



June 30, 2009

Mrs. Charlene Frizzera
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: CMS-1406-P, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and Fiscal Year 2010 Rates and to the Long-Term Care Hospital Prospective Payment System and Rate Year 2010 Rates; Proposed Rule (Vol. 74, No. 98), May 22, 2009.

Dear Mrs. Frizzera:

The Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA) write to address several issues raised by the Centers for Medicare & Medicaid Services (CMS) Inpatient Prospective Payment System (IPPS) Proposed Rule for Fiscal Year 2010.

SHEA was founded in 1980 to advance the application of the science of healthcare epidemiology and prevent healthcare-associated infections. SHEA 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.

IDSA represents over 8,000 physicians and scientists devoted to patient care, education, research, and community health planning in infectious diseases (ID). Our members care for patients of all ages with serious infections, including meningitis, pneumonia, tuberculosis, surgical infections, HIV/AIDS, those with cancer or transplants who have life-threatening infections caused by unusual microorganisms, and new and emerging infections, such as severe acute respiratory syndrome (SARS) and influenza.

Our comments primarily reflect the concerns of our members in hospitals and health systems who as patient care providers have a vested interest in the effective operation of the IPPS and the prevention of healthcare-associated infection (HAI). We will primarily address the Hospital-acquired Conditions (HAC) related to HAI and the proposed quality measures for Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) for 2011 and 2012 that involve HAIs.

HOSPITAL-ACQUIRED CONDITIONS

The Deficit Reduction Act (DRA) required CMS to identify by October 1, 2007 at least two preventable complications of care that could cause patients to be assigned to a complication or comorbidity (CC) diagnosis-related group (DRG). The conditions must be either high-cost or high-volume or both, result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis, and be reasonably preventable through the application of evidence-based guidelines. The DRA mandated that for discharges occurring on or after October 1, 2008, the presence of one or more of these preventable conditions would not lead to the patient being assigned to a higher-paying DRG. In the FY 2008 inpatient PPS final rule, CMS adopted eight conditions for which it would no longer pay a higher DRG rate if the conditions were not present on admission. In the FY 2009 rule, CMS selected two additional conditions and expanded one of the original categories.

This year, CMS is not proposing to add or remove any hospital-acquired conditions. Rather, the agency stated that it is focused on evaluating the impact to date of the hospital-acquired conditions policy. We strongly support CMS' careful evaluation of the policy and believe that a robust evaluation of the program should be conducted before CMS considers the inclusion of any additional categories of HAC. In its HAC program assessment, we encourage CMS to include an evaluation of potential unintended consequences, validation of relevant data collected and an exploration of how information learned from present-on-admission coding could be used to better understand and prevent hospital-acquired conditions. Ultimately, improving the care of patients should be the end goal of this policy.

- **SHEA and IDSA support further review of the HAC program and urge CMS to continue to use any information learned from the evaluation to examine ways that the quality of patient care can be improved.**

QUALITY MEASURE REPORTING

General Comments

The *Deficit Reduction Act of 2005* (DRA) expanded quality reporting requirements for hospitals to be eligible to receive a full market basket update and provided the Secretary with the discretion to add quality measures that reflect consensus among affected parties and replace existing quality measures when they are no longer appropriate.

In the proposed rule, CMS puts forward four new measures to be included for the fiscal year (FY) 2011 annual payment determination. To receive a full market basket update, hospitals would have to pledge to report data on these and all measures currently included in the pay-for-reporting annual payment update program and pass the established data validation tests. In the

rule, beyond adding these four measures to the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program and payment in FY 2011, CMS proposes removing one measure and combining two others. This brings the total number of measures required to receive a full payment update to 46. At the same time, CMS lists 69 proposed candidate measures for inclusion beginning in FY 2012. SHEA and IDSA are concerned about the volume of measures under consideration for FY 2012. Although we will address primarily those measures related to HAI, we would first note that half of the measures put forward by CMS have not as yet been endorsed by the National Quality Forum (NQF). The NQF is designed to permit interested healthcare stakeholders to come together to identify measures that are useful and appropriate for quality improvement and public reporting. SHEA and IDSA would encourage CMS to embrace the requirement articulated in the DRA that quality measures be selected only when there is "consensus among affected stakeholders." In light of this charge, the consideration of measures not yet endorsed by NQF would appear problematic.

As related to the proposed HAI measures, it is important to acknowledge the set of metrics proposed in the Department of Health and Human Services' (HHS) HAI Action Plan. These measures are consensus-based, developed in a public-private partnership and are presently in the process of being implemented and tested in all states. As you are aware, HHS has been charged to integrate HAI measures across all HHS agencies including CDC, CMS, and AHRQ. As the HHS-HAI metrics are implemented and tested, we recommend that CMS make a conscious effort to consider and align these consensus-based metrics among the HAI measures currently listed in the 2012 quality measures in order to avoid potential redundancy and inappropriate omissions.

- **SHEA and IDSA believe it is necessary that any measures included in the pay-for-reporting program first be subjected to the rigorous, consensus-based assessment processes of NQF, HQA or other federally recognized entities.**
- **The HHS HAI Action Plan includes a comprehensive examination of potential metrics. Future modifications to the CMS quality metrics should be aligned with these consensus measures**

Measures for FY 2011

CMS proposes the following HAI related measure changes:

- *Add SCIP-Infection-9: Postoperative Urinary Catheter Removal on Postoperative day 1 or 2;*
- *Add SCIP-Infection-10: Perioperative Temperature Management;*
- *Adds Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care.*

We believe that the SCIP measures are mature enough for public reporting and tying to payment as they are NQF endorsed and sufficiently field tested. We also believe they are based on sound evidence and hospitals can rely on clear guidelines to achieve the appropriate processes. However, we caution CMS to consider whether it is appropriate to adopt SCIP-9 in 2011 if it plans to implement the nursing sensitive measure, *Catheter-Associated Urinary Tract Infection* (UTI), in 2012. Each of these two measures work toward the same goal of reducing UTIs among hospital patients. Ultimately, we believe that the broader outcome measure should eventually supplant the related process measure, which is likely to become outdated as science evolves. It should be noted that the HHS-HAI Action plan has also included a CA-UTI metric that should be considered alongside other UTI related measures when aligning and selecting the final measure for 2012. This integrated approach could be applied to the consideration of all future measures. As some of the proposed nursing sensitive measures are currently undergoing NQF measure maintenance review, SHEA and IDSA recommend that CMS postpone any consideration of these measures until the NQF review process is completed. It would be burdensome, confusing and unnecessary for related process and outcome measures with the same objectives to continually feed into the program. CMS should formally build into its retirement framework a process for determining when closely-related process measures should be removed in favor of broader, more robust outcomes measures.

- **SHEA and IDSA support SCIP-10 in FY 2011 and support SCIP-9 until a broader-based measure is adopted based on the results of NQF review and finalization of the HHS HAI Action Plan.**

Measures for FY 2012

CMS has proposed 69 measures for possible inclusion in RHQDAPU beginning in FY 2012. The list includes measures pertaining to a wide range of areas such as stroke, venous thromboembolism, complications of care, timeliness of emergency care, mortality, surgical care improvement, cardiac and nursing sensitive care and healthcare-associated infections (HAI). Although CMS provides more specific information than in last year's rule, SHEA and IDSA further ask that in the future CMS make the detailed measure specifications readily available in one location during the comment period so that experts and stakeholders in the field can easily examine and comment on the measures in a timely fashion. We again note that for proposed HAI measures, it is essential that CMS consider the metric set proposed in the HHS HAI Action Plan. In looking to the future, as the HHS-HAI metrics are implemented and field tested, SHEA and IDSA recommend a deliberate effort to consider these metrics when selecting the final HAI measures.

SHEA and IDSA encourage CMS to continue to pursue more strategic implementation of measures and to prioritize the measures according to: (1) value in improving quality and reducing costs, (2) utility to beneficiaries, (3) level of burden imposed on providers, and (4)

readiness for implementation. As the number of measures in the program proliferates, we also ask that CMS consider whether a measure represents an intermediate step on a process map of a clinical entity already measured and/or is likely highly correlated with another existing or proposed measure. In all cases, the goal should be to avoid redundancy and to promote the measure that is, all things equal, closest to the outcome of interest to the patient, and in alignment with best clinical evidence.

In addition, SHEA and IDSA propose that CMS consider an assessment of the feasibility of constructing measures from data contained already included in the typical hospital Electronic Health Record (EHR) and other commonly used data collection and surveillance systems, including the degree to which the measure adds information not captured in other measures. The HHS HAI Action Plan emphasizes the use of the Centers for Disease Control and Prevention's (CDC's) National Healthcare Safety Network (NHSN) system for data collection of the proposed metrics. We urge CMS to adopt NHSN data elements and specifications since it is important that hospitals are able to continue using NHSN software or other vendor systems that report directly to NHSN. This should improve the ability of seamless data transfer to CMS in the future and further reduce redundancy.

Finally, the very process by which measures are selected and deployed should be approached in a more deliberative manner. SHEA and IDSA encourage CMS to select a few measures in each category including HAI, each year that meet these objectives and grow the program slowly and steadily. This approach has the added advantage of allowing for continual assessment of the measures themselves in order to maximize rigor and the overall impact on the quality of care for patients.

I. Measures supported for the future *with conditions*

CMS proposes a total of eight hospital-acquired infections across the measure topics:

Measure Topic	Measure
HAI	Methicillin-resistant <i>Staphylococcus aureus</i> (MRSA)
HAI	<i>Clostridium difficile</i> infection (CDI)
Nursing Sensitive/HAI	Ventilator-associated pneumonia
Nursing Sensitive/HAI	Catheter-associated urinary tract infection
Nursing Sensitive/HAI	Catheter-associated blood stream infections
Outcomes	Infection due to medical care
Outcomes	Post-operative sepsis
Cardiac Surgery	Deep Sternal wound infection rate

SHEA and IDSA are partners with HHS in its Hospital-acquired Infection (HAI) Action Plan and supported the six conditions chosen as the focus of the prevention targets in this comprehensive document. As stated in the plan, catheter-associated urinary tract infections (CA-UTI), surgical site infections (SSI), catheter-associated bloodstream infections (CA-BSI) and ventilator-associated pneumonia (VAP) account for about 75 percent of the HAIs acquired in an acute care hospital setting. These four infections have the strongest evidence and best practices for prevention. The seriousness of methicillin-resistant *Staphylococcus aureus* (MRSA) and *Clostridium difficile* infection (CDI) warranted inclusion on the list as well, but have serious challenges in terms of specific, standardized metrics and would not be ready for consideration in 2012. Although SHEA and IDSA supported these six conditions for the plan's purpose of establishing national goals, we do not believe that all of the conditions that overlap with CMS' proposal are ready to be added to the RHQDAPU program. In fact the final set of metrics proposed for implementation of the HHS-HAI plan is not expected to include VAP because of the challenge of identifying more objective criteria to define and diagnose VAP. As has been noted, the metrics for MRSA and CDI are viewed as developmental, require field testing and are not recommended for 2012. Although we discuss some of the infections below, additional related comments are within the measure sets in which the infections are proposed.

Once NQF completes its measure maintenance review, we believe that the nursing sensitive measures, CA-BSI in the ICU and possibly CA-UTI in the ICU will be ready for public reporting and tying to payment in FY 2012 as noted earlier. CA-BSI, has been thoroughly specified, is salient to consumers, and holds important information for hospitals to use in their quality improvement programs. Again, these measures are part of CDC's NHSN system, and we urge CMS to adopt NHSN data elements and specifications.

- **SHEA and IDSA support CA-BSI in the ICU for payment in FY 2012 assuming the measures are fully transparent.**

II. Measures needing substantial development before implementation

Unless significant advancements are made in the restructuring of these measures and their specifications, SHEA and IDSA do not currently support the inclusion of these measures in the RHQDAPU program.

Patient Safety Indicators (PSI) - HAI related

- PSI-7 *Infection Due to Medical Care*
- PSI-13 *Post Operative Sepsis*

We believe these AHRQ measures (intended for *research*) have not been sufficiently developed through the consensus building process. While the measures may have value to hospitals for internal quality improvement purposes, they currently lack the sensitivity and specificity required

for use as comparative, publicly reported measures. Because they are derived from administrative data, they are less sensitive than measures derived from clinical chart abstraction at identifying relevant patients and excluding other patients. As CMS is aware, some of the AHRQ indicators have very high false positive rates, meaning they indicated potential problems, but further investigation showed the care was adequate and the indicator was not accurate. Thus, these measures continue to need extensive field testing and respecification.

CMS proposes eight hospital-acquired infections

MRSA, CDI and VAP: As noted above, we support selected HAI measures proposed by CMS for inclusion in RHQDAPU in 2012, but do not support the inclusion of MRSA, CDI and VAP. Although we agree that these infections should be included among the prevention targets in the HHS plan, we do not believe the measures are sufficiently developed for tying to payment. There is no question that MRSA and CDI are a growing problem due to epidemic strains in the community. We have much to learn about distinguishing community-acquired strains from hospital-onset strains as well as the best interventions for prevention.

Another major challenge VAP presents is identifying objective criteria for definitions and diagnosis. VAP is part of the HHS Action plan but the final set of proposed plan metrics is not expected to include VAP because it is challenging to develop a robust definition using objective criteria for diagnosing VAP. Hospitals measure VAP and MRSA for internal improvement but this does not mean that the measures are ready and appropriate for public reporting and tying to reimbursement in 2012. CMS should monitor the progress of the HHS-HAI plan to determine if meaningful definitions of VAP in ICUs emerge and if appropriate metrics for both MRSA and VAP develop that are useful for consumers and hospitals before it implements measures within RHQDAPU.

In addition, we are concerned about the appropriateness of CDI as a quality measure for 2012 for a number of reasons. First, questions exist regarding the CDC preventability guidelines and there are concerns in the field regarding the difficulties in quantifying this condition in addition to its level of "preventability." As noted, there is still much to learn about the most accurate method to collect and report this information, since there are many issues related to establishing the timing of onset, that is, community-acquired, or hospital-associated, as well as determination of actual disease versus colonization. We agree that outbreaks due to transmission within hospitals are preventable by appropriate infection prevention and control precautions, but what is not well understood by providers and consumers is that cases will continue to occur in some individuals as an unintended and non-preventable consequence following treatment with appropriate antibiotics or antineoplastics that are necessary to treat underlying conditions. In other words, sometimes CDI is a known side effect of following evidence-based care for patients that is weighed against the risk of not providing such treatments for the underlying condition.

Deep sternal wound infection rate: This has been listed as part of the cardiac registry measures for the past two years, and is also an NHSN measure. We would be supportive of CMS considering this measure in the future as it is available through NHSN and suggest that CMS consider testing its ability to receive such data from CDC.

SHEA and IDSA urge CMS to better define measures in this area, validate, and field test them as part of its measure selection plan before inclusion in the RHQDAPU program.

CMS proposes eleven Nursing Sensitive measures including three HAI rates

- Catheter-Associated Urinary Tract Infection in the ICU
- Ventilator-Associated Pneumonia in the ICU
- Central Line-Associated Blood Stream Infection in the ICU

As already noted, some of the proposed nursing sensitive measures are currently in the NQF measure maintenance review; CMS should postpone any consideration of these measures until the NQF review process is completed. If, however, NQF completes its process and CMS adopts these measures it should consider whether other highly related measures should be deleted, combined or modified in light of earlier discussions of alignment and reduced redundancy.

SHEA and IDSA tentatively support the adoption of selected HAI measures in FY 2012 assuming these measures are endorsed by the NQF, all methodologies are made fully transparent and they are aligned with other validated measures.

III. Measure needing more information

We do not have enough information at this time to appropriately comment on the measure below. CMS should provide additional information, such as results of field testing on these measures in next year's rule if it still believes at that time that the measures are ready for integration into the program.

CMS proposes one SCIP measure:

- Short half-life prophylactic administered preoperatively redosed within 4 hours after preoperative dose.

Without measure specifications available, we are unclear whether the SCIP redosing measure uses data elements that are already collected for the SCIP Measure set. If this is the case, we would support its adoption in FY 2012. We would hope this could be examined and perhaps incorporated as an element of a single measure of "appropriate antibiotic prophylactic timing."

Mrs. Charlene Frizzera
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We thank CMS for working to improve the quality of patient care. SHEA and IDSA stand ready to assist CMS with a measurement approach that ties payment to conditions with a high prevention rate and associated actionable evidence-based practice guidelines.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark E. Rupp".

Mark E. Rupp, MD
President, SHEA

A handwritten signature in black ink, appearing to read "Anne A. Gershon".

Anne A. Gershon, MD
President, IDSA