



June 13, 2008

Mr. Kerry Weems
Acting Administrator,
Centers for Medicare & Medicaid Services
Attention:
CMS-1390-P, Mail Stop C4-26-05 7500 Security Boulevard,
Baltimore, MD 21244-1850

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Proposed Rule -- CMS-1390-P "Preventable Hospital-Acquired Conditions (HACs), Including Infections"

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 2009. We want to first thank CMS for their consideration last year of our input on the inaugural list of proposed conditions.

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. IDSA's members focus on the epidemiology, diagnosis, investigation, prevention and treatment of infectious diseases in the U.S. and abroad. Both groups have worked collaboratively and are in essential agreement with our colleagues in key organizations representing infectious disease and infection control authorities in our nation's acute healthcare facilities.

As organizations with considerable expertise in the prevention, detection, control, and treatment of infections, SHEA and IDSA support the Congress and CMS in their efforts to reduce adverse events in our hospitals. According to the Deficit Reduction Act of 2005, CMS was required by October 1, 2007 to identify "at least two conditions that are (a) high cost or high volume or both, (b) result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis, and (c) could reasonably have been prevented through the application of evidence-based guidelines." The inaugural list of eight conditions to which the HAC provision applies includes the following: Catheter-associated urinary tract infections, Stage III and IV pressure ulcers, foreign object retained after surgery, air embolism, blood incompatibility, falls/trauma, mediastinitis after coronary artery bypass grafting (CABG), and vascular-catheter-associated infections. For

discharges occurring on or after October 1, 2008, hospitals will not receive additional payment for these conditions if they are not present on admission and if they are the only complication or comorbidity or major complication or comorbidity.

The “reasonably preventable” clause is at the center of the debate over which HACs to designate for non-payment. While the preventability of some HACs, including the so-called “never events” such as foreign objects retained after surgery and blood incompatibility, are not in question, a significant proportion of healthcare-associated infections (HAIs) cannot be reasonably prevented even with complete adherence to evidence-based guidelines. This is due to other risk factors (such as patient comorbidities) that cannot be completely mitigated. As such, we urge the Agency to work with stakeholders, including SHEA and IDSA, to examine other markers of HAI prevention efforts, such as adherence to evidence-based process measures rather than the occurrence of specific events. And perhaps most importantly, we request further clarification from CMS on the definition of “reasonably preventable” for future evaluation of candidate conditions.

In addition, there may also be unintended consequences of designating HACs for non-payment that are not “reasonably preventable.” For example, we encourage CMS to look for these unintended consequences, particularly with regard to catheter-associated urinary tract infections, which were designated as an HAC for 2008. We are concerned that this designation will lead to unnecessary treatment of bladder bacteruria in hospitalized patients with indwelling urinary catheters, which could result in additional emergence of resistant bacterial and yeast infections and unnecessary cases of *C. difficile*-associated diarrhea.

RECOMMENDATIONS FOR FY 2009

In the 2009 IPPS Proposed Rule, CMS requests comments on several additional candidate HACs along with justifications for these selections. These additional candidate HACs, which are described in **Section F: Preventable HACs, Including Infections**, include the following:

1. Surgical site infections (SSIs) following total knee replacement, laparoscopic gastric bypass and gastroenterostomy, and varicose vein ligation and stripping
2. Legionnaires’ Disease
3. Glycemic control
4. Iatrogenic pneumothorax
5. Delirium
6. Ventilator-associated pneumonia (VAP)
7. Deep venous Thrombosis/Pulmonary Embolism
8. *Staphylococcus aureus* septicemia
9. *Clostridium difficile*-associated disease (CDAD)
10. Methicillin-resistant *Staphylococcus aureus* (MRSA).

The following comments will focus on the 2009 proposed HACs that are infectious in nature and for which SHEA’s and IDSA’s members have specific expertise (namely, items **1, 2, 6, 8, 9, and 10**).

