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Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates; Proposed Rule

systems of incorporating these variables into the MedPAR.

Finally, RTI's medium-term recommendations include encouraging providers to use existing standard cost centers, particularly those for Blood and Blood Administration and for Therapeutic Radiology, in the current Medicare cost report. We believe this recommendation is closely related to the one for improved cost reporting instructions. Therefore, we will consider this recommendation as part of any further effort we may undertake to revise cost reporting instructions or change the cost report.

c. Long-Term Recommendations

RTI's long-term recommendations include adding new cost centers to the Medicare cost report and/or undertaking the following activities:

- Add ''Devices, Implants and Prosthetics'' under the line for ''Medical Supplies Charged to Patients.'' Consider also adding a similar line for IV Solutions as a subscripted line under the line for ''Drugs Charged to Patients.''
- Add CT Scanning and MRI as subscripted lines under the line for ''Radiology-Diagnostic.'' About one-third of hospitals that offer CT Scanning and/or MRI services are already reporting these services on nonstandard line numbers. More consistent reporting for both cost centers would eliminate the need for statistical estimation on the radiology CCRs.
- In consultation with hospital industry representatives, determine the best way to separate cardiology cost centers and add a new standard cost center for cardiac catheterization and/or for all other cardiac diagnostic laboratory services. About 20 percent of hospitals already include a nonstandard line on their cost reports for catheterization. Creating a new standard cost center could improve consistency in reporting and substantially improve the program charge mismatching that now occurs.
- In consultation with hospital industry representatives, consider establishing a new cost center to capture intermediate care units as distinct from routine or intensive care.
- Establish expert study groups or other research vehicles to study options for improving patient-level charging within nursing units. Nursing accounts for one-fourth of IPPS charges and 41 percent of the computed costs from our claims analysis file. Historically, nursing charges and costs have been assigned to patients without relying on individual measures of service use. Consideration should be given to finding ways to improve precision in nursing cost-finding that will improve relative resource weights without adding substantial administrative costs to either the Medicare program or to hospitals.

We agree with RTI that attention should be paid to these issues as we consider changes to the Medicare cost report. The cost report has not been revised in nearly 10 years. During this time, there have been significant changes to the Medicare statute and regulations that have affected the Medicare payment policies. Necessary incremental changes have been made to the Medicare cost report over the years to accommodate the Medicare wage index, disproportionate share payments, indirect and direct graduate medical education payments, reporting of uncompensated care costs, among others. The adoption of cost-based weights for the IPPS beginning in FY 2007 has brought further attention to the importance of the Medicare cost report and how hospitals report costs and charges. We recently began doing a comprehensive review of the Medicare cost report and plan to make updates that will consider its many uses. As we update the cost report, we will give strong consideration to RTI's recommendations and potential long-term improvements that could be made to the IPPS cost-based relative weighting methodology.

F. Hospital-Acquired Conditions, Including Infections

(If you choose to comment on issues in this section, please include the caption ''DRGs: Hospital-Acquired Conditions'' at the beginning of your comment.)

1. General

Medicare's IPPS encourages hospitals to treat patients efficiently. Hospitals receive the same DRG payment for stays that vary in length. In many cases, complications acquired in the hospital do not generate higher payments than the hospital would otherwise receive for other cases in the same DRG. To this extent, the IPPS does encourage hospitals to manage their patients well and to avoid complications, when possible. However, complications, such as infections, acquired in the hospital can trigger higher payments in two ways. First, the treatment of complications can increase the cost of hospital stays enough to generate outlier payments. However, the outlier payment methodology requires that hospitals experience large losses on outlier cases (for example, in FY 2007, the fixed-loss amount was $24,485 before a case qualified for outlier payments, and the hospital then only received 80 percent of its costs above the fixed-loss cost threshold). Second, there are about 121 sets of DRGs that split based on the presence or absence of a complication or comorbidity (CC). The CC DRG in each pair would generate a higher Medicare payment. If a condition acquired during the beneficiary's hospital stay is one of the conditions on the CC list, the result may be a higher payment to the hospital under a CC DRG. Under the proposed MS–DRGs, there will be 258 sets of DRGs that are split into 2 or 3 subgroups based on the presence or absence of a major CC (MCC) or CC. If a condition acquired during the beneficiary's hospital stay is one of the conditions on the MCC or CC list, the result may be a higher payment to the hospital under the MS–DRGs. (See section II.C. of the FY 2007 IPPS final rule (71 FR 47881) for a detailed discussion of proposed DRG reforms.)

2. Legislative Requirement

Section 5001(c) of Pub. L. 109–171 requires the Secretary to select, by October 1, 2007, 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, hospitals will not receive additional payment for cases in which one of the selected conditions was not present on admission. That is, the case will be paid as though the secondary diagnosis was not present. Section 5001(c) provides that we can revise the list of conditions from time to time, as long as the list contains at least two conditions. Section 5001(c) also requires hospitals to submit the secondary diagnoses that are present at admission when reporting payment information for discharges on or after October 1, 2007.

3. Public Input

In the FY 2007 IPPS proposed rule (71 FR 24100), we sought input from the public about which conditions and which evidence-based guidelines should be selected in order to implement section 5001(c) of Public Law 109–171. The comments that we received were summarized in the FY 2007 IPPS final rule (71 FR 48051 through 48053). In that final rule, we indicated that the next opportunity for formal public comment would be this FY 2008 proposed rule and encouraged the public to comment on our proposal at that time.

In summary, the majority of the comments that we received in response to the FY 2007 IPPS proposed rule addressed conceptual issues concerning the selection, measurement, and prevention of hospital-acquired infections. Many commenters encouraged CMS to engage in a collaborative discussion with relevant experts in designing, evaluating, and implementing this section. The commenters urged CMS to include individuals with expertise in infection control and prevention, as well as representatives from the provider community, in the discussions.

Many commenters supported the statutory requirement for hospitals to submit information regarding secondary diagnoses present on admission beginning in FY 2008, and suggested that it would better enable CMS and health care providers to more accurately differentiate between comorbidities and hospital-acquired complications. MedPAC, in particular, noted that this requirement was recommended in its March 2005 Report to Congress and indicated that this information is important to Medicare's value-based purchasing efforts. Other commenters cautioned us about potential problems with relying on secondary diagnosis codes to identify hospital-acquired complications, and indicated that secondary diagnosis codes may be an inaccurate method for identifying true hospital-acquired complications.

A number of commenters expressed concerns about the data coding requirement for this payment change and asked for detailed guidance from CMS to help them identify and document hospital-acquired complications. Other commenters expressed concern that not all hospital-acquired infections are preventable and noted that sicker and more complex patients are at greater risk for hospital-acquired infections and complications. Commenters suggested that CMS include standardized infection-prevention process measures, in addition to outcome measures of hospital-acquired infections.

Some commenters proposed that CMS expand the scope of the payment changes beyond the statutory minimum of two conditions. They noted that the death, injury, and cost of hospital-acquired infections are too high to limit this provision to only two conditions. Commenters also recommended that CMS annually select additional hospital-acquired complications for the payment change. Conversely, a number of commenters proposed that CMS initially begin with limited demonstrations to test CMS' methodology before nationwide implementation. One commenter recommended that CMS include appropriate consumer protections to prevent providers from billing patients for the nonreimbursed costs of the hospital-acquired complications and to prevent hospitals from selectively avoiding patients perceived at risk of complications.

In addition to the broad conceptual suggestions, some commenters recommended specific conditions for possible inclusion in the payment changes, which we discuss in detail in section II.D.4. of this preamble. We also discuss throughout section II.D. of this preamble other comments that we have considered in developing hospital-acquired conditions that would be subject to reporting.

4. Collaborative Effort

CMS worked with public health and infectious disease experts from the Centers for Disease Control and Prevention (CDC) to identify a list of hospital-acquired conditions, including infections, as required by section 5001(c) of Public Law 109–171. As previously stated, the selected conditions must meet the following three criteria: (a) High cost or high volume or both; (b) result in the assignment of the 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. CMS and CDC staff also collaborated on developing a process for hospitals to submit a Present on Admission (POA) indicator with each secondary condition. The statute requires the Secretary to begin collecting this information as of October 1, 2007. The POA indicator is required in order for us to determine which of the selected conditions developed during a hospital stay. The current electronic format used by hospitals to obtain this information (ASC X12N 837, Version 4010) does not provide a field to obtain the POA information. We are in the process of issuing instructions to require acute care IPPS hospitals to submit the POA indicator for all diagnosis codes effective October 1, 2007. The instructions will specify how hospitals under the IPPS will submit this information in segment K3 in the 2300 loop, data element K301 on the ASC X12N 837, Version 4010 claim. Specific instructions on how to select the correct POA indicator for a diagnosis code are included in the ICD–9–CM Official Guidelines for Coding and Reporting. These guidelines can be found at the following Web site: *http://www.cdc.gov/nchs/datawh/ftpserv/ftpicd9/ftpicd9.htm*

CMS and CDC staff also received input from a number of groups and organizations on hospital-acquired conditions, including infections. Many of these groups and organizations recommended the selection of conditions mentioned in the FY 2007 IPPS final rule, including the following because of the high cost or high volume (frequency) of the condition, or both, and because in some cases preventable guidelines already exist:

- Surgical site infections. The groups and organizations stated that there were evidence-based measures to prevent the occurrence of these infections which are currently measured and reported as part of the Surgical Care Improvement Program (SCIP).
- Ventilator-associated pneumonias. The groups and organizations pointed out that these conditions are currently measured and reported through SCIP. However, other organizations counseled against selecting these conditions because they believed it was difficult to obtain good definitions and that it was not always clear which ones are hospital-acquired.
- Catheter associated bloodstream infections.
- Pressure ulcers, as an alternative to hospital-acquired infections. The groups and organizations pointed out that the specific language in section 5001(c) of Public Law 109–171 mentions hospital-acquired conditions; therefore, the language does not restrict the Secretary to the selection of infections.
- Hospital falls, as an alternative to hospital-acquired infections. The injury prevention groups included this condition among a group referred to as ''serious preventable events,'' also commonly referred to as ''never events'' or ''serious reportable events.'' A serious preventable event is defined as a condition which should not occur during an inpatient stay.

In addition to the aforementioned conditions, we received other recommendations for the selection of hospital-acquired conditions. These recommendations were also based on the high cost and the high volume of the condition, or both, or the fact that preventable guidelines exist. The recommendations include—

- Bloodstream infections/septicemia. Some commenters suggested that we focus on one specific organism, such as staph aureus septicemia.
- Pneumonia. Some commenters recommended the inclusion of a broader group of pneumonia patients, instead of restricting cases to ventilator-associated pneumonias. Some commenters

mentioned that while prevention guidelines exist for pneumonia, it is not clear how effective these guidelines may be in preventing pneumonia.

• Vascular catheter associated infections. Commenters pointed out that there are CDC guidelines for these infections. Other commenters pointed out that while this condition certainly deserves focused attention by health care providers, there is not a clear one unique ICD–9–CM code that identifies vascular catheter-associated infections. Therefore, these commenters suggested that there would be difficulty separately identifying these conditions.

• Clostridium difficile-associated disease (CDAD). Several commenters identified this condition as a significant public health issue. Other commenters pointed out that while prevalence of this condition is emerging as a public health problem, there is not currently a strategy for reasonably preventing these infections.

• Methicillin-resistant staphylococcus aureus (MRSA). Several commenters pointed out that MRSA has become a very common bacteria occurring both in and outside the hospital environment. However, other organizations pointed out that the code for MRSA (V09.0, Infection with microorganism resistant to penicillins Methicillin-resistant staphylococcus aureus) is not currently classified as a CC. Therefore, the commenters stated that MRSA does not lead to a higher reimbursement when the code is reported.

• Serious preventable events. As stated earlier, some commenters representing injury prevention groups suggested including a broader group of conditions than hospital falls which should not be expected to occur during a hospital admission. Hey notes that these conditions are referred to as ''serious preventable events,'' and include events such as the following: (a) Leaving an object in during surgery; (b) operating on the wrong body part or patient, or performing the wrong surgery; (c) air embolism as a result of surgery; and (d) providing incompatible blood or blood products. Other commenters indicated that serious preventable events are so rare that they should not be selected as a hospital condition that cannot result in a case being assigned to a higher paying DRG.

5. Criteria for Selection of the Hospital-Acquired Conditions

CMS and CDC staff greatly appreciate the many comments and suggestions offered by organizations and groups that were interested in providing input into the selection of the initial hospital-acquired conditions.

CMS and CDC staff evaluated each recommended condition under the three criteria established by section 1886(d)(4)(D)(iv) of the Act. In order to meet the higher payment criterion, the condition selected must have an ICD–9–CM diagnosis code that clearly identifies the condition and is classified as a CC, or as an MCC as proposed for the MS–DRGs in this proposed rule. Some conditions recommended for inclusion among the initial hospital-acquired conditions did not have codes that clearly identified the conditions. Because there has not been national reporting of a POA indicator for each diagnosis, there is no Medicare data to determine the incidence of the reported secondary diagnoses occurring after admission. To the extent possible, we used information from the CDC on the incidence of these conditions. CDC's data reflect the incidence of hospital-acquired conditions in 2002. We also examined FY 2006 Medicare data on the frequency that these conditions were reported as secondary diagnoses. We developed the following criteria to assist in our analysis of the conditions. The conditions described were those recommended for inclusion in the initial hospital-acquired infection provision.

• Coding—Under section 1886(d)(4)(D)(ii)(I) of the Act, a discharge is subject to the payment adjustment if ''the discharge includes a condition identified by a diagnosis code'' selected by the Secretary under section 1886(d)(4)(D)(iv) of the Act. We only selected conditions that have (or could have) a unique ICD–9–CM code that clearly describes the condition. Some conditions recommended by the commenters would require the use of two or more ICD–9–CM codes to clearly identify the conditions. Although we did not exclude these conditions from further consideration, the need to utilize multiple ICD–9–CM codes to identify them may present operational issues. For instance, below we describe in detail the complexities associated with selecting septicemia as a hospital-acquired condition that would be subject to section 5001(c) of the DRA. In some cases, septicemia may be a reasonably preventable condition with proper hospital care. However, in other cases, clinicians may argue that the condition arose from further development of another infection the patient did have upon admission and the septicemia was not preventable. As we indicate in detail below, there could be a significant variety of clinical scenarios and potential coding vignettes to describe situations where septicemia occurs. Although we could select septicemia, we would also have to identify many exclusions for situations where the septicemia is not preventable. The vast number of clinical scenarios that we would have to account for could complicate implementation of the provision.

• Burden (High Cost/High Volume)—Under section 1886(d)(4)(D)(iv)(I) of the act, we must select cases that have conditions that are high cost or high volume, or both.

• Prevention guidelines—Under section 1886(d)(4)(D)(iv)(II) of the Act, we must select codes that describe conditions that could reasonably have been prevented through application of evidence-based guidelines. We evaluated whether there is information available for hospitals to follow to prevent the condition from occurring.

• CC—Under section 1886(d)(4)(D)(iv)(III) of the Act, we must select codes that result in assignment of the case to a DRG that has a higher payment when the code it present as a secondary diagnosis. The condition must be an MCC or a CC that would, in the absence of this provision, result in assignment to a higher paying DRG.

• Considerations—We evaluate each condition above according to how it meets the statutory criteria in light of the potential difficulties that we would face if the condition were selected.

6. Proposed Selection of Hospital-Acquired Conditions

We discuss below our analysis of each of the conditions that were raised as possible candidates for selection under section 5001(c) of Pub. L. 109–171 according to the criteria described above in section II.D.5. of this preamble. We also discuss any considerations, which would include any administrative issues surrounding the selection of a proposed condition. For example, the condition may only be able to be identified by multiple codes, thereby requiring the development of special GROUPER logic to also exclude similar or related ICD–9–CM codes from being classified as a CC. Similarly, a condition acquired during a hospital stay may arise from another condition that the patient had prior to admission, making it difficult to determine whether the condition was reasonably preventable. Following a discussion of each condition, we provide a summary table that describes the extent to which each condition meets each of the above criteria. We present 13 conditions in rank order. In our view, the conditions listed at the top of the table best meet the statutory selection criteria, while the conditions

listed lower may meet the selection criteria but could present a particular challenge (that is, they may be preventable only in some circumstances but not in others). Therefore, we would submit that the first conditions listed should receive the highest consideration of selection among our initial group of hospital-acquired conditions. We encourage comments on whether or not we have ranked these conditions appropriately. We also encourage additional comments on clinical, coding, and prevention issues that may affect the conditions selected. While we have ranked these conditions, there may be compelling public health reasons for including conditions that are not at the top of our list. We ask commenters to recommend how many and which conditions should be selected for implementation on October 1, 2008, along with justifications for these selections.

(a) Catheter-Associated Urinary Tract Infections

• Coding—ICD–9–CM code 996.64 (Infection and inflammatory reaction due to indwelling urinary catheter) clearly identifies this condition. The hospital would also report the code for the specific type of urinary infection. For instance, when a patient develops a catheter associated urinary tract infection during the inpatient stay, the hospital would report code 996.64 and 599.0 (Urinary tract infection, site not specified) to clearly identify the condition. There are also a number of other more specific urinary tract infection codes that could also be coded with code 996.64. These codes are classified as CCs. If we were to select catheter-associated urinary tract infections, we would implement the decision by not counting code 996.64 and any of the urinary tract infection codes listed below when both codes are present and the condition was acquired after admission. If only code 996.64 were coded on the claim as a secondary diagnosis, we would not count it as a CC.

Burden (High Cost/High Volume)—CDC reports that there are 561,667 catheter-associated urinary tract infections per year. For FY 2006, there were 11,780 reported cases of Medicare patients who had a catheter associated urinary tract infection as a secondary diagnosis. The cases had average charges of $40,347 for the entire hospital stay. According to a study in the *American Journal of Medicine,* catheter-associated urinary tract infection is the most common nosocomial infection, accounting for more than 1 million cases in hospitals and nursing homes nationwide.[12] Approximately 11.3 million women in the United States had at least one presumed acute community-acquired urinary tract infection resulting in antimicrobial therapy in 1995, with direct costs estimated at $659 million and indirect costs totaling $936 million. Nosocomial urinary tract infection necessitates one extra hospital day per patient, or nearly 1 million extra hospital days per year. It is estimated that each episode of symptomatic urinary tract infection adds $676 to a hospital bill. In total, according to the study, the estimated annual cost of nosocomial urinary tract infection in the United States ranges between $424 and $451 million.

Prevention guidelines—There are widely recognized guidelines for the prevention of catheter-associated urinary tract infections. Guidelines can be found at the following Web site: *http://www.cdc.gov/ncidod/dhqp/gl_catheter_assoc.html.*

CC—Codes 996.64 and 599.0 are classified as CCs in the current CMS DRGs as well as in the proposed MS–DRGs.

Considerations—The primary prevention intervention would be not using catheters or removing catheters as soon as possible, both of which are worthy goals because once catheters are in place for 3 to 4 days, most clinicians and infectious disease/infection control experts do not believe urinary tract infections are preventable. While there may be some concern about the selection of catheter associated urinary tract infections, it is an important public health goal to encourage practices that will reduce urinary tract infections. Approximately 40 percent of Medicare beneficiaries have a urinary catheter during hospitalization based on Medicare Patient Safety Monitoring System (MPSMS) data.

As stated above in the Coding section, this condition is clearly identified through ICD–9–CM code 996.64. Code 996.64 is classified as a CC. The hospital would also report the code for the specific type of urinary infection. For instance, when a patient develops a catheter associated urinary tract infection during the inpatient stay, the hospital would report codes 996.64 and 599.0 or another more specific code that clearly identifies the condition. These codes are classified as CCs under the current CMS DRGs as well as the proposed MS–DRGs. To select catheter-associated urinary tract infections as one of the hospital-acquired conditions that would not be counted as a CC, we would not classify code 996.64 as a CC if the condition occurred after admission. Furthermore, we would also not classify any of the codes listed below as CCs if present on the claim with code 996.64 because these additional codes identify the same condition. The following codes represent specific types of urinary infections. We did not include codes for conditions that could be considered chronic urinary infections, such as code 590.00 (Chronic pyelonephritis, without lesion or renal medullary necrosis). Chronic conditions may indicate that the condition was not acquired during the current stay. We would not count code 996.64 or any of the following codes representing acute urinary infections if they developed after admission and were coded together on the same claim.

• 112.2 (Candidiasis of other urogenital sites)
• 590.10 (Acute pyelonephritis, without lesion of renal medullary necrosis)
• 590.11 (Acute pyelonephritis, with lesion of renal medullary necrosis)
• 590.2 (Renal and perinephric abscess)
• 590.3 (Pyeloureteritis cystica)
• 590.80 (Pyelonephritis, unspecified)
• 590.81 (Pyelitis or pyelonephritis in diseases classified elsewhere)
• 590.9 (Infection of kidney, unspecified)
• 595.0 (Acute cystitis)
• 595.3 (Trigonitis)
• 595.4 (Cystitis in diseases classified elsewhere)
• 595.81 (Cystitis cystica)
• 595.89 (Other specified type of cystitis, other)
• 595.9 (Cystitis, unspecified)
• 597.0 (Urethral abscess)
• 597.80 (Urethritis, unspecified)
• 599.0 (Urinary tract infection, site not specified)

We believe the condition of catheter-associated urinary tract infection meets all of our criteria for selection as one of the initial hospital-acquired conditions. We can easily identify the cases with ICD–9–CM codes. The condition is a CC under both the current CMS DRGs and the proposed MS–DRGs that are discussed earlier in this proposed rule. The condition meets our burden criterion with its high cost and high frequency. There are prevention guidelines on which the medical community agrees. Of all 13 conditions discussed in this proposed rule, we believe this condition best meets the

[12] Foxman, B.: ''Epidemiology of urinary tract infections: incidence, morbidity, and economic costs,'' *The American Journal of Medicine,* 113 Suppl. 1A, pp. 5s–13s, 2002.

criteria discussed. Therefore, we are proposing the selection of catheter-associated urinary tract infections as one of the initial hospital-acquired conditions.

We encourage comments on both the selection of this condition and the related conditions that we are proposing to exclude from being counted as CCs.

(b) Pressure Ulcers

Coding—Pressure ulcers are also referred to as decubitus ulcers. The following codes clearly identify pressure ulcers.

- 707.00 (Decubitus ulcer, unspecified site)
- 707.01 (Decubitus ulcer, elbow)
- 707.02 (Decubitus ulcer, upper back)
- 707.03 (Decubitus ulcer, lower back)
- 707.04 (Decubitus ulcer, hip)
- 707.05 (Decubitus ulcer, buttock)
- 707.06 (Decubitus ulcer, ankle)
- 707.07 (Decubitus ulcer, heel)
- 707.09 (Decubitus ulcer, other site)

Burden (High Cost/High Volume)—This is both a high-cost and high-volume condition. For FY 2006, there were 322,946 reported cases of Medicare patients who had a pressure ulcer as a secondary diagnosis. These cases had average charges for the hospital stay of $40,381.

Prevention guidelines—Prevention guidelines can be found at the following Web sites: *http://www.npuap.org/positn1.html. http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat2.chapter.4409*

CC—Decubitus ulcer codes are classified as CCs under the current CMS DRGs. Codes 707.00, 707.01, and 707.09 are CCs under the proposed MS–DRGs. Codes 707.02 through 707.07 are considered MCCs under the proposed MS–DRGs. As discussed earlier, MCCs result in even larger payments than CCs.

Considerations—Pressure ulcers are an important hospital-acquired complication. Prevention guidelines exist (non-CDC) and can be implemented by hospitals. Clinicians may state that some pressure ulcers present on admission cannot be identified (skin is not yet broken (Stage I) but damage to tissue is already done and skin will eventually break down. However, by selecting this condition, we would provide hospitals the incentive to perform careful examination of the skin of patients on admission to identify decubitus ulcers. If the condition is present on admission, the provision will not apply. We are proposing to include pressure ulcers as one of our initial hospital-acquired conditions. This condition can be clearly identified through ICD–9–CM codes. These codes are classified as a CC under the current CMS DRGs and as a CC or MCC under the proposed MS–DRGs. Pressure ulcers meet the burden criteria because they are both high cost and high frequency cases. There are clear prevention guidelines. While there is some question as to whether all cases with developing pressure ulcers can be identified on admission, we believe the selection of this condition will result in a closer examination of the patient's skin on admission. This will result in better quality of care. We welcome comments on the proposed inclusion of this condition.

Serious Preventable Events

Serious preventable events are events that should not occur in health care. The injury prevention community has developed information on serious preventable events. CMS reviewed the list of serious preventable events and identified those events for which there was an ICD–9–CM code that would assist in identifying them. We identified four types of serious preventable events to include in our evaluation. These include leaving an object in a patient; performing the wrong surgery (surgery on the wrong body part, wrong patient, or the wrong surgery); air embolism following surgery; and providing incompatible blood or blood products. Three of these serious preventable events have unique ICD–9–CM codes to identify them. There is not a clear and unique code for surgery performed on the wrong body part, wrong patient, or the wrong surgery. Each of these events is discussed separately.

(c) Serious Preventable Event—Object Left in During Surgery

Coding—Retention of a foreign object in a patient after surgery is identified through ICD–9–CM code 998.4 (Foreign body accidentally left during a procedure).

Burden (High Cost/High Volume)—For FY 2006, there were 764 cases reported of Medicare patients who had an object left in during surgery reported as a secondary diagnosis. The average charges for the hospital stay were $61,962. This is a rare event. Therefore, it is not high volume. However, an individual case will likely have high costs, given that the patient will need additional surgery to remove the foreign body. Potential adverse events stemming from foreign body could further raise costs for an individual case.

Prevention guidelines—There are widely accepted and clear guidelines for the prevention of this event. Prevention guidelines for avoiding leaving objects in during surgery are located at the following Web site: *http://www.qualityindicators.ahrq.gov/psi_download.htm.* This event should not occur.

CC—This code is a CC under the current CMS DRGs as well as under the proposed MS–DRGs.

Considerations—There are no significant considerations for this condition. There is a unique ICD–9–CM code and wide agreement on the prevention guidelines. We are proposing to include this condition as one of our initial hospital-acquired conditions. The cases can be clearly identified through an ICD–9–CM. This code is a CC under both the current CMS DRGs and the proposed MS–DRGs. There are clear prevention guidelines. While the cases may not meet the high frequency criterion, they do meet the high-cost criterion. Individual cases can be high cost. We welcome comments on including this condition as one of our initial hospital-acquired conditions.

(d) Serious Preventable Event—Air Embolism

Coding—An air embolism is identified through ICD–9–CM code 999.1 (Complications of medical care, NOS, air embolism).

Burden (High Cost/High Volume)—This event is rare. For FY 2006, there were 45 reported cases of air embolism for Medicare patients. The average charges for the hospital stay were $66,007.

Prevention guidelines—There are clear prevention guidelines for air embolisms. This event should not occur. Serious preventable event guidelines can be found at the following Web site: *http://www.qualityindicators.ahrq.gov/psi_download.htm.*

CC—This code is a CC under the current CMS DRGs and is an MCC under the proposed MS–DRGs.

Considerations—There are no significant considerations for this condition. There is a unique ICD–9–CM code and wide agreement on the prevention guidelines. In addition, as stated earlier, the condition is a CC under the current CMS DRGs and an MCC under the proposed MS–DRGs. While the condition is rare, it does meet the cost burden criterion because individual cases can be expensive. Therefore, air embolism is a high-cost condition because average charges per case are high. We welcome comments on the proposal to include this condition.

(e) Serious Preventable Event—Blood Incompatibility

Coding—Delivering ABO-incompatible blood or blood products is identified by ICM–9–CM code 999.6 (Complications of medical care, NOS, ABO incompatibility reaction).

Burden (High Cost/High Volume)—This event is rare. Therefore, it is not high volume. For FY 2006, there were 33 reported cases of blood incompatibility among Medicare patients, with average charges of $46,492 for the hospital stay. Therefore, individual cases have high costs.

Prevention guidelines—There are prevention guidelines for avoiding the delivery of incompatible blood or blood products. The event should not occur. Serious preventable event guidelines can be found at the following Web site: *http://www.qualityindicators.ahrq.gov/psi_download.htm*

CC—This code is a CC under the current CMS DRGs as well as the proposed MS–DRGs.

Considerations—There are no significant considerations for this condition. There is a unique ICD–9–CM code which is classified as a CC under the CMS DRGs as well as the proposed MS–DRGs. There is wide agreement on the prevention guidelines. While this may not be a high-volume condition, average charges per case are high. Therefore, we believe this condition is a high-cost condition and, therefore, meets our burden criterion. We are proposing to include this condition as one of our initial hospital-acquired conditions.

(f) Staphylococcus Aureus Bloodstream Infection/Septicemia

Coding—ICD–9–CM Code 038.11 (Staphylococcus aureus septicemia) identifies this condition. However, 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).

Burden (High Cost/High Volume)—CDC reports that there are 290,000 cases of staphylococcus aureus infection annually in hospitalized patients of which approximately 25 percent are bloodstream infections or sepsis. For FY 2006, there were 29,500 cases of Medicare patients who had staphylococcus aureus infection reported as a secondary diagnosis. The average charges for the hospital stay were $82,678. Inpatient staphylococcus aureus result in an estimated 2.7 million days in excess length of stay, $9.5 billion in excess charges, and approximately 12,000 inpatient deaths per year.

Prevention guidelines—CDC guidelines are located at the following Web site: *http://www.cdc.gov/ncidod/dhqp/gl_intravascular.html.*

CC—Codes 038.11, 995.91, 998.59, and 999.3 are classified as CCs under the current CMS DRGs and as MCCs under the proposed MS–DRGs.

Considerations—Preventive health care associated bloodstream infections/septicemia that are preventable are primarily those that are related to a central venous/vascular catheter, a surgical procedure (postoperative sepsis) or those that are secondary to another preventable infection (for example, sepsis due to catheter-associated urinary tract infection). Otherwise, physicians and other public health experts may argue whether septicemia is reasonably preventable. The septicemia may not be simply a hospital-acquired infection. It may simply be a progression of an infection that occurred prior to admission. Furthermore, physicians cannot always tell whether the condition was hospital-acquired. We examined whether it might be better to limit the septicemia cases to a specific organism (for example, code 038.11 (Staphylococcus aureus septicemia)). CDC staff recommended that we focus on staphylococcus aureus septicemia because this condition is a significant public health issue. As stated earlier, there is a specific code for staphylococcus aureus septicemia, code 038.11. Therefore, the cases would be easy to identify. However, as stated earlier, while this type of septicemia is identified through code 038.11, coders may also provide sepsis code 995.91 or 995.92 to more fully describe the staphylococcus aureus septicemia. Codes 995.91 and 995.92 are reported as secondary codes and further define cases with septicemia. Codes 995.91 and 995.92 are CCs under the current CMS DRGs and MCCs under the proposed MS–DRGs.

- 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 indexed here).

To implement this condition as one of our initial ones, we would have to exclude the specific code for staphylococcus aureus septicemia, 038.11, and the additional septicemia codes, 995.91, 995.92, 998.59, and 999.3.

We acknowledge that there are additional issues involved with the selection of this condition that may involve developing an exclusion list of conditions present on admission for which we would not apply a CC exclusion to staphylococcus aureus septicemia. For example, a patient may come into the hospital with a staphylococcus aureus infection such as pneumonia. The pneumonia might develop into staphylococcus aureus septicemia during the admission. It may be appropriate to consider excluding cases such as those of patients admitted with staphylococcus aureus pneumonia that subsequently develop staphylococcus aureus septicemia from the provision. In order to exclude cases that did not have a staphylococcus aureus infection prior to admission, we would have to develop a list of specific codes that identified all types of staphylococcus aureus infections such as code 482.41 (Pneumonia due to staphylococcus aureus). We likely would not apply the new provision to cases of staphylococcus aureus septicemia if a patient were admitted with staphylococcus aureus pneumonia. However, if the patient had other types of infections, not classified as being staphylococcus aureus, and then developed staphylococcus aureus septicemia during the admission, we would apply the provision and exclude the staphylococcus aureus septicemia as a CC. We were not able to identify any other specific ICD–9–CM codes that identify specific infections as being due to staphylococcus aureus.

Other types of infections, such as urinary tract infections, would require the reporting of an additional code, 041.11 (Staphylococcus aureus), to identify the staphylococcus aureus infection. This additional coding presents administrative issues, because it will not always be clear which condition code 041.11 (Staphylococcus aureus) is describing. We do not believe it would be appropriate to make code 041.11, in combination with other codes, subject to the hospital-acquired conditions provision until we better understand how to address the

administrative issues that would be associated with their selection. Therefore, we would exclude staphylococcus aureus septicemia cases with code 482.41 reported as being subject to the hospital-acquired conditions provision. Stated conversely, we would allow staphylococcus aureus septicemia to count as a CC if the patient was admitted with staphylococcus aureus pneumonia.

We recognize that there may be other conditions which we should consider for this type of exclusion. We are proposing to include staphylococcus aureus bloodstream infection/ septicemia (code 038.11) as one of our initial hospital-acquired conditions. We would also exclude codes 995.91, 998.59, and 999.3 from counting as an MCC/CC when they are reported with code 038.11. The condition can be clearly identified through ICD–9–CM codes that are classified as CC under the current CMS DRGs and MCCs under the proposed MS–DRGs. The condition meets our burden criterion by being both high cost and high volume. There are prevention guidelines which we acknowledge are subject to some debate among the medical community. We also acknowledge that we would have to exclude this condition if a patient were admitted with a staphylococcus aureus infection of a more limited location, such as pneumonia. We encourage commenters to make suggestions on this issue and to recommend any other appropriate exclusion for staphylococcus aureus septicemia. We encourage comments on the appropriateness of selecting staphylococcus aureus septicemia as one of our proposed initial hospital-acquired conditions.

(g) Ventilator Associated Pneumonia (VAP) and Other Types of Pneumonia Coding '' Pneumonia is identified through the following codes:

- 073.0 (Ornithosis with pneumonia)
- 112.4 (Candidiasis of lung)
- 136.3 (Pneumocystosis)
- 480.0 (Pneumonia due to adenovirus)
- 480.1 (Pneumonia due to respiratory syncytial virus)
- 480.2 (Pneumonia due to parainfluenza virus)
- 480.3 (Pneumonia due to SARS-associated coronavirus)
- 480.8 (Pneumonia due to other virus not elsewhere classified)
- 480.9 (Viral pneumonia, unspecified)
- 481 (Pneumococcal pneumonia [Streptococcus pneumoniae pneumonia])
- 482.0 (Pneumonia due to Klebsiella pneumoniae)
- 482.1 (Pneumonia due to Pseudomonas)
- 482.2 (Pneumonia due to Hemophilus influenzae [H. influenzae])
- 482.30 (Pneumonia due to Streptococcus, unspecified)
- 482.31 (Pneumonia due to Streptococcus, Group A)
- 482.32 (Pneumonia due to Streptococcus, Group B)
- 482.39 (Pneumonia due to other Streptococcus)
- 482.40 (Pneumonia due to Staphylococcus, unspecified)
- 482.41 (Pneumonia due to Staphylococcus aureus)
- 482.49 (Other Staphylococcus pneumonia)
- 482.81 (Pneumonia due to Anaerobes)
- 482.82 (Pneumonia due to Escherichia coli [E. coli])
- 482.83 (Pneumonia due to other gram-negative bacteria)
- 482.84 (Pneumonia due to Legionnaires' disease)
- 482.89 (Pneumonia due to other specified bacteria)
- 482.9 (Bacterial pneumonia unspecified)
- 483.0 (Pneumonia due to Mycoplasma pneumoniae)

There is not a unique code that identifies ventilator associated pneumonia. The creation of a code for ventilator associated pneumonia was discussed at the September 29, 2006 meeting of the ICD–9–CM Coordination and Maintenance Committee meeting. Many issues and concerns were raised at the meeting concerning the creation of this proposed new code. It has been difficult to define ventilator-associated pneumonia. We plan to continue working closely with the CDC to develop a code that can accurately describe this condition for implementation in FY 2009. CDC will address the creation of a unique code for this condition at the September 28–29, 2007 ICD–9–CM Coordination and Maintenance Committee meeting.

While we list 27 pneumonia codes above, our clinical advisors do not believe that all of the codes mentioned could possibly be associated with ventilator-associated pneumonia. Our clinical advisors specifically question whether the following codes would ever represent cases of ventilator-associated pneumonia: 073.0, 480.0, 480.1, 480.2, 480.3, 480.8, 480.9, and 483.0. Therefore, we have a range of pneumonia codes, all of which may not represent cases that could involve ventilator-associated pneumonia. In addition, we do not have a specific code that uniquely identifies cases of ventilator-associated pneumonia.

Burden (High Cost/High Volume)—CDC reports that there are 250,205 ventilator-associated pneumonias per year. Because there is not a unique ICD–9–CM code for ventilator-associated pneumonia, there is not accurate data for FY 2006 on the number of Medicare patients who had this condition as a secondary diagnosis. However, we did examine data for FY 2006 on the number of Medicare patients who listed pneumonia as a secondary diagnosis. There were 92,586 cases with a secondary diagnosis of pneumonia, with average charges of $88,781. According to the journal *Critical Care Medicine,* patients with ventilator-associated pneumonia have statistically significantly longer intensive care lengths of stay (mean = 6.10 days) than those who do not (mean = 5.32–6.87 days). In addition, patients who develop ventilator-associated pneumonia incur, on average, greater than or equal to $10,019 in additional hospital costs compared to those who do not.[13] Therefore, we believe that this is a high-volume condition.

Prevention guidelines—Prevention guidelines are located at the following Web site: *http://www.cdc.gov/ncidod/ dhqp/ gl_hcpneumonia.html*. However, it is not clear how effective these guidelines are in preventing pneumonia. Ventilator-associated pneumonia may be particularly difficult to prevent.

CC—All of the pneumonia codes listed above are CCs under the current CMS DRGs and under the proposed MS–DRGs, except for the following pneumonia codes which are non-CCs: 073.0, 480.0, 480.1, 480.2, 480.3, 480.8, 480.9, 483.0. However, as mentioned earlier, there is not a unique ICD–9–CM code for ventilator-associated pneumonia. Therefore, this condition does not currently meet the statutory criteria for being selected.

Considerations—Hospital-acquired pneumonias, and specifically ventilator associated pneumonias, are an important problem. However, based on our work with the medical community to develop specific codes for this condition, we have learned that it is difficult to define what constitutes ventilator associated pneumonia. Although prevention guidelines exist, it is not clear how effective these are in preventing pneumonia. Clinicians cannot always tell which pneumonias are acquired in a hospital. In addition,

[13] Safdar N.: Clinical and Economic Consequences of Ventilator-Associated Pneumonia: A Systematic Review, *Critical Care Medicine*, 2005, 33(10), pp. 2184–2193.

as mentioned above, there is not a unique code that identifies ventilator-associated pneumonia. There are a number of codes that capture a range of pneumonia cases. It is not possible to specifically identify if these pneumonia cases are ventilator-associated or arose from other sources. Because we cannot identify cases with ventilator-associated pneumonia and there are questions about its preventability, we are not proposing to select this condition as one of our initial hospital-acquired conditions. However, we welcome public comments on how to create an ICD–9–CM code that identifies ventilator-associated pneumonia, and we encourage participation in our September 28–29, 2007 ICD–9–CM Coordination and Maintenance Committee meeting where this issue will be discussed. We will reevaluate the selection of this condition in FY 2009.

(h) Vascular Catheter-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). This code includes infections associated with all vascular devices, implants, and grafts. It does not uniquely identify a vascular catheter associated infections. Therefore, there 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.

Burden (High Cost/High Volume)—CDC reports that there are 248,678 central line associated bloodstream infections per year. It appears to be both high cost and high volume. However, we were not able to identify Medicare data on these cases because there is no existing unique ICD–9–CM code.

Prevention guidelines—CDC guidelines are located at the following Web site: *http://www.cdc.gov/ncidod/dhqp/gl_intravascular.html*.

CC—Code 996.62 is a CC under the current CMS DRGs and the proposed MS–DRGs. However, as stated earlier, this code is broader than vascular catheter-associated infections. Therefore, there is not a unique ICD–9–CM code to identify the condition at this time, and it does not currently meet the statutory criteria to be selected. However, as indicated above, we will be creating a code(s) to identify this condition and may select it as a condition under the provision beginning in FY 2009.

Considerations—There is not yet a unique ICD–9–CM code to capture this condition. If one is implemented on October 1, 2007, we would be able to specifically identify these cases. Some patients require long-term indwelling catheters, which are more prone to infections. Ideally catheters should be changed at certain time intervals. However, circumstances might prevent such practice (for example, the patient has a bleeding diathesis). In addition, a patient may acquire an infection from another source which can colonize the catheter. As mentioned earlier, 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. Without a specific code for infections due to a catheter, it would be difficult to identify these patients. Given the current lack of an ICD–9–CM code for this condition, we are not proposing to include it as one of our initial hospital-acquired conditions at this time. However, we believe it shows merit for inclusion in future lists of hospital-acquired conditions once we have resolved the coding issues and are able to better identify the condition in the Medicare data. We will reevaluate the selection of this condition in FY 2009.

We encourage comments on this condition which was identified as an important public health issue by several organizations that provided recommendations on hospital-acquired conditions. We are particularly interested in receiving comments on how we should handle additional associated infections that might develop along with the vascular catheter-associated infection.

(i) Clostridium Difficile-Associated Disease (CDAD)

Coding—This condition is identified by ICD–9–CM code 008.45 (Clostridium difficile).

Burden (High Cost/High Volume)—CDC reports that there are 178,000 cases per year in U.S. hospitals. For FY 2006, there were 110,761 reported cases of Medicare patients with CDAD as a secondary diagnosis, with average charges for the hospital stay of $52,464. Therefore, this is a high-volume condition.

Prevention guidelines—Prevention guidelines are not available. Therefore, we do not believe this condition can reasonably be prevented through the application of evidence-based guidelines.

CC—Code 008.45 is a CC under the current CMS DRGs and the proposed MS–DRGs.

Considerations—CDAD is an emerging problem with significant public health importance. If found early CDAD cases can easily be treated. However, cases not diagnosed early can be expensive and difficult to treat. CDAD occurs in patients on a variety of antibiotic regiments, many of which are unavoidable, and therefore preventability is an issue. We are not proposing to include CDAD as one of our initial hospital-acquired conditions at this time, given the lack of prevention guidelines. We welcome public comments on CDAD, specifically on its preventability and whether there is potential to develop guidelines to identify it early in the disease process and/or diminish its incidence. We will reevaluate the selection of this condition in FY 2009.

(j) Methicillin-Resistant Staphylococcus Aureus (MRSA)

Coding—MRSA is identified by ICD–9–CM code V09.0 (Infection with microorganisms resistant to penicillins). One would also assign a code(s) to describe the exact nature of the infection.

Burden (High Cost/High Volume)—For FY 2006, there were 95,103 reported cases of Medicare patients who had MRSA as a secondary diagnosis. The average charges for these cases were $31,088. This condition is a high-cost and high-volume infection. MRSA has become a very common bacteria occurring both in and outside of the hospital environment.

Prevention guidelines—CDC guidelines are located at the following Web site: *http://www.cdc.gov/ncidod/dhqp/pdf/ar/mdroGuideline2006.pdf*.

CC—Code V09.0 is not a CC under the current CMS DRGs and the proposed

MS–DRGs. The specific infection would be identified in a code describing the exact nature of the infection, which may be a CC.

Considerations—As stated earlier, preventability may be hard to ascertain since the bacteria has become so common both inside and outside the hospital. There are also considerations in identifying MRSA infections because hospitals would report the code for MRSA along with additional codes that would describe the exact nature of the infection. We would have to develop a list of specific infections that could be the result of MRSA. We are not proposing to include MRSA as one of our initial hospital-acquired conditions because the condition is not a CC. We recognize that associated conditions may be a CC. We welcome comments on the proposal not to include this condition. Should there be support for including this condition, we request recommendations on what codes might be selected to identify the specific types of infections associated with MRSA.

(k) Surgical Site Infections

Coding—Surgical site infections are identified by ICD–9–CM code 998.59 (Other postoperative infection). The code does not tell the exact location or nature of the postoperative wound infection. The code includes wound infections and additional types of postoperative infections such as septicemia. The coding guidelines instruct the coder to add an additional code to identify the type of infection. To implement this condition we would have to remove both code 998.59 and the specific infection from counting as a CC if they occurred after the admission. We would have to develop an extensive list of possible infections that would be subject to the provision. We may also need to recommend the creation of a series of new ICD–9–CM codes to identify various types of surgical site infections, should this condition merit inclusion among those that are subject to the proposed hospital-acquired conditions provision.

Burden (High Cost/High Volume)—CDC reports that there are 290,485 surgical sites infections each year. As stated earlier, there is not a unique code for surgical site infection. Therefore, we examined Medicare data on patients with any type of postoperative infection. For FY 2006, there were 38,763 reported cases of Medicare patients who had a postoperative infection. These patients had average charges for the hospital stay of $79,504. We are unable to determine how many of these patients had surgical site infections.

Prevention guidelines—CDC guidelines are available at the following Web site: *http://www.cdc.gov/ncidod/dhqp/gl_surgicalsite.html*

CC—Code 998.59 is a CC under the current CMS DRGs and the proposed MS–DRGs.

Considerations—As mentioned earlier, code 998.59 is not exclusive to surgical site infections. It includes other types of postoperative infections. Therefore, code 998.59 does not currently meet the statutory criteria for being subject to the provision because it does not uniquely identify surgical site infections. To identify surgical site infections, we would need new codes that provide more detail about the type of postoperative infection as well as the site of the infection. In addition, one would report both code 998.59 as well a more specific code for the specific type of infection, making implementation difficult. 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. However, we welcome public comments on whether we can develop criteria and codes to identify preventable surgical site infections that would assist us in reducing their incidence. We are exploring ways to identify surgical site infections and will reevaluate this condition in FY 2009.

(l) Serious Preventable Event—Surgery on Wrong Body Part, Patient, or Wrong Surgery

Coding—Surgery performed on the wrong body part, wrong patient, or the wrong surgery would be identified by ICD–9–CM code E876.5 (Performance of inappropriate operation). This diagnosis code does not specifically identify which of these events has occurred.

Burden (High Cost/High Volume)—As stated earlier, there are not unique ICD–9–CM codes which capture surgery performed on the wrong body part or the wrong patient, or the wrong surgery. Therefore, we examined Medicare data on the code for performance of an inappropriate operation. For FY 2006, there was one Medicare case reported with this code, and the patient had average charges for the hospital stay of $24,962. This event is rare. Therefore, it is not high volume. Individual cases could have high costs. However, we were unable to determine the impact with our limited data.

Prevention guidelines—There are prevention guidelines for performing the correct surgery on the correct patient or correct patient's body part. This event should not occur.

CC—This code is not a CC under the current CMS DRGs and the proposed MS–DRGs. Therefore, it does not meet the criteria for selection under section 1886(d)(4)(D)(iv) of the Act. However, Medicare does not pay for performing surgery on the wrong body part or patient, or performing the wrong surgery. These services are not considered to be reasonable and necessary and are excluded from Medicare coverage.

Considerations—There are significant considerations for the selection of this condition. There is not a unique ICD–9–CM code that would describe the nature of the inappropriate operation. All types of inappropriate operations are included in code E876.5. Unlike other conditions, performance of an inappropriate operation is not a complication of a prior medical event that was medically necessary. Rather, in this case, there was a needed intervention but it was done to either the wrong body part or the wrong patient, or was not the correct operation. Thus, a service was completed that was not reasonable and necessary and Medicare does not pay for any inpatient service associated with the wrong surgery. It is not necessary for us to select this condition because Medicare does not pay for it under any circumstances.

(m) Falls

Coding—There is no single code that shows that a patient has suffered a fall in the hospital. Codes would be assigned to identify the nature of any resulting injury from the fall such as a fracture, contusion, concussion, etc. There is a code to indicate that a patient fell from bed, code E884.4 (Fall from bed). One would then assign a code that identifies the external cause of the injury (the fall from the bed) and an additional code(s) for any resulting injury (a fractured bone).

Burden (High Cost/High Volume)—As stated earlier, there is not a code to capture all types of falls. Therefore, we examined Medicare data on the number of Medicare beneficiaries who fell out of bed. For FY 2006, there were 2,591 cases reported of Medicare patients who fell out of bed. These patients had average charges of the hospital stay of $24,962. However, depending on the nature of the injury, costs may vary in specific cases.

Prevention guidelines—Falls may or may not be preventable. Serious preventable event guidelines can be found at the following Web site: *http://www.qualityindicators.ahrq.gov/psi_download.htm*

CC—Code E884.4 is not a CC under the current CMS DRGs or the proposed MS–DRGs.

Considerations—There are not clear codes that identify all types of falls. Hospitals would also have to use additional codes for fractures and other injuries that result from the fall. In addition, depending on the circumstances, the falls may or may not be preventable. We are not proposing the inclusion of falls as one of our initial hospital-acquired conditions at this time because we can only identify a limited number of these cases, and they are not classified as a CC. However, we welcome public comments on how to develop codes or coding logic that would allow us to identify injuries that result from falls in the hospital so that Medicare would not recognize the higher costs associated with treating patients who acquire these conditions in the hospital. We will reevaluate this condition in FY 2009.

The following table summarizes whether or not the potential conditions meet our criteria and if there are significant considerations with selecting the particular condition. As mentioned earlier, we have listed these conditions in the priority order according to how well they meet the statutory criteria. As discussed earlier, we are proposing to select the first six conditions (catheter associated urinary tract infections through Staphylococcus aureus septicemia) as our initial hospital-acquired conditions. We would not include the last seven conditions (ventilator-associated pneumonia through falls) as initial hospital-acquired conditions. We welcome comments on how appropriately we have evaluated and proposed the selection of the first six conditions. We also encourage specific comments on any additional conditions we should select for October 1, 2008 implementation. We request commenters to include a rationale for selecting any suggested additional conditions, as well as an analysis of why each suggested additional condition meets the criteria under section 1886(d)(4)(D)(iv) of the Act and whether there would be coding issues or other considerations associated with selecting each condition.

PROPOSED HOSPITAL-ACQUIRED CONDITIONS AND CRITERIA

Proposed hospital-acquired condition	Coding—unique code?	Burden—high cost and/or high volume?	Prevention guidelines?	CC?	Considerations?
1. Catheter associated urinary tract infections.	Yes	Yes	Yes	Yes	Minimal—additional infection codes.
2. Pressure ulcers (Decubitus ulcers)	Yes	Yes	Yes	Yes	No.
3. Serious preventable event—Object left in surgery.	Yes	Yes—high cost in specific circumstances.	Yes	Yes	No.
4. Serious preventable event—air embolism.	Yes	Yes—high cost in specific circumstances.	Yes	Yes	No .
5. Serious preventable event—Blood incompatibility.	Yes	Yes—high cost in specific circumstances.	Yes	Yes	No.
6. Staphylococcus aureus septicemia	Yes—multiple codes reported.	Yes	Yes	Yes	Multiple codes.
7. Ventilator associated pneumonia (VAP)/Pneumonia/.	No VAP code, multiple pneumonia codes.	Yes	Yes	No—no unique codes.	Preventability issues. VAPs—identification issues.
8. Vascular catheter associated infections.	No	Yes	Yes	Yes—but code is too broad.	Preventability issues.
9. Clostridium difficile-associated disease (CDAD).	Yes	Yes	No	Yes	Preventability issues.
10. Methicillin-resistant staphylococcus aureus (MRSA).	Yes	Yes	Yes	No	Preventability issues.
11. Surgical site infections	No	Yes	Yes	Yes—but code is too broad.	Cannot identify.
12. Serious preventable event—Wrong surgery.	Yes	Yes—high cost in specific circumstances.	Yes	No	Not a CC.
13. Falls	No—not for all types of falls.	Yes—high cost in specific circumstances.	No—for all types of falls.	No	Cannot identify.

As stated earlier, we are soliciting comments on the six conditions we proposed to include among the initial hospital-acquired conditions. We welcome any comments on the clinical aspects of the conditions and on which conditions should be selected for implementation on October 1, 2008. We also solicit comments on any problematic issues for specific conditions that may support not selecting them as one of the initial conditions. We encourage comments on how some of the administrative problems can be overcome if there is support for a particular condition.

7. Other Issues

Under section 1886(d)(4)(D)(vi) of the Act, ''[a]ny change resulting from the application of this subparagraph shall not be taken into account in adjusting the weighting factors under subparagraph (C)(i) or in applying budget neutrality under subparagraph (C)(iii).'' Subparagraph (C)(i) refers to DRG classifications and relative weights. Therefore, the statute requires the Secretary to continue counting the conditions selected under section 5001(c) of the DRA as MCCs or CCs when updating the relative weights annually. Thus, the higher costs

associated with a case with a hospital-acquired MCC or CC will continue to be assigned to the MCC or CC DRG when calculating the relative weight but payment will not be made to the hospital at one of these higher-paying DRGs. Further, subparagraph (C)(iii) refers to the budget neutrality calculations that are done so aggregate payments do not increase as a result of changes to DRG classifications and relative weights. Again, the higher costs associated with the cases that have a hospital-acquired MCC or CC will be included in the budget neutrality calculation but Medicare will make a lower payment to the hospital for the specific case that include an MCC or CC. Thus, to the extent that the provision applies and cases with an MCC or CC are assigned to a lower-paying DRG, section 5001(c) of the DRA will result in cost savings to the Medicare program. We note that the provision will only apply when the selected conditions are the only MCCs and CCs present on the claim. Therefore, if a nonselected MCC or CC is on the claim, the case will continue to be assigned to the higher paying MCC or CC DRG, and there will be no savings to Medicare from the case. We believe the provision will apply in a small minority of cases because it is rare that one of the selected conditions will be the only MCC or CC present on the claim. We provide our estimate of the savings associated with this provision in the impact section of this proposed rule.

G. Proposed Changes to Specific DRG Classifications

1. Pre-MDC: Intestinal Transplantation

(If you choose to comment on issues in this section, please include the caption ''DRGs: Intestinal Transplantation'' at the beginning of your comment.)

In the FY 2005 IPPS final rule (69 FR 48976), we reassigned intestinal transplant cases from CMS DRG 148 (Major Small and Large Bowel Procedures with CC) and CMS DRG 149 (Major Small and Large Bowel Procedures without CC) to CMS DRG 480 (Liver Transplant and/or Intestinal Transplantation). In the FY 2006 IPPS final rule (70 FR 47286), we continued to evaluate these cases to see if a further DRG change was warranted. While we found that intestinal only transplants and combination liver-intestine transplants have higher average charges than other cases in CMS DRG 480, these cases are extremely rare (there were only 4 cases in FY 2004) and the insufficient number of cases does not warrant creating a separate DRG.

For FY 2008, we examined the September 2006 update of the FY 2006 MedPAR file and found 1,208 cases assigned to CMS DRG 480. In the proposed MS–DRGs described in section II.C. of the preamble of this proposed rule, we are proposing to split CMS DRG 480 into two severity levels: proposed MS–DRG 005 (Liver Transplant and/or Intestinal Transplant with MCC) and proposed MS–DRG 006 (Liver Transplant and/or Intestinal Transplant without MCC). The following table displays our results:

Proposed MS–DRG	Number of cases	Average length of stay	Average charges
MS–DRG 006—All cases	446	10.05	$129,519
MS–DRG 006—Intestinal transplant cases only	3	34	354,793
MS–DRG 005—All cases	762	22.25	243,271
MS–DRG 005—Intestinal transplant cases only	9	40.22	460,089
MS–DRG 005—Intestinal and liver transplant	1	56	1,179,425

Under the proposed MS–DRGs, 10 of 13 intestinal transplant cases are assigned to proposed MS–DRG 005 based on the secondary diagnosis of the patient. The three remaining intestinal transplant cases do not have an MCC and would have been assigned to proposed MS–DRG 006, absent further changes to the DRG logic. These three intestinal transplants have average charges of approximately $354,793 and an average length of stay of 34 days. Average charges and length of stay for these three cases are more comparable to the average charges of approximately $243,271 and average length of stay of 40.22 days for all cases assigned to proposed MS–DRG 005. For this reason, we are proposing to move all intestinal transplant cases to proposed MS–DRG 005. As part of this proposal, we would redefine proposed MS–DRG 005 as ''Liver Transplant with MCC or Intestinal Transplant.'' The presence of a liver transplant with MCC or an intestinal transplant would assign a case to the higher severity level. Proposed MS–DRG would also be redefined as ''Liver Transplant without MCC.''

2. MDC 1 (Diseases and Disorders of the Nervous System)

a. Implantable Neurostimulators

(If you choose to comment on issues in this section, please include the caption ''DRGs: Neurostimulators'' at the beginning of your comment.)

We received a joint request from three manufacturers to review the DRG assignment for cases involving neurostimulators. The commenters are concerned that:

- Neurostimulator cases may be assigned to 30 different DRGs in 12 different MDCs depending upon the patient's principal diagnosis.
- Neurostimulator cases represent a small proportion of the total cases in their assigned DRG and have higher costs.
- The 11 new ICD–9–CM codes created beginning in FY 2007 that identify pain are assigned to MDC 23 (Factors Influencing Health Status and Other Contacts With Health Services) rather than MDC 1 (Diseases and Disorders of the Nervous System). The commenters are concerned that these pain codes will be a common principal diagnosis for patients who receive a neurostimulator and will be assigned to MDC 23, which contains a wide variety of dissimilar diagnoses. The new ICD–9–CM codes are: 338.0 (Central pain syndrome), 338.11 (Acute pain due to trauma), 338.12 (Acute post-thoracotomy pain), 338.18 (Other acute postoperative pain), 338.19 (Other acute pain), 338.21 (Chronic pain due to trauma), 338.22 (Chronic post-thoracotomy pain), 338.28 (Other chronic postoperative pain), 338.29 (Other chronic pain), 338.3 (Neoplasm related pain (acute)(chronic)), and 338.4 (Chronic pain syndrome)

The commenters recommended that we:

- Reroute all spinal and peripheral neurostimulator cases into a common set of base DRGs.