application of this methodology. In the FY 2007 IPPS final rule, we discussed our rationale for implementing cost-based weights over a 3-year transition period. We stated that the 3-year transition would mitigate the annual payment effects from the changes to the relative weights while we further study whether to make adjustments to account for charge compression. We believe that the cost-based methodology reduces bias in the relative weights and makes Medicare's payments more accurate for both medical and surgical DRGs. Therefore, any delays in the transition would not further our goal of payment accuracy. We believe that current efforts to improve cost reporting and our decision not to implement regression-based CCRs will alleviate concerns about additional fluctuations in hospital payments from further changes to the relative weight methodology. Furthermore, we believe that, for some types of hospitals (such as rural hospitals), the payment changes from MS–DRGs are the opposite of those that will occur from the transition to cost-based weights. For this reason, we believe a 2-year transition of the MS–DRG system that coincides with the remaining two years of the transition to cost-based weights will reduce the magnitude of annual payment changes and achieve our long-term goal of improvements in payment accuracy. Therefore, we are continuing with the 3-year transition to cost-based weights. For FY 2008, the DRG relative weights will be a blend of 33 percent of charge-based weights and 67 percent of cost-based weights. For the first year of the MS–DRG transition, the relative weights will be a blend of 50 percent of the CMS–DRG weight and 50 percent of the MS–DRG weight.

F. Hospital-Acquired Conditions, Including Infections

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 lead to higher Medicare 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 estimated costs above the fixed-loss cost threshold). Second, under the MS–DRGs we are adopting in this final rule with comment period, there are 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. (We refer readers to section II.D. of this final rule with comment period for a detailed discussion of 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 regarding conditions with evidence-based guidelines that should be selected in order to implement section 5001(c) of Pub. L. 109–171. The comments that we received were summarized in the FY 2007 IPPS final rule (71 FR 48051 through 48053). In the FY 2008 IPPS proposed rule (72 FR 24716), we again sought formal public comment on conditions that we proposed to select under section 5001(c). As discussed below, in this final rule with comment period, we first summarize the comments we received on the FY 2007 IPPS proposed rule. We then explain our detailed proposals included in the FY 2008 proposed rule, followed by a summary of the public comments on each condition proposed and our responses to those public comments.

In summary, the majority of the comments that we received in response on 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 discussed in detail in the preamble of the proposed rule and in section II.D.4. of this final rule with comment period. We also discuss throughout section II.D. of the preamble of this final rule with comment period other comments that we have considered in developing hospital-acquired conditions that would be subject to reporting.

As it is not addressed elsewhere, we are responding here to the comment about hospitals billing patients for costs of hospital-acquired complications that are not counted as MCCs and CCs. Section 5001(c) does not make the additional cost of a hospital acquired complication a noncovered cost. The additional costs that a hospital would incur as a result of a hospital-acquired complication remains a covered Medicare cost that is included in the hospital's IPPS payment. Medicare's payment to the hospital is for all inpatient hospital services provided during the stay. The hospital cannot bill the beneficiary for any charges associated with the hospital-acquired complication. With respect to the concern about a hospital avoiding patients that are at high risk of complications, we note that the policy is selecting only those conditions that are ''reasonably preventable.'' Thus, we are only selecting those conditions where, if hospital personnel are engaging in good medical practice, the additional costs of the hospital-acquired condition will, in most cases, be avoided and the risk of selectively avoiding patients at high risk of complications will be minimized. We further note that Medicare's high cost outlier policy is unaffected by section 5001(c). The hospital's total charges for all inpatient services provided during the stay will continue to be used to determine whether the case qualifies for an outlier payment. Thus, there will continue to be limitations on a hospital's financial risk of treating high cost cases even if, despite the hospital maintaining good medical practice to avoid complications, a reasonably preventable condition occurs after admission. Finally, as stated further below, we are continuing to work to identify exclusions for situations where the policy should not apply for the selected condition.