We support including SSIs following total knee replacement and varicose vein stripping as HACs. Additionally, we share CMS’s concerns regarding MRSA as an HAC and agree that this condition should not be included. We also encourage CMS to utilize

adherence to evidenced-based process measures (such as the timely and appropriate delivery of antimicrobial prophylaxis to reduce the risk of SSI) as the use of HAI outcomes measures un-tempered by risk adjustment could lead hospitals to reduce admissions to seriously ill, immune-compromised patients.

We do not support including the following as HACs: SSIs following laparoscopic gastric bypass and gastroenterostomy, Legionnaires' disease, Ventilator-associated pneumonia (VAP), *Staphylococcus aureus* septicemia, and *Clostridium difficile*-associated disease (CDAD) as currently proposed. We strongly agree that these conditions cause serious morbidity to patients and that every effort should be made to eliminate HAIs that are preventable by applying state-of-the-art and evidence-based science. However, each condition noted above poses challenges in three areas: 1) the critical need for accurate diagnostic and POA codes (which in most cases do not currently exist); 2) the inability to identify these outcomes properly and consistently (definition issues); and 3) the fact that, in many individual cases, the referenced complications may not be reasonably preventable.

SHEA and IDSA do not believe that any of the six HAI-related conditions is always “reasonably preventable.” While great progress has been made in developing evidenced-based measures to reduce the risk of and thus the incidence of HAIs, not all infections can be prevented, even when reliable science and appropriate care processes are applied. Thus, even after accurate diagnostic and POA codes have been developed and definitional issues have been resolved, we believe that CMS will need to develop exclusion codes or modifiers for HAI-related conditions that allow hospitals to risk adjust certain patients.

We offer the following detailed comments on conditions 1, 2, 6, 8, 9 and 10:

#1 Surgical site infections (SSIs) following total knee replacement, laparoscopic gastric bypass and gastroenterostomy, and varicose vein ligation and stripping

We agree with CMS that SSI is a complication that should be included for consideration as a candidate HAC. SSIs cause a substantial degree of patient morbidity, mortality, and increased healthcare costs. Evidence-based guidelines for the prevention of SSI do exist (Mangram AJ et al. Guideline for prevention of surgical site infection, 1999. Hospital Infection Control Practices Advisory Committee Infection Control and Hospital Epidemiology 1999;20:250-78) and, when followed, should reduce the risk of SSI. For certain procedures, such as elective surgeries involving clean surgical sites in patients with relatively few underlying comorbid conditions, adherence to such guidelines can reduce the already low risk for SSI even further. SSI following total knee replacement appears to meet the criteria for inclusion as an HAC: namely, the condition is high volume and cost, occurring in more instances in FY2007 than 3 of the 8 existing HACs and having similar or higher costs than 5 of the 8 HACs. It is generally a clean, elective procedure, making it a lower risk procedure for infection. Application of evidence-based guidelines would be expected to prevent many SSIs following this procedure. There are, however, some exceptions. For example, patients undergoing reconstructive total knee replacement following debulking of an underlying tumor or malignancy or following an existing infection of a prosthetic knee arthroplasty may have an increased SSI risk (due to underlying immune suppression from pre-surgical chemotherapy or radiation, tissue destruction due to the

underlying disease, and/or preexisting infection) that would not be as reduced as in the patient undergoing elective total knee replacement for degenerative arthritis. Therefore, it is essential that diagnostic coding account for such differences in the underlying patient population. We, therefore, recommend that this HAC should include only SSI in an uncomplicated total knee replacement in a previously unoperated and uninfected knee.

As with the inclusion of mediastinitis following CABG, we would also recommend amendment of this candidate condition to include only deep tissue and organ-space (i.e. prosthetic joint) infections following total knee replacement. Superficial incisional SSIs may be confused with non-infectious processes, such as allergic reactions to incisional bandages which may lead to erythema surrounding the incision, also a diagnostic criterion for superficial SSI. The diagnosis of these deep infections, on the other hand, is typically less subjective and less uncertain. However, further modifications to existing codes will be needed to ensure accurate capture of deep SSI post-total knee replacement.

