

Leslie V. Norwalk, Esq.
Acting Administrator,
Centers for Medicare & Medicaid Services
Attention:
CMS-1533-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 2007 Rates; Proposed Rule -- CMS-1533-P "DRGs: Hospital-Acquired Conditions"

Introduction

The Society for Healthcare Epidemiology of America (SHEA) wishes to thank the Centers for Medicare & Medicaid Services for the opportunity to provide additional input to the CMS proposed IPPS changes.

SHEA was founded in 1980 to advance the application of the science of healthcare epidemiology. SHEA works to maintain the utmost quality of patient care and healthcare worker safety in all healthcare settings. It upholds its high success rate in infection control and prevention, while applying epidemiologic principles and prevention strategies to a wide range of quality-of-care issues. SHEA is a growing organization, strengthened by its membership in all branches of medicine, public health, and healthcare epidemiology.

As an organization with considerable expertise in the prevention, detection, and control [and treatment] of healthcare-associated infections (HAIs), we are responding to the current CMS proposals outlined in Section F: CMS-1533-P Hospital-Acquired Conditions, beginning on page 172. We appreciate the opportunity to comment on how many and which conditions should be selected for implementation in FY 2009. Further, we 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, namely: the Association for Professionals in Infection Control and Epidemiology (APIC) and the Infectious Diseases Society of America (IDSA).

We applaud the foresight of CMS in this arena, as we have a shared vision of preventing adverse events, including HAIs, in the patients we serve in our respective care settings. We have participated in discussions with the Centers for Disease Control and Prevention (CDC) and appreciate that the broader scope of the Deficit Reduction and Reconciliation Act (DRA) of 2005 is "Hospital-Acquired Conditions." However we will focus most of our comments on HAIs, where we believe we have the most expertise. We hope that these suggestions will help finalize decisions that must be made this year in order to implement the proposed rule scheduled for October 1, 2008 (FY 2009).

We understand the DRA requires that by October 1, 2007, CMS must 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." For discharges occurring on or after October 1, 2008, we understand hospitals will not receive additional payment for cases in which one of the selected conditions was not *present on admission* (POA). That is, the case will be paid as though the secondary diagnosis was not present. The DRA requires hospitals to submit the secondary diagnoses that are present at admission when reporting payment information for discharges on or after October 1, 2007. CMS recently announced that the start date for coding conditions present on admission (POA) would be delayed to January 1, 2008 because of technical difficulties in the software program that accepts the new information.

In the proposed rule, CMS is seeking comments on how many and which conditions should be selected for implementation in FY 2009, along with justifications for these selections.

Six conditions proposed for consideration for FY 2009

CMS asks for comments on six conditions that include three serious preventable events as defined by the National Quality Forum (NQF):

1. Catheter-associated urinary tract infections;
2. Pressure ulcers;
3. Object left in during surgery;
4. Air embolism;
5. Blood incompatibility; and
6. *Staphylococcus aureus* septicemia.

We support CMS in this effort to identify appropriate conditions that should not occur in our hospitals. The challenge is two-fold: meeting criteria defined by Congress while also ensuring accuracy in the billing data that enable the appropriate identification of cases. We emphasize our belief and our concern that transition to the MS-DRG system requiring implementation of POA codes will demand enormous resources in a very short time period for training and education of clinical and coding staff.

Recommendations for FY 2009

Support

Although our organization's focus is infection prevention, we do **support numbers 3, 4 and 5** that is, the three serious preventable events: object left in during surgery, air embolism and blood incompatibility, as appropriate conditions to include for FY 2009. These conditions have been identified and supported by the National Quality Forum (NQF) and are currently identifiable by discrete ICD-9 codes. For the most part, these conditions can also be coded by hospitals without dependence on POA codes. POA codes *will* be necessary for "object left during surgery" because recognition of this condition can occur months to years after the initial event and, according to a recent review, lead to readmission in 30% of cases.¹ These are events that can cause great harm to patients and for which there are known methods of prevention.. It will of course be essential to ensure that the definitions, surveillance methods, and coding of these events are consistently applied and that certain specific medical circumstances are noted as exceptions. For example when patients deliberately have objects left in place, as opposed to

accidental retained foreign objects, in emergencies when patients deliberately receive unmatched blood, or when air embolism is technically unavoidable because of a specific surgical procedure.

No support for FY 2009

We **do not support numbers 1, 2 and 6 for FY 2009; i.e.**, catheter-associated urinary tract infections, pressure ulcers, and *Staphylococcus aureus* septicemia as currently proposed. We strongly agree that every effort should be made to eliminate HAIs that are preventable by applying state-of-the-art and evidence-based science. We believe these three indicators are potential candidates for the future, but each condition poses challenges in three areas: the critical need for accurate POA codes (which do not currently exist), the ability to identify these outcomes properly and consistently (definition issues), and the fact that, in many cases, the referenced complications may not be reasonably or entirely preventable.