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 Pub. L. 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 issued instructions requiring acute care IPPS hospitals to submit the POA indicator for all diagnosis codes, effective October 1, 2007, through Change Request No. 5499, with a release date of May 11, 2007. The instructions specify how hospitals under the IPPS 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 indicated 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.
- Hospital falls. 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.
- 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 indicated that there are CDC guidelines for these infections. Other commenters stated that while this condition certainly deserves focused attention by health care providers, there is not a 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 indicated 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 indicated that MRSA has

become a very common bacteria occurring both in and outside the hospital environment. However, other organizations stated 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. They noted 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 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 the 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 are 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, the complexities associated with selecting septicemia as a hospital-acquired condition subject to section 5001(c) of the DRA may present operational issues in identifying whether or not the condition was present upon admission. 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.

• MCC or 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 is 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 evaluated 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. 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 the preamble of this final rule with comment period. 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 that describes how each condition was considered for the proposed rule, whether we are selecting it to be subject to the provision in this FY 2008 IPPS final rule or if it will continue to be considered for the future. In the proposed rule, we presented 13 conditions. The summary discussion and table reflect changes to the order of the conditions. The summary presents the conditions that best meet the statutory criteria and which conditions we are selecting to be subject to the payment adjustment for hospital-acquired conditions beginning in FY 2009. In the proposed rule, we encouraged comments on these conditions. We asked commenters to recommend how many and which conditions should be selected in the FY 2008 IPPS final rule along with justifications for these selections. We also encouraged additional comments on clinical, coding, and prevention issues that may affect the conditions selected. While, in this final rule with comment period, we present these 13 conditions in the order they were proposed, we have re-ranked these conditions based on how well they meet the statutory criteria according to compelling public health reasons in addition to public comment and internal analysis.

We received approximately 127 timely public comments on this section from hospitals and health care systems, provider associations, consumer groups, purchasers, medical device manufacturers, pharmaceutical companies, information technology companies, and health care research organizations.

Comment: Some commenters urged CMS to use discretion in selecting hospital-acquired conditions that will be subject to the statutory provision and suggested that CMS limit the number of conditions selected. A large majority of

commenters strongly supported the inclusion of three of the serious preventable events (object left in surgery, air embolism and blood incompatibility) and generally commented that the remaining conditions are not always preventable or may not have unique codes established.

A number of commenters both supported and opposed the conditions other than the three serious preventable events mentioned above. The commenters were generally optimistic about considering proposed conditions for the future upon resolution of suggested issues. A few commenters proposed that CMS initially begin with limited demonstrations to test CMS' methodology before nationwide implementation. These commenters specifically mentioned the Michigan Hospital Association Keystone Center.

The commenters who suggested not including conditions other than the three serious preventable events mentioned above noted that sicker and more complex patients are at greater risk for hospital-acquired infections and complications. In particular, the commenters believed some of the conditions proposed are a biological inevitability at a certain predictable rate regardless of safe practice. In addition, the commenters expressed concern about the difficulty of distinguishing between hospital-acquired and community-acquired infections. The commenters also believed that CMS should use incentives to allow hospitals to adopt innovative infection prevention technologies and provide necessary treatments for infections. Finally, a few commenters submitted additional conditions that were not included in the 13 conditions we considered in the proposed rule.

Response: In general, we discuss our responses to each of these comments below in the context of the specific conditions they reference. With respect to the general comment that we should only select the three serious preventable events, we believe there is a significant public health interest in selecting more than just these conditions. According to the commenters, many of the other conditions we considered are not always preventable and, therefore, should not be selected. The statute indicates that the provision should apply to conditions that ''could reasonably have been prevented through the application of evidence-based guidelines.'' Therefore, for this reason, we are selecting other conditions in addition to the serious preventable events to be subject to this provision in this final rule with comment period. We discuss the application of the statutory criteria to each of the conditions we considered below and why we believe the condition is ''reasonably preventable.''

(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 966.64 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.[22] 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 CMS DRGs as well as in the 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 CMS DRGs as well as the 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

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

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 CMS DRGs and the MS–DRGs. The condition meets our burden criterion with its high cost and high frequency. There are prevention guidelines on which the medical community agrees to avoid catheter-associated urinary tract infections. We believe this condition best meets the criteria discussed. Therefore, we proposed the selection of catheter-associated urinary tract infections as one of the initial hospital-acquired conditions.

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

Comment: Most commenters suggested that a large number of physicians believe urinary tract infections may not be preventable after several days of catheter placement. A few commenters submitted the following statement from the proposed rule (72 FR 24719): ''once catheters are in place for 3–4 days, most clinicians and infection control experts do not believe UTIs are preventable.'' The commenters also noted the potential difficulty in identifying this condition at admission.