We do not disagree with the inclusion of SSI following varicose vein ligation and stripping, as this procedure is a low risk procedure involving a clean surgical site. Use of evidenced-based practices should reduce the incidence of this complication. It should be noted, however, that given the very low risk of infection following varicose vein surgery, routine antibiotic prophylaxis is not recommended following varicose vein surgery as with other higher risk procedures (Antimicrobial Prophylaxis for Surgery, The Medical Letter, December 2006;4:83+). In addition, the data provided by CMS in the call for comments indicate that SSI following this procedure is not of a high volume (3 cases noted in FY2007), a finding that corroborates the very low infection risk for this procedure.

We do not support the inclusion of SSI following laparoscopic gastric bypass and gastroenterostomy, chiefly due to concerns regarding the degree to which such infections can be prevented. While the use of evidenced-based practices will reduce SSI risk in patients undergoing these procedures, the nature of the procedure and the underlying morbidity in the patient population increase the likelihood of post-surgical complications. Specifically, the nature of these procedures, which disrupts the integrity of the gastrointestinal tract, exposes patients to gastrointestinal bacteria thereby leading to a higher risk of SSI. In addition, these procedures are predominantly performed on morbidly obese patients who are predisposed to experience post-surgical complications. Obesity itself confers an increased risk for wound complications post-surgery due to impaired wound healing, alterations in tissue distribution of prophylactic antimicrobials, and unrecognized alterations in blood glucose.

Several additional concerns should be noted regarding the inclusion of SSI outcomes as HAC which relate to the pathophysiology of these infections and the nature of their detection and treatment. Many SSIs are not diagnosed during the index hospitalization following surgery. In fact, with lengths of hospitalization decreasing, many SSIs may not develop or become manifest until after hospital discharge. SSIs may be detected in the outpatient setting during the initial post-surgical follow-up, while the more severe infections often result in readmission for further treatment (i.e. surgical debridement or institution of antibiotic therapy). Thus, many SSIs may be POA on a subsequent

hospitalization. Readmission may also not occur at the same institution where the initial surgery was performed. For complicated infections, referral to a tertiary or higher-volume medical center may occur.

Finally, infections of surgical procedures that involve use of a prosthetic device, as is the case with total knee replacements, may develop up to 12 months following the procedure, according to definitions from the Centers for Disease Control and Prevention (CDC). Accurately capturing these events, particularly months following the initial surgery, will be essential. Consideration of all of these factors must occur prior to implementation of SSI as an HAC.

Finally, we would encourage CMS to utilize measures that monitor adherence to key SSI prevention processes (i.e. timely delivery of appropriate surgical antibiotic prophylaxis) as opposed to SSI outcomes when assessing the quality of healthcare delivery and the prevention of HAIs in hospitalized patients. Many of these measures, such as those utilized via CMS's Surgical Care Improvement Project (SCIP), have been increasingly implemented and used as measures of surgical quality. Such process measures would also be less prone to the logistic concerns noted with the use of SSI outcomes above.

#2 Legionnaires' Disease

We **do not support** inclusion of Legionnaire's Disease because it fails to meet the criteria set forth in the DRA act, particularly the requirement that the condition be reasonably preventable. The natural habitat of *Legionella* spp. is water, and, therefore, *Legionella* spp. are commonly present in water supplies. Despite this, hospital water supplies that harbor *Legionella* are not commonly associated with nosocomial legionellosis. For this reason, the CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC) Environmental Infection Control guideline does not recommend routine environmental surveillance for *Legionella* spp. in hospitals without populations at high risk for *Legionella* infection such as stem cell transplant patients (Sehulster L, Chinn RY. Guidelines for environmental infection control in health-care facilities. Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). MMWR Recomm Rep 2003; 52:1-42). Instead, a clinical approach is advocated which includes environmental screening only after a case of nosocomial *Legionella* infection is confirmed. Nosocomial legionellosis is an infrequent occurrence. According to the Medpar database, only 351 cases were identified in 2007. Thus, most hospitals do not report even a single case in a year. The

HICPAC Environmental Guidelines clearly recommend against routine testing of hospital water supplies for *Legionella* spp. Conducting environmental surveillance would obligate hospital administrators to initiate water-decontamination programs if *Legionella* spp. are identified. Therefore, periodic monitoring of water from the hospital's potable water system and from aerosol-producing devices is not widely recommended in facilities that have not experienced cases of health-care-associated legionellosis. Clearly, an unintended consequence of including Legionnaire's Diseases as a HAC would be that many institutions would react to this HAC by diverting resources from infection prevention to unnecessarily screen water supplies for *Legionella* spp. and, when *Legionella* is recovered, expend scarce resources to treat

hospital water systems. As a further example of unforeseen consequences, we note that *Legionella* remediation efforts are costly and often ineffective and paradoxically may cause further damage to the hospital's water handling systems and pipes. Thus, we believe inclusion of this HAC might be more likely to benefit manufacturers of water treatment technologies than patients.

We agree with the statement that Legionnaires' disease is typically acquired outside of the hospital setting and may be difficult to diagnose as POA. *Legionella* pneumonia often begins as a focal infiltrate that progresses to multilobar involvement several days into the illness. This progression after presentation can be mistaken for a secondary infection. In addition, diagnosis of *Legionella* infection can be delayed. The main diagnostic tests include urinary antigen, which often has a slow turn-around-time, and culture isolation. Culture is best obtained via bronchoscopy or other invasive means. These invasive tests are more likely to be done on patients with progressive illness who have been hospitalized for several days. Finally, many patients who are most at risk for legionellosis have frequent hospital admissions. Given the long incubation period of this infection, when not identified as part of an outbreak, distinguishing between hospital acquired and community acquired cases can be quite challenging.

#6 Ventilator-associated pneumonia (VAP)

We **do not support** the inclusion of VAP as a candidate HAC. We agree that VAP is a serious infection responsible for excess morbidity and occasionally mortality in hospitalized ventilator-dependent patients, and that reducing the incidence of VAP is a desirable goal. In addition, we support the implementation of risk reduction strategies that involve modifiable risk factors. However, we do not believe VAP meets the CMS criteria for use as a HAC, both because of the lack of clear diagnostic criteria for identifying patients who have the condition (in distinction from other pulmonary processes that are often complications of their underlying disease), and because of our concerns that evidence for "preventability" of this condition is not sufficiently strong.

One of the criteria specified by CMS for its HACs is that clear ICD-9 codes identify the condition. In the case of VAP, although clarifications have been made to the ICD-9 codes themselves, the difficulty in identifying the condition remains problematic because of the lack of clear diagnostic criteria. Many patients who require ventilators have underlying primary lung conditions and/or other systemic conditions, such as sepsis or other types of shock that are associated with severe lung abnormalities. These conditions in turn lead to abnormal chest radiographic findings, fever, and alterations in oxygenation and ventilation, making the use of these abnormalities in defining VAP problematic. Further complicating the diagnosis of VAP is the fact that many patients develop evidence of inflammation and airway colonization in the presence of endotracheal tubes, so that even the laboratory indicators often used to determine whether infection is present can be misleading. In addition, many of the underlying lung conditions themselves make patients more vulnerable to pneumonia, the risk of which may be increased by the presence of a ventilator, but which cannot be solely attributed to a ventilator. As emphasized in a recent paper by Uckay and colleagues (Uckay I, Ahmed QA, Sax H, Pittet D. Ventilator-associated pneumonia as a quality indicator for patient safety? Clin Infect Dis 2008;46:557-563), "It is agreed that the definition of VAP is one of the most difficult diagnostic challenges in the critically ill

patient.” Not only is VAP one of the most challenging diagnoses for clinicians to make, but even post-mortem examination does not always clarify the issue. There is simply no “gold standard” for making a diagnosis of VAP. As long as VAP remains such a diagnostic challenge, clarity about which patients have this condition will not be achieved through coding alone.

A second criterion for selection of HACs relates to their preventability: the condition must be “reasonably preventable through application of evidence-based guidelines.” In the case of VAP the subtle differences between risk reduction—implementation of measures designed to lower the risk of acquiring pneumonia—and infection prevention—avoidance of infection—become important. Although there are studies suggesting lowering of VAP rates through implementation of a number of management strategies, such as elevation of the head of the bed, or improvement in oral care for ventilated patients, no studies suggest that routine implementation of these measures would prevent all VAPs. It is likely that implementing the same set of evidence-based risk reduction strategies might be enough to prevent VAP in some low risk patients who require short-term intubation, and fail to prevent it in other patients with underlying lung disease, and other co-morbidities, who require longer term ventilator support.

Moreover, all available evidence regarding the impact of preventive strategies in VAP prevention is limited by the lack of standard clinical definitions to distinguish those who do have pneumonia from those who have other pulmonary conditions. As was pointed out in another recent paper considering the use of VAP as a quality measure for public reporting and inter-hospital comparisons, “... if ventilator-associated pneumonia rates are used in determining hospitals’ compensation or are factored into their public reputations, the rate of diagnosis may decline simply because observers shift their interpretations of such criteria as “change in secretion character” or “worsening gas exchange.” Even well-intentioned observers might report substantial decreases in the rate of ventilator-associated pneumonia that reflect haziness in the surveillance definition rather than true improvements in the quality of care. Such changes in interpretation might not be deliberate— they would certainly be almost impossible to detect” (Klompas M, Platt R. Ventilator-associated pneumonia—The wrong quality measure for Benchmarking. *Ann Intern Med* 2007;147:803-805). SHEA and IDSA strongly support the implementation of evidence based risk reduction measures, while cautioning against the expectation that even 100% implementation would result in complete prevention of this condition.

Without a clear way to determine with certainty who actually has the condition, and with the number of variables, many of which are not modifiable, that contribute to a patient’s likelihood of developing pneumonia while on a ventilator, we believe that VAP is a poor candidate for consideration as a HAC, and we cannot support its inclusion in 2009.

#8 *Staphylococcus aureus* Septicemia

We agree with CMS that most preventable cases of *S. aureus* septicemia are related to vascular catheters. Since vascular catheter-associated infections have already been selected for the HAC payment provision, including a separate *S. aureus* indicator

would add many causes of septicemia that are less preventable or whose causation is more difficult to ascertain. Therefore, we **do not support** this candidate HAC.

Other causes of *S. aureus* septicemia include surgical site infections, ventilator associated pneumonia, skin and soft tissue infections, dialysis shunt/fistulas and primary septicemia. Some of these infections, such as VAP, are candidate HACs and are discussed elsewhere. In addition, the majority of dialysis shunt/fistula infections and skin and soft tissue infections leading to septicemia occur outside the hospital setting. We believe that selected expansion of specific surgical site infection HACs would be a better approach to capture additional cases of preventable *S. aureus* septicemia than a broad inclusion of *S. aureus* septicemia.

#9 Clostridium difficile-associated disease (CDAD)

We **oppose the inclusion of CDAD** as a HAC for several reasons. First, for many cases it is virtually impossible to ascertain where the infection was acquired. Although *Clostridium difficile* has been traditionally thought of as a healthcare-associated pathogen, it is now well recognized as a community-acquired pathogen as well. The series of factors that must be in place in order for a patient to develop disease due to *C. difficile* is complex, and not yet fully understood. Many patients who develop their first symptoms of CDAD in the hospital have received antibiotics in the outpatient setting, or in long term care facilities, and, increasingly, cases have been identified in patients who have no traditional risk factors (MMWR, 2005; 54, No.47; 2005:1201-1205. MMWR 2008; 57, No. 13: 340-343). Since *C. difficile* can be acquired in the community, and since the pathogen and its spores can persist for long periods, it would be difficult to accurately distinguish CDAD that begins in the hospital, even with judicious use of antibiotics, as nosocomial or community acquired. Attempting to distinguish patients who have CDAD “present on admission” is not only difficult, but does not make sense given the complexity of how this disease develops, the long incubation period, and the frequent exposure to non-hospital healthcare settings that many patients have.

More than perhaps any other healthcare-associated infection, preventive strategies for CDAD span the spectrum of healthcare settings, from home health to intensive care. Although SHEA and IDSA support the use of a number of simple tools available to prevent spread of *C. difficile* within hospitals and other facilities (e.g. hand hygiene, thorough environmental cleaning, and the use of contact precautions for patients who have diarrhea), we are not aware of any studies in which these methods were shown to eliminate CDAD from the hospital environment (McFarland, et al. AAIC 2007; 35; 4:241-248. Beaulieu, et al. CID 2006;42: 725-29. Pepin, et al. CID 2006; 42:725-27). Moreover, we would point out that antibiotic exposure is the risk factor for CDAD. SHEA and IDSA strongly support antibiotic stewardship programs in hospitals and appropriate use of antibiotics across all healthcare settings. However, even the elimination of inappropriately prescribed antibiotics would not prevent many cases of CDAD which develop in patients who receive antibiotics appropriately as part of management of infectious diseases.

#10 Methicillin-resistant Staphylococcus aureus (MRSA)

We strongly agree with the decision by CMS not to include MRSA as a HAC. We agree that many of the clinically significant healthcare-associated infections due to MRSA will be identified as HAC through vascular catheter associated bloodstream infection and surgical site infection categories. We agree with CMS that colonization with *Staphylococcus aureus*

(SA) is not a pathological state; efforts to eliminate this organism from its natural habitat are not only impossible, but likely inadvisable. SHEA and IDSA believe that efforts should continue to focus on preventing healthcare-associated infections due to all pathogens, including MRSA, but **do not support** excessive focus on prevention of infections due to a single organism. We recognize the variability in the community prevalence of MRSA as a subset of SA, the range of organisms that may be predominant pathogens at different hospitals and in different regions, and commend CMS for its continued commitment to widely applicable prevention strategies directed at device and procedure associated infections due to all pathogens.

CONCLUSION

We again want to commend CMS for their efforts toward improving patient safety and eliminating preventable complications of healthcare. Such efforts have and will continue to assist our members in the field in their dedicated efforts to prevent HAIs. The fight against HAIs is a challenging one, as there are many complex factors involved in the development of an infectious complication. Some of these factors, such as failure to use recommended aseptic techniques, are entirely correctable. Other factors, unfortunately, may only be mitigated (such as controlling elevated blood glucose -- but not eliminating diabetes -- in patients presenting for cardiac surgery) or cannot be modified during the course of hospitalization (such as obesity, underlying immune suppression, and acuity of the presenting illness), or at all (extremes of age, underlying organ dysfunction). Thus, most evidenced-based guidelines targeting HAIs have been shown to reduce the risk for, **but not to eliminate entirely**, the specific HAI. Our organizations would like to continue to work with CMS to identify and develop alternative measures for the assessment of implementation of HAI prevention strategies, because continuing to rely solely on HAI outcomes will not account for the variability in the underlying risk for infection in the patient populations for a specific healthcare facility. In particular, we encourage CMS to utilize adherence to evidenced-based process measures (such as the timely and appropriate delivery of antimicrobial prophylaxis to reduce the risk of SSI) in future efforts. Adherence to these measures are increasingly being tracked and reported to regulatory and quality programs, such as via SCIP. Use of these measures may be less subject to bias, especially that introduced by variability in patient populations which may be seen when HAI outcomes are utilized as a measurement of healthcare quality. Perhaps there are ways to combine process with outcome measures to develop thresholds for performance that would be more useful than either measure alone. As noted above, care must be taken to identify unintended consequences that may result from the designation of specific conditions as HACs, as the goal of the program should not be to cause undue harm but to protect patients.

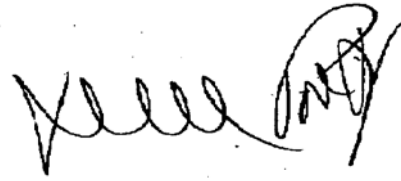
Finally, our societies will continue to work with the CDC and other organizations such as APIC, the Council of State and Territorial Epidemiologists (CSTE), the Institute for Healthcare Improvement (IHI) to investigate novel methods for the prevention of HAIs, to

evaluate tools to improve implementation of proven prevention practices, and to disseminate successful infection prevention practices. We are committed to improving the safety of healthcare and look forward to working with CMS toward this goal.

Sincerely,



Patrick J. Brennan, MD
President, SHEA



Donald M. Poretz, MD, FIDSA
President, IDSA