As noted earlier, CMS proposes to rely on POA coding, a requirement that has now been pushed back to January 1, 2008 due to technical difficulties. CMS is aware of the experiences reported by the Agency for Healthcare Research and Quality (AHRQ)² which concluded that: “The level of hospital and coder commitment to accurate collection depended on the support and involvement of regional health information management associations, the amount of education provided by the state, and the availability of clearly defined coding guidelines.” CMS is also aware of two states already using POA codes, whose experience demonstrated that implementation requires a minimum of two years to achieve reliability. The process requires intensive education of clinicians to identify and record the complication enabling proper and accurate coding to determine the proper DRG assignment. We look to CMS to provide educational support. Until CMS is satisfied that POA coding accuracy is reliable, we do not believe any of these conditions can be selected. Although “object left in during surgery” also poses POA challenges, this condition is relatively rare. Definitions become critical in order to identify and apply appropriate interventions. Some of the relevant definitions are currently under review and require updating before they can be implemented successfully in a hospital reporting program.

We do not believe that each of these three conditions is always reasonably preventable. In our previous letter to CMS³, we noted that even when reliable science and appropriate care processes are applied in the treatment of patients, not all infections can be prevented. After POA codes are functioning reliably, each of the following conditions will need additional exclusion codes to minimize the risk of including nonpreventable infections.

We offer the following specific comments on each of these conditions

#1 Catheter- associated urinary tract infection (ICD-9-CM Code 996.64 - Infection and inflammatory reaction due to indwelling catheter)

CMS accepts the opinion of infectious disease experts that urinary tract infections may not be preventable after catheters have been in place for several days. The evidence based guideline referenced by CMS (http://www.cdc.gov/ncidod/dhqp/gl_catheter_assoc.html) was published in 1981 and is scheduled to be reviewed and updated by CDC’s Healthcare Infection Control Practices Advisory Committee (HICPAC). Although *preventive* interventions focus on timely removal of appropriately placed urinary catheters, there are patients who genuinely need

long-term catheterization and who may suffer the complication of catheter-associated inflammation. Some host factors that appear to increase the risk of acquiring catheter-associated urinary tract infections including advanced age and debilitation may not be modifiable.

It is understood that this condition would require an initial cross check with POA codes, and only then, after excluding all the proposed codes, including chronic conditions, would a decision be made as to whether to classify as a concurrent condition (CC). In addition to the numerous exclusionary codes listed by CMS, we propose the code list exclude conditions such as immunosuppression (e.g., bone marrow transplant or burn patient), patients in whom a catheter is placed for therapeutic installation of antimicrobial and/or chemotherapeutic agents, patients who have sustained urinary tract trauma, or patients requiring permanent use of catheters such as patients with anatomic conditions who cannot have their catheter discontinued. Further, we would ask CMS to consider a new code for "inflammatory reaction from the indwelling catheter" distinct from catheter-associated UTI.

Unintended consequences: Even as POA coding is implemented and considered reliable, there may also be unintended consequences as suggested by anecdotal reports from Pennsylvania. In order to document that catheter-associated bacteriuria was present on admission, clinicians may feel obligated to order urine cultures at the time of hospital admission and then attempt – often unnecessarily – to sterilize the patient’s urine. Authorities on the management of urinary tract infections and bacteriuria associated with an indwelling bladder catheter agree that such antibiotic therapy is usually not warranted when the patient has no symptoms of either a urinary tract or a systemic infection. Treatment under these circumstances is often associated with superinfection and selection of antibiotic-resistant pathogens such as Klebsiella or Candida species.

#2 Pressure ulcers – (ICD-9-CM Codes 707.00 through 707.09)

We believe this indicator could improve initial patient assessment for pressure ulcers, but there are a number of additional concerns that should be addressed by CMS beyond POA coding issues. This condition is not limited to hospitals; given the large number of transfers between hospitals and long-term care facilities a thorough examination and documentation of existing pressure ulcers on admission is of prime importance. According to Medicare coding rules, POA coding of pressure ulcers must rely solely on physicians’ notes and diagnoses and cannot make use of notes from nurses and other practitioners. Although non-CDC guidelines exist and this condition is less complicated in terms of exclusion codes, all the concerns expressed previously about POA codes remain relevant.