Still other commenters believed this condition is difficult to code because the ICD–9–CM codes do not distinguish between catheter-associated inflammation and infection. The commenters asked CMS to consider a new code for ''inflammatory reaction from indwelling catheter'' distinct from ''catheter associated urinary tract infection.''

In addition, the commenters noted that prevention guidelines are still being debated. The commenters referenced the prevention guideline published in 1981 and posted on the Web site at: *http://www.cdc.gov/ncidod/dhqp/gl_catheter_assoc.html.*

A few commenters also recommended exceptions for this condition, including patients with immunosuppression, patients who have a catheter placed for therapeutic installation of antimicrobial/chemotherapy agent, patients with sustained urinary tract trauma, and patients in need of permanent use of a catheter.

Commenters stated that Medicare reimbursement does not cover the increased cost of antibiotic-coated catheters which have been shown to reduce the incidence of catheter infections. These same commenters asked CMS to change Medicare payment policy to encourage the application of proven existing technology.

Commenters provided two potential examples of unintended consequences if this condition is to be implemented. First, the commenters believed that physicians and hospitals will increase urinalysis testing to identify urinary tract infections prior to admission. Second, the commenters suggested that physicians and hospitals will use more antibiotics to ''clean'' the urine of bacteria upon admission.

Response: CMS seeks to reduce the incidence of preventable catheter associated urinary tract infections by reducing unnecessary and inappropriate use of indwelling urinary catheters in hospitalized Medicare patients. There is widespread evidence that catheters may lead to an increased risk of infection if they are in place for several days. In addition, there are prevention guidelines to assist physicians in determining how long a urinary catheter should be left in place that can prevent catheter-associated urinary tract infections. Therefore, we believe that catheter-associated urinary tract infections are reasonably preventable by following well-established prevention guidelines, and we are selecting this condition.

Concerning the request for the creation of a new code for ''inflammatory reaction from indwelling catheter,'' we recommend the commenter contact the CDC. The CDC is responsible for maintaining the diagnosis part of the ICD–9–CM codes. We encourage commenters to send specific requests for new or revised ICD–9–CM diagnosis codes to Donna Pickett, CDC, at 3311 Toledo Road, Room 2402, Hyattsville, MD 20782, or via e-mail to *dfp4@cdc.gov.* Additional information on requesting a new ICD–9–CM diagnosis code may be obtained from the Web site at: *http://www.cdc.gov/nchs/icd9.htm.*

The commenters are correct that prevention guidelines for avoiding catheter-associated urinary tract infections are scheduled to be updated by CDC's Healthcare Infection Control Practices Committee (HICPAC). The National Quality Forum (NQF) is currently working to update hospital-acquired infection definitions. The effort currently underway will update prevention guidelines that have been in place since 1981. We believe the ongoing effort to update prevention guidelines for avoiding catheter-associated urinary tract infections provides further evidence that this condition is a strong candidate to be selected because of how well it meets the statutory criteria.

We appreciate the many comments urging CMS to consider implementing exceptions for catheter-associated urinary tract infections when it is a hospital-acquired condition but is not preventable. We will carefully consider these suggestions as we plan for the implementation of this new requirement in FY 2009.

With respect to the comment about encouraging the use antibiotic-coated catheters, we continue to work in cooperation with device companies and other associations to ensure that Medicare beneficiaries receive the most current therapeutic modalities. We annually update Medicare inpatient hospital payment rates to reflect hospital resource use for the latest medical technology and other innovations in how care is delivered.

We do not agree there will be significant unintended consequences of selecting catheter-associated urinary tract infections. As stated earlier, we believe this condition is generally avoidable if medical professionals carefully follow longstanding prevention guidelines. We believe hospitals, physicians, and others that treat Medicare patients will focus on taking medically appropriate steps to determine the length of time a catheter is in place. We do not believe it is inappropriate to perform a urinalysis upon admission to the hospital if clinically indicated. We would not

consider doing so an unintended consequence.

We appreciate all the public comments on this condition, and have considered all of these points of view. We believe this condition meets the criteria of the DRA:

- There are unique codes that identify catheter-associated urinary tract infections that are currently considered to be a CC under the MS–DRGs;
- Prevention guidelines currently exist and will be updated prior to the October 1, 2008 implementation date of this provision; and
- As shown above, catheter-associated urinary tract infections are high cost/high volume conditions.

Therefore, in this final rule with comment period, we are selecting the condition of catheter-associated urinary tract infections to be subject to the provision beginning October 1, 2008.

(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 condition is both high-cost and high volume. 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* and *http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat2.chapter.4409.*

CC—Decubitus ulcer codes are classified as CCs under the CMS DRGs. Codes 707.00, 707.01, and 707.09 are CCs under the MS–DRGs. Codes 707.02 through 707.07 are considered MCCs under the 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. In the proposed rule, we proposed 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 CMS DRGs and as a CC or MCC under the 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 and better quality of care. We welcomed comments on the proposed inclusion of this condition.

Comment: A majority of commenters supported the intent of selecting the condition of pressure ulcers, but had concerns about how the provision would be implemented in practice. A large majority of commenters believed hospitals will more carefully examine the skin of patients if this condition is selected. However, many commenters cited difficulty in detecting stage 1 pressure ulcers on admission, particularly in certain patient populations.

The commenters cited the Guidance to Surveyors for Long-Term Care Facilities (CMS Manual System Pub. 100–07, State Operations Provider Certification issued November 2004, page 5), noting CMS'' previous acknowledgment that some pressure ulcers are ''unavoidable.'' The commenters cited evidence of an increased risk of pressure ulcer reoccurrence after a patient has had at least one stage IV ulcer.

The commenters expressed concern about how this condition will be coded upon admission. The commenters also suggested that present-on-admission coding of pressure ulcers will rely solely on physicians' notes and diagnoses, according to Medicare coding rules. The commenters were concerned that the current ICD–9–CM codes for pressure ulcers are not precise enough to delineate differences in wound depth, which is an important factor for determining the severity of an ulcer.

The commenters recommended that CMS supplement ICD–9–CM codes for pressure ulcers with severity adjustments for complications and comorbidities that are present on admission. Because patients with pressure ulcers often have other complicating conditions, the commenters stated that it is unlikely that pressure ulcers would potentially be the only secondary diagnosis that would change the DRG assignment from one without a CC to one with a CC. Lastly, the commenters noted that accurate identification of a pressure ulcer requires the education and expertise of a trained physician.

The commenters suggested that CMS 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.

Response: We appreciate the overwhelming public support for the intent of selecting this condition, provided we can address the concerns raised in the public comments. We acknowledge the commenters' concern that CMS previously stated some pressure ulcers are ''unavoidable.'' However, we believe improved screening to identify pressure ulcers upon admission for inpatient care will increase the quality of care. By screening patients entering the hospital for pressure ulcers, the ulcers will be discovered earlier and improve treatment of this preventable condition. We agree that the POA coding of pressure ulcers will rely on the attending physician, who has primary responsibility for documenting and diagnosing a patient's clinical conditions. Pressure ulcers that are identified through screening upon admission that are documented properly will continue to be assigned to a higher paying DRG.

With respect to the comment about patients with pressure ulcers having other complications and comorbidities, we note that many of the new MS–DRGs are subdivided into two or more severity levels. We will continue to evaluate the need for additional severity levels within base MS–DRGs. On the specific issue of the MS–DRGs that include pressure ulcers, we note that these MS–DRGs are already divided into three severity levels as follows:

- MS–DRG 573 (Skin Graft &/or Debridement for Skin Ulcer or Cellulitis with MCC)

• MS–DRG 574 (Skin Graft &/or Debridement for Skin Ulcer or Cellulitis with CC)

• MS–DRG 575 (Skin Graft &/or Debridement for Skin Ulcer or Cellulitis without CC/MCC)

We are aware that many patients with pressure ulcers may also have other comorbid and complicating conditions that will continue to assign the patient to a higher paying DRG. We do not believe this fact should preclude physicians and hospitals from screening patients for pressure ulcers upon admission. As we indicated in the proposed rule (72 FR 24726), we believe only a minority of cases will have one of the selected conditions as the only CC or MCC present on the claim. However, we believe it will continue to lead to improvements in the quality of care. We believe the selection of this condition will lead the physician and hospital to perform a proper skin exam upon admission, leading to earlier identification and treatment of pressure ulcers.

With respect to the comment that accurate identification of a pressure ulcer requires the education and expertise of a trained physician, we agree. Hospitals should be using properly educated and trained physicians to identify and treat pressure ulcers (as well as all other medical conditions).

We appreciate all the public comment on this condition, and have considered all of these points of view. We believe the condition of pressure ulcers meets the criteria of the DRA:

• There are unique codes that identify pressure ulcers that are currently considered to be a CC or an MCC under the MS–DRGs;

• Prevention guidelines to avoid pressure ulcers currently exist; and

• As shown above, pressure ulcers are high-cost/high-volume conditions.

Therefore, in this final rule with comment period, we are selecting the condition of pressure ulcers to be subject to the payment adjustment for hospital acquired conditions beginning October 1, 2008. We referred the matter concerning the need for additional, detailed ICD–9–CM codes to the CDC. We believe further specificity in the ICD–9–CM codes will aid in distinguishing early from late stage pressure ulcers prior to the implementation date of this provision on October 1, 2008.

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 the 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. This event should not occur. Prevention guidelines for avoiding leaving objects in during surgery are located at the following Web site: *http://www.qualityindicators.ahrq.gov/psi_download.htm.*

CC—This code is a CC under the CMS DRGs as well as under the 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 proposed to include this condition as one of our initial hospital-acquired conditions. The cases can be clearly identified through an ICD–9–CM code. This code is a CC under both the CMS DRGs and the 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. In the proposed rule, we welcomed comments on including this condition as one of our initial hospital-acquired conditions.

Comment: A large majority of commenters supported CMS' efforts to identify the condition of ''object left in surgery'' as one that should not occur in the hospital setting. The commenters supported selecting this condition in this year's IPPS rule.

The commenters applauded CMS for identifying a hospital acquired condition that has discrete ICD–9–CM codes and known methods of prevention. In addition, a few commenters noted that prevention guidelines for this condition are fully identified and endorsed by the NQF. MedPAC also complimented CMS for its efforts to identify ''object left in surgery'' and stated that CMS should not allow a case to be classified as a CC/MCC if this ''never event'' occurs during a patient's stay.

The commenters urged CMS to make exceptions for objects deliberately left in place in surgery as opposed to accidental retained foreign objects. The commenters noted that a patient may return to the hospital months or years after an object was left in during surgery, and it is necessary to have POA codes to identify patients that return to a different hospital to have the object removed. All of the commenters recognized that this event can cause great harm to patients.

Response: We believe exceptions for this condition are not necessary. The code that identifies this event, 998.4 (Foreign body accidentally left during a procedure) specifically states that the object was accidentally left in during the surgery. This code would not be assigned if a device or implant was deliberately implanted into a patient. In addition, as stated earlier, we recognize the important role of the attending physician in designating whether or not the serious preventable event occurred during the current admission. We agree with the commenters that a patient may return to the hospital months or years after the surgery to have the foreign object removed. In this circumstance, the hospital would code the condition as present on admission and the provision would not apply. By documenting the event early, the correct POA code can be applied. We agree with the commenters that this serious preventable event should be selected as a hospital-acquired condition in this final rule with comment period. Therefore, we are including this condition in the list of those to be implemented in FY 2009.

(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 CMS DRGs and is an MCC under the 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 CMS DRGs and an MCC under the 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. In the proposed rule, we welcomed comments on the proposal to include this condition.

Comment: A large number of commenters supported CMS' efforts to select this condition as one that should not occur in the hospital setting. The commenters considered this an appropriate condition to include for the final rule. The commenters applauded CMS for identifying a hospital acquired condition that has discrete ICD–9–CM codes and known methods of prevention.

In addition, the commenters noted that prevention guidelines for this condition are fully identified and endorsed by the NQF. MedPAC also complimented CMS for its efforts to identify ''air embolism'' and stated that CMS should not allow a case to be classified as a CC/MCC if this ''never event'' occurs during a patient's stay.

The commenters urged CMS to make exceptions for situations when air embolism is technically unavoidable because of a special surgical procedure. All of the commenters recognized that this event can cause great harm to patients.

Response: We appreciate the support for the selection of this condition. We also welcome specific recommendations that would clearly define an appropriate exception to this condition, including any appropriate ICD–9–CM diagnosis and procedure codes which the commenter believes clearly define such an occurrence and the justification for an exception. At this point, we do not believe such an exception is necessary.

We agree with commenters that this serious preventable event should be included in the FY 2008 final rule. Therefore, we are including the condition of air embolism in the list of those to be implemented in FY 2009.

(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 CMS DRGs as well as the 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 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 proposed to include this condition as one of our initial hospital acquired conditions.

Comment: A large number of commenters supported CMS' efforts to identify ''blood incompatibility'' as one condition that should not occur in the hospital setting. The commenters considered this an appropriate condition to include for FY 2009. The commenters applauded CMS for identifying a hospital acquired condition that has discrete ICD–9–CM codes and known methods of prevention. In addition, the commenters noted that prevention guidelines for this condition are fully identified and endorsed by the NQF. MedPAC also complimented CMS for its efforts to identify ''blood incompatibility'' and stated that CMS should not allow a case to be classified as a CC/MCC if this ''never event'' occurs during a patient's stay.

The commenters urged CMS to make exceptions for situations when blood incompatibility is technically unavoidable in emergencies when patients deliberately receive unmatched blood. All of the commenters recognized that this event can cause great harm to patients.

Response: As suggested by commenters, hospitals should not be transfusing incompatible blood. The condition meets the criteria for being selected. It is a potential hospital acquired condition that has discrete ICD–9–CM codes and known methods of prevention. Prevention guidelines for this condition are fully identified and endorsed by the NQF. We acknowledge that there may a rare emergency where a hospital does not have compatible blood available for transfusion. We welcome specific recommendations that would define circumstances where blood incompatibility is unavoidable, including any appropriate ICD–9–CM diagnosis and procedure codes, which the commenters believe clearly define such an occurrence. If providers can provide such a clinical scenario that can be identified by existing or new ICD–9–CM codes, we will consider excluding this situation from the provision. We agree with the commenters that this serious preventable event should be included in the FY 2008 final rule. Therefore, we are including the condition of blood incompatibility in the list of those to be implemented in FY 2009.

(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, and vaccination (ventilator-associated pneumonia is 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 CMS DRGs and as MCCs under the 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 CMS DRGs and MCCs under the 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, and vaccination (ventilator-associated pneumonia is 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 proposed to include staphylococcus aureus bloodstream infection/septicemia (code 038.11) as one of our initial hospital-acquired conditions. We also proposed to exclude codes 995.91, 998.59, and 999.3 from counting as an MCC/CC when they were reported with code 038.11. The condition can be clearly identified through ICD 9 CM codes that are classified as CC under the CMS DRGs and MCCs under the 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. In the proposed rule, we encouraged commenters to make suggestions on this issue and to recommend any other appropriate exclusion for staphylococcus aureus septicemia. We also encouraged comments on the appropriateness of selecting staphylococcus aureus septicemia as one of our proposed initial hospital acquired conditions.

Comment: Many commenters opposed CMS' proposed selection of this condition as part of the FY 2008 final rule. There were a minority of commenters who strongly supported the selection of this condition. These commenters noted the existence of technologies that allow the physician to determine the presence of Staphylococcus Aureus upon admission. Many more commenters stated that accurately identifying staphylococcus aureus septicemia on admission will be difficult, particularly in patients who may have a staphylococcus aureus infection in a limited location. Several commenters referenced the FY 2008 IPPS proposed rule, which stated ''physicians cannot always tell whether the condition was hospital acquired.'' Other commenters also noted that there is still debate

among physicians regarding the prevention guidelines for staphylococcus aureus septicemia. The proliferation of changes in coding guidelines presents coding problems for hospitals to accurately identify present-on-admission status according to some comments. Specifically, the commenters noted that codes to identify sepsis are very complex and have had recent changes. For instance, there is a code that currently includes septicemia that develops postoperatively, but does not clearly distinguish between intravascular and catheter-associated sources of septicemia. The commenters also suggested that additional coding may be necessary to accurately identify this condition in the many forms it often presents upon admission. Some commenters suggested that the addition of codes may create a challenge for coding staff to identify the correct code.

A large majority of commenters urged CMS to narrow the category for staphylococcus aureus septicemia to include only patients for whom it is reasonably clear that the hospital was the source of the infection and that it could have been reasonably prevented.

Response: We appreciate the plethora of comments regarding staphylococcus aureus septicemia. The commