
- Manifestations of Poor Glycemic Control,
- Pressure Ulcers Stages III & IV,
- Vascular Catheter-Associated Infection,
- Catheter-Associated Urinary Tract Infection, and
- Falls and Trauma.

SHEA supports the *concept* of including HAI-HACs, i.e., Vascular catheter-associated infections and catheter-associated urinary tract infections (CAUTI), in RHQDAPU. Ultimately, as discussed below, we support the collection of healthcare-associated infection (HAI) measures through CDC’s NHSN. However, CMS has not clearly specified how these metrics would be constructed. For example, CAUTI is NQF endorsed but it is unclear if CAUTI is the same as the nursing sensitive measure: “Urinary catheter-associated urinary tract infection for intensive care unit (ICU) patients per 1000 catheter days” (NQF 0138) or how vascular catheter-associated infections would overlap with: “Central line-associated blood stream infection (CLABSI)” (NQF

#0139). Thus, it is difficult for SHEA to provide further comments without clarification.

- **CMS should remove vascular catheter-associated infections and CAUTI conditions from the existing HAC policy once they are defined and transitioned into RHQDAPU.**

SHEA believes that the non-risk adjusted HACs could continue payment under the existing policy that prevents a HAC from qualifying a case for higher payment as they are too rare to establish meaningful rates. Based on the Research Triangle Incorporated (RTI) study, CMS notes in the rule the prevalence of the following conditions that were not present on admission over a nine-month period that were proposed by CMS for inclusion in RHQDAPU: 172 foreign objects retained after surgery, 23 air embolisms, eight blood incompatibility cases, and 344 manifestations of poor glycemic control. In addition, CMS must maintain at least two conditions under the existing HAC policy by law. SHEA believes it makes most sense to retain the rare events under this policy and not include them under RHQDAPU. This will also prevent a single event counting toward both reduced payment under the existing policy and putting a facility financially at risk under VBP at the same time.

- **SHEA believes that the remaining conditions should continue under the existing policy that prevents a HAC from qualifying a case for higher payment as they are too rare to establish meaningful rates.**
- **SHEA strongly urges CMS to ensure that the existing HAC policy, the infections in VBP and the one percent reduction to payments for HACs starting in FY 2015 remain mutually exclusive policies with separate conditions in each pay-for-quality category.**
- **SHEA urges CMS to make the long-term goal to cultivate more global hospital-wide assessments of harm rather than targeting individual organisms or HACs as is its current practice.**

CMS invites comments on the retirement of:

- SCIP-Inf-6 Surgery patients with appropriate hair removal
- SCIP-Inf-2 Prophylactic antibiotic selection for surgical patients
- SCIP-Inf-4 Cardiac Surgery controlled post-operative glucose
- PN- 3b Blood culture performed before first antibiotic received in hospital

Retirement should occur when the standard of care has changed or performance of the preponderance of hospitals is at or very near perfect or, when an outcome measure is integrated that can take the place of a process measures (e.g. urinary tract infection rates versus catheter removal timing). Data collection should not continue, due to burden, unless there is a compelling argument that the standard of care may deteriorate if collection and monitoring does not continue.

Thus we agree that the following measure is topped out and should be retired:

- SCIP-Infection-6: Surgery patients with appropriate hair removal

The following measures' performance is not topped out, however; there are ongoing specification and abstraction concerns with these measures that prevent the providers from achieving top performance.

- PN- 3b Blood culture performed before first antibiotic received in hospital
- SCIP-Infection-2: Prophylactic antibiotic selection for surgical patients
- SCIP-Infection-4 Cardiac surgery controlled post-operative glucose

- **SHEA recommends that these measures be retired.**

Measures For 2013

CMS proposes requiring hospitals to participate in the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) by January 1, 2011 and publicly report data in FY2013

1. Central Line Associated Blood Stream Infection (NQF #0139)
2. Surgical Site Infection (NQF # 0299)

SHEA is a strong proponent of NHSN, a free, publicly available system and supports participation in NHSN which allows data to be directly available to CDC. Use of NHSN supports the use of data mining systems and other electronic media that assists hospitals to electronically collect data, allows NHSN data to be immediately shared with the CDC, and CDC to then funnel the data to the CMS QualityNet without reentry of data.

Given the number of HAI measures that will be required from the HHS HAI Action plan to be in place for the VBP program eligibility by FY 2013, use of NHSN at the moment would be overwhelming and labor intensive. The processes to directly link electronic surveillance activities and electronic health records to the NHSN, and the techniques that are rapidly evolving to further automate this data collection process are close, but not yet complete.

CMS notes that currently 21 states mandate public reporting of infections through NHSN. The majority of states mandate reporting of CLABSI, although each state varies in their selection of surgical procedures listed in NHSN's operative procedures that are monitored for SSI. NHSN is widely utilized by thousand of hospitals, but the modules differ from state to state and from hospital to hospital in states without legislative mandates.

However, hospitals that are not currently participating in NHSN did not budget for the needed staff or additional electronic systems that could further support NHSN data input process. Many hospitals will have less than five months warning before compliance is required that would require data submission January 1, 2011 in order to collect data over a two-base period (one not being quite a full calendar year of data) and submit October 1, 2012 (FY 2013) for reimbursement. Newly enrolled hospitals need time to hire and/or train staff on NHSN and begin internal validation. Each type of HAI has a separate module in NHSN that requires

training. We question whether the data submitted without quality testing from these new hospitals will be sufficiently robust for both public reporting and reimbursement. Currently, state resources vary widely in providing electronic systems enabling vendors to transmit data directly in to NHSN and thus to CDC. Currently most hospitals are entering surveillance data manually and without a reasonable time frame, hospitals risk diverting staff away from critical prevention activities that have been shown to dramatically prevent HAIs as noted earlier. Again, SHEA does support the use of NHSN for the reasons noted earlier and simply requests time to submit data in a planned, systematic way. Alternative systems can not provide the level of risk adjusted data needed to measure true HAI rates and improvements.

Validation of the data is an effort CDC has recommended in the HHS-HAI Action Plan. We note that some American Recovery and Reinvestment Act (ARRA) funding has been provided to states and allocated to fund validation activities as part of the Action Plan. Since CDC is continuing development of a 'gold standard' for validation, SHEA urges CMS to work with CDC and consider the staffing qualifications, and funding as well as the timeline for submitting NHSN data.

We are pleased to learn that the digital certificate system on the NHSN website will soon be replaced by a password system, which will decrease the time necessary to enroll hospitals in NHSN. Despite this, SHEA remains concerned about the ability to enroll the additional 1,000 hospitals in order to meet CMS timelines.

- **Given these challenges and the need for alerting and educating non-enrolled hospitals, SHEA believes CMS *should require only one measure starting January 1, 2011 for payment in FY 2013.***
- **SHEA urges CMS to work with CDC to ensure validation processes, criteria for training and the necessary state health department funding support beyond CY 2011.**

Several HAI measures in the HHS Action Plan are not developed or testing sufficiently to be ready for public reporting or linking to payment determinations at this time. Nevertheless, we understand that Congress has required the inclusion of these measures as part of the national (VBP) program beginning in FY 2013. The plan includes CAUTI, Methicillin-resistant *Staphylococcus aureus* (MRSA), *Clostridium difficile* infection (CDI), ventilator-associated pneumonia (VAP), surgical-site infections (SSI) and CLABSI. We again note that the measures are at different stages of development, for example, VAP is lacking a standardized definition and neither MRSA nor CDI are clearly defined nor NQF endorsed.

- **In order to satisfy this Congressional mandate, yet balance the concerns stated above, SHEA believes CMS should finalize its proposal to collect *only the NQF endorsed nursing sensitive CLABSI in ICUs for data collection starting January 1, 2011.***

This will provide hospitals with experience with this as a RHQDAPU measure before it is included in VBP as required by law, i.e., data collection over two base periods in order to calculate improvement and attainment scores.

- **SHEA believes that CLABSI is the only measure that is sufficiently vetted through the consensus process to be adopted quickly and meet the statutory requirement.**

Once CMS completes its measure maintenance review, SHEA believes that CLABSI will be ready for public reporting and tying to payment in FY 2013. The measure is thoroughly specified, is the most commonly used module in NHSN for those already enrolled, is salient to consumers and holds important information for hospitals to use in their quality improvement programs. It is important that hospitals are able to continue using the NHSN software or other systems that generate reports to submit to NHSN without the need for full manual abstraction of data to satisfy this requirement rather than having to join an additional registry.

- **SHEA supports CLABSI for payment in FY 2013 assuming the measure is fully transparent, utilizes NHSN, and hospitals do not have to join a registry to report the information.**

The other action plan HAIs (CAUTI, SSI, CDI, MRSA, and VAP) are not yet ready for inclusion in the RHQDAPU and VBP programs and should be phased in over time. Each of these can be collected through NHSN once the measures are further developed and the remainder of hospitals begin participating in NHSN. At this point in time, MRSA and CDI require clinically enhanced data to sufficiently identify whether the infections are community- or hospital-acquired, and such measures are still in development as discussed below. VAP is still lacking a clear definition. CMS has noted the challenges of collecting MRSA and CDI for HACs from claims data when each was proposed in past years and we believe CMS would agree these need to be developed very carefully. CDC has developed less labor intensive modules that can address some of the above issues in time.

- **CMS should consider SSI and CAUTI as the second step of infections to be included in RHQDAPU and then into VBP, as these are well-specified and many hospitals have experience reporting these measures.**
- **The remaining HHS-HAI Action plan measures (CDI, MRSA, and VAP) are not yet ready for inclusion in the RHQDAPU and VBP programs and given the multiple constraints should be phased in over time.**

CMS had also proposed that hospitals collect SSI in CY 2011. However we do not believe that hospitals can undertake this measure in 2011 given the general constraints outlined earlier. The HHS HAI Action plan never intended hospitals to collect data on *all* surgical procedures, and CMS has not defined which procedures will be required or the minimum threshold per procedure when the numbers of cases would be too small to be meaningful. We urge CMS to seek guidance from CDC on this issue. The manual collection of these infections through chart-abstraction for *all* procedures would be overwhelming to most facilities.

For example, it is critical for hospitals to select surgical procedures and determine priorities based on risks of their population and programs. CDC's NHSN provides the capacity to select procedures that fit large academic, as well as community and specialty hospitals with different populations and surgical procedures. Given the extensive elements that need to be collected to determine SSIs, hospitals need to balance the burden of prospective surveillance coupled with chart review for all *other* HAI measures proposed by CMS, as well as other infection prevention and control responsibilities. We recommend CMS work with CDC, to identify and publish a list of procedures applicable to most hospitals and permit hospitals to select procedure(s) that best fit their population. Hospitals should be permitted to begin with one procedure the first year and add as appropriate in a systematic manner given the importance of validating both numerator and denominator data. Initial measures that might be considered include SSI deep sternal wound infections following CABG procedures or SSI following total hip/knee replacement, as many facilities include outcome monitoring of these SCIP procedures.

- **SHEA urges CMS with CDC to undertake data analyses to determine which procedures are most likely to affect improvement and then provide a list of surgical procedures applicable to most hospitals. CMS should address the cutoff threshold of number of cases per procedure that would ensure meaningful data, using NHSN defined procedures and metrics for submission.**
- **SHEA urges CMS in collaboration with CDC to permit hospitals to select procedures most applicable to their populations and programs from the published list. Hospitals should be permitted to submit one procedure in the first year using a systematic, stepwise process for any additional procedures in subsequent years.**
- **Clarification should be made whether any or all procedures apply to specific populations such as adult or pediatric populations in non-Children's hospitals or both.**

As each NHSN measure is adopted into RHQDAPU, CMS should also consider the overlap with the existing HAC policy. As these measures are integrated into the RHQDAPU program, CMS should discontinue them in the existing HAC policy to the extent that they overlap and should not consider them for the one percent payment reduction that is to be implemented in FY 2015.

- **SHEA urges CMS to structure the three payment policies to ensure that each category is mutually exclusive and hospitals are not penalized under more than one policy for the same event.**
- **SHEA hopes that HHS will release a revised HAI Action Plan later this year that provides some additional information on the measures and an appropriate implementation schedule and that CMS follows with a concrete plan within its future rulemakings.**

SHEA's proposed submission plan:

We do understand the intent of Congress is to submit HHS HAI Action Plan measures by October 1, 2012 (FY 2013) for eligibility in the VBP program. Given the constraints as outlined above and being aware of the efforts CDC is making to simplify the enrollment process for this web-based program, we propose the following submission plan:

1) **CLABSI** (NQF 0139; NQF endorsed Nursing sensitive measure) for ICU and high-risk nursery (HRN) patients [for non-Children's hospitals] defined as the number of central line-associated blood stream infections per 1000 catheter-days

- Data collection January 1, 2011 with submission October 1, 2012 (FY 2013)

2) **Surgical site infections** (NQF 0299) Percentage of surgical site infections occurring within thirty days after the operative procedure if no implant is left in place or with one year if an implant is in place in patients who had an NHSN operative procedure performed during a specified time period and the infection appears to be related to the operative procedure. For the type and number of procedures to be determined, *see SHEA's earlier recommendations*.

- Data collection January 1, 2012, with submission October 1, 2013 (FY 2014)

3) **CAUTI**-Nursing sensitive measure (NQF 0138) Urinary catheter-associated urinary tract infection for intensive care unit (ICU) patients per 1000 catheter days

- Data collection January 1, 2012, with submission October 1, 2013 (FY 2014)

4) **Remaining HHS HAI Action Plan measures** should be considered only after further input and refinement from CDC since they are either not yet NQF endorsed or do not have clear definitions.

- **SHEA believes it is prudent to address one NQF endorsed, measure (CLABSI) collected via NHSN for submission in FY 2013 until there is assurance that all hospitals are enrolled and functionally operational in NHSN. SHEA recommends delay in the submission of SSI and CAUTI measures until FY 2014 for the reasons outlined above.**
- **SHEA, as discussed under the HAC section, understands that during the transition of HAC SSI and HAC vascular-related BSI, from HAC to RHQDAPU, these measures may require payment under current HAC policy until the transition to RHQDAPU or VBP is complete. Once that system is in place we would expect the retrieval of these HAC measures using the current algorithms to end and no longer be linked to the HAC payment policy.**

Registry overlap

As noted earlier SHEA does not support use of proprietary data bases, e.g., the four eligible registries as currently proposed by CMS. In the case of SSI, we request CMS to clarify how they will reconcile the overlapping elements for procedures that are collected within registries (if CMS continues to require participation in a registry) such as the Society for Thoracic Surgery's (STS) deep sternal wound infection, and ensure STS will match the NHSN fields used for mediastinitis. It will be important to be assured that data transferred from both systems to CMS

will be exactly the same. Given that STS is proprietary there is no way to know whether the data being transferred will be the same as NHSN.

- **SHEA strongly recommends the reconciliation of overlapping measures since the fields though similar, must be exactly the same to avoid duplication of effort and confusion over interpretation. Alternatively, the STS SSI measure should be removed from the registry requirement.**

Data collection periods

Again, following CMS's timeline, SHEA seeks reconsideration of the scheduled data collection to start with January 1, 2011 discharges, particularly noting these data are tied to payment in FY 2013. A significant number of facilities are not currently reporting to NHSN, and even if all were enrolled by December 2010, there is no buffer period for testing and ensuring valid data. Given the number of HAI measures that need to be collected and tested in the NHSN system, SHEA recommends only one HHS-HAI measure should start data collection on **January 1, 2011** and be tied to payment in **FY 2013** –based on CMS requirement for two base periods of data submission. Numerous questions need to be answered to ensure we have a valid and reliable data collection and reporting system. As noted several times, SHEA recommends only CLABSI start January 2011.

- **SHEA reiterates and strongly urges CMS to require only *one* HAI data measure (CLABSI) be submitted Oct 1, 2012 (FY2013).**

Measures for 2014

CMS proposes two vaccination measures:

1. Global Flu Immunization, and
2. Global Pneumonia Immunization.

SHEA supports flu and pneumococcal vaccinations but implementation of these measures are quite complicated when applied to all populations. Recording the assessment of each patient for level of risk and contraindications, and assigning a status level needs to be considered and neither measure is NQF endorsed at this time.

- **SHEA urges CMS to continue the dialogue on these two measures and review by NQF before determining if they should be considered for adoption.**

Measures for 2015

CMS proposes Influenza Vaccination of Healthcare Personnel

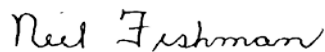
SHEA applauds CMS for adding this measure to the RHQDAPU program. We note that “healthcare personnel” (HP) in general continue to have low influenza vaccination rates and support the addition of this measure to the RHQDAPU program. However, SHEA suggests that the definition of healthcare personnel be clearly defined. In recent CDC analyses it was noted

that rates among *hospital* personnel were much higher than overall HP rates. Although they all need to be higher, careful consideration of definition is imperative given the impact on reimbursement for hospitals. A threshold would need to be developed and exemptions must be made for facilities at times of vaccine shortage.

- **SHEA recommends this measure be considered for future reporting but with much more specification and definition.**

We again thank CMS for listening to our suggestions from prior years to focus on HAI prevention and support our ability to measure HAI reduction using rate-based, risk-adjusted measures developed from evidence-based guidelines and definitions. We hope it remains clear that our time concerns are in our common interests to balance infection prevention activities with quality documentation and validated data using the best possible system, NHSN. SHEA stands ready to assist CMS as it moves into an approach that provides incentive payment for minimizing HAIs, based on associated actionable evidence-based practice guidelines.

Sincerely,

A handwritten signature in cursive script that reads "Neil O. Fishman".

Neil O. Fishman, MD
President, SHEA

Attachment