The National Pressure Ulcer Advisory Panel recently released revised guidelines for staging pressure ulcers⁴ and included a new definition for a suspected deep tissue injury. Although difficult to detect initially, this condition may rapidly evolve into an advanced pressure ulcer, and it is especially difficult to detect in individuals with darker skin tones. Even detection of stage I pressure ulcers on admission is difficult as the skin, although damaged, is not yet broken. Certain patients, including those at the end of life, may be exceptionally prone to developing pressure ulcers, despite receiving appropriate care. If CMS decides to include pressure ulcers under the hospital-acquired conditions policy, the agency should exclude

patients enrolled in the Medicare hospice benefit and patients with certain diagnoses that make them more highly prone to pressure ulcers such as hemiplegia, quadriplegia, wasting syndrome with advanced AIDS and/or protein malnutrition associated with a variety of serious end stage illnesses.

#6 *Staphylococcus aureus* Bloodstream Infection/Septicemia (ICD-9-CM Code 038.1)

CMS states: The codes selected to identify septicemia are somewhat complex. The following ICD-9-CM codes may also be reported to identify septicemia: 995.91 (sepsis) and 995.92 (severe sepsis). These codes are reported as secondary codes and further define cases with septicemia; 998.59 (other postoperative infections). This code includes septicemia that develops postoperatively; 999.3 (other infection). This code includes but is not limited to "sepsis/septicemia resulting from infusion, injection, transfusion, vaccination (ventilator-associated pneumonia also included here)."

Accurately ascertaining for DRG purposes that *Staphylococcus aureus* septicemia was present on admission may be a major challenge, since there is no specific vascular catheter code. Patients may be admitted to the hospital with a localized *S. aureus* infection such as pneumonia or a skin/soft tissue infection. *S. aureus* septicemia may subsequently develop as a consequence of the localized infection, but distinguishing this septicemia as POA and not as a hospital-acquired condition may be difficult. Additionally, the recent proliferation of changes in coding guidelines for sepsis complicates efforts of coding personnel to accurately capture POA status. Even if POA coding can be reliably established, the category of *S. aureus* septicemia is simply too large and varied to determine that the infections were reasonably preventable. We believe this category is feasible only if a subset of patients can be identified for whom it is reasonably clear that the infection was acquired by the patient in the hospital and that it could have been reasonably prevented by evidence-based interventions. The prevention guidelines for *S. aureus* septicemia primarily relate to device-associated infections for which there is no specific code. As with CA-UTI, additional conditions should be added to CMS's current list of exclusions, such as patients with severe immunosuppression (e.g., leukemia, bone marrow transplant, or HIV/AIDS).

Seven conditions mentioned but not recommended for consideration for FY 2009

7. Ventilator associated pneumonias.
8. Vascular catheter associated infections
9. *Clostridium difficile*- associated disease (CDAD)
10. Methicillin-resistant *Staphylococcus aureus* (MRSA)
11. Surgical site infections
12. Serious preventable event-- Wrong surgery
13. Falls

CMS has clearly identified the problems with each of these indicators based on lack of unique codes, complication codes or guidelines addressing reasonable preventability. Five of these seven conditions relate to infectious diseases, all of which are important causes of healthcare-associated mortality and morbidity. Consequently, we recommend that CMS continue to address the coding challenges and determine if these conditions warrant inclusion in the hospital-

acquired conditions policy in the future.⁵ Identification of these conditions requires not only reliable use of POA codes but other unique definition and coding issues. Current efforts and measurable results show hospitals are reducing these complications, but they are not easily identified under current coding logic. Although judicious antibiotic use and appropriate infection control measures can reduce the burden of CDAD, a significant percentage of CDAD is unavoidable. Distinguishing community-acquired from hospital-associated CDAD is challenging, thus making this condition the least attractive of the group.

Potential FY 2009 recommendations

Of the infection-related conditions for which CMS requested comment, we will specifically address two with the most potential in the near term. We suggest two approaches that do *not* depend on POA codes, though do require coding and cross referencing. We recommend these be considered for FY 2009 UNTIL after POA coding is implemented and proven to be reliable, permitting reconsideration of several of the initial six proposed conditions.

#8 Vascular-associated infections Coding--The code used to identify vascular catheter associated infections is ICD-9-CM code 996.62 (Infection due to other vascular device, implant, and graft).

CMS states: "This code includes infections associated with all vascular devices, implants, and grafts. It does not uniquely identify vascular catheter associated infections. Therefore, there it is not a unique ICD-9-CM code for this infection. CDC and CMS staff requested that the ICD-9-CM Coordination and Maintenance Committee discuss the creation of a unique ICD-9-CM code for vascular catheter associated infections because the issue is important for public health. The proposal to create a new ICD-9-CM was discussed at the March 22-23, 2007 meeting of the ICD-9-CM Coordination and Maintenance Committee. A summary of this meeting can be found at: <http://www.cdc.gov/nchs/icd9.htm>. Coders would also assign an additional code for the infection such as septicemia. Therefore, a list of specific infection codes would have to be developed to go along with code 996.62. If the vascular catheter associated infection was hospital-acquired, the DRG logic would have to be modified so that neither the code for the vascular catheter associated infection along with the specific infection code would count as a CC."

Although we acknowledge the comments above and agree that as stated this condition would problematic, we would suggest another approach-- not dependent on POA or a special code for vascular catheters. We agree that at the moment there is no specific code for ***catheter-associated blood stream infection*** (CA-BSI) -- a reasonably preventable condition. However--***there are specific codes for insertion of catheters***. There may be an alternative approach to circumvent the absence of a unique ICD-9-CM code for CA-BSI, using specific codes for insertion of catheters, although this approach may be cumbersome to implement.

It is possible to:

- a) Screen for bloodstream infection codes (996.62)

- b) Exempt or exclude all vascular surgery and other implantable device codes and other obvious sources of existing conditions causing BSI prior to catheter placement
- c) Examine the record for CPT codes for central venous catheter (CVC) placement occurring on the same admission in which the 996.62 code occurs after insertion. For example, one would include CPT code 36556 (insertion of non-tunneled centrally inserted central venous catheter-age 5 or older) or 36569 (insertion of peripherally inserted non-tunneled catheter-age 5 or older)
- d) Risk of including catheters from *prior admission or placed at another institution* is reduced by **excluding** long term catheter insertions such as the tunneled central venous catheter using codes 36557 through 36566.
 - Code 36557 Insertion of tunneled centrally inserted central venous catheter without subcutaneous port or pump, younger than 5
 - Code 36558 Insertion of tunneled centrally inserted central venous catheter without subcutaneous port or pump, 5 yrs or older
 - 36560 - Insertion of tunneled centrally inserted central venous catheter with a subcutaneous port , younger than 5
 - 36561 - Insertion of tunneled centrally inserted central venous catheter with a subcutaneous port 5 yrs or older
 - 36563- Insertion of tunneled centrally inserted central venous catheter with a subcutaneous pump, younger than 5
 - 36565 - Insertion of tunneled centrally inserted central venous access device requiring 2 catheters via 2 separate venous access sites; without subcutaneous port or pump (e.g., Tesio type catheter)
 - 36566 - Insertion of tunneled centrally inserted central venous access device requiring 2 catheters via 2 separate venous access sites; with subcutaneous port or pump

#11 Surgical site infections are identified by ICD–9–CM code 998.59 (Other postoperative infection)

CMS notes that "While there are prevention guidelines, it is not always possible to identify the specific types of surgical infections that are preventable. Therefore, we are not proposing to select surgical site infections as one of our proposed hospital-acquired conditions at this time."

Although we agree with postponing consideration of surgical site infections at this time, we would suggest focusing efforts on a *single high volume surgical procedure* such as coronary artery bypass graft codes - e.g., "CABG without valve," for which there *is* a CC code for mediastinitis, and for which there are guidelines addressing preventability. Further, CMS might consider post-operative sepsis, using a specific procedure code such as CABG (with or without valve). CMS could also consider a similar logic as noted above using postoperative sepsis following 'CABG without valve' with mediastinitis and

- a) Screen for bloodstream infection codes (996.62)
- b) Screen for CC code for mediastinitis (519.2)
- c) Exempt or exclude all cardiovascular surgery and other implantable codes

- d) Examine the record for CABG codes ‘without valve’ occurring on the same admission

In addition to our comments regarding specific conditions, we would like clarification from CMS *on how hospitals may appeal a CMS decision if an error in coding occurs, and a particular patient incorrectly falls under the hospital-acquired conditions policy and is not eligible for a higher complication or comorbidity DRG payment.*

Our coalition continues to work with the Centers for Disease Control and Prevention to prevent these conditions and 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,



Victoria J. Fraser, MD
SHEA President

References

¹ Lincourt AE, Harrell, A, Cristiano J et al. Retained Foreign Bodies after Surgery. J. Surgical Research 2007; 138:170-4.

² AHRQ POA The Case for the Present-on-Admission (POA) Indicator Report# 2006-01 Healthcare Cost and Utilization Project (HCUP), Agency for Healthcare Research and Quality Access at www.hcup-us.ahrq.gov/reports/methods.jsp

³ APIC-IDSA-SHEA letter to Mark McClellan dated June 12, 2006

⁴ National Pressure Ulcer Guidelines accessed at www.npuap.org/documents/PU_Definition_Stages.pdf

⁵ Estimating Health Care-Associated Infections and Deaths in U.S. Hospitals, 2002. Klevens M, Edwards JR, Richards, Jr. CL, Horan TC, Gaynes RP, Pollock DA, Cardo DM. Public Health Reports. March–April 2007; 122: 160-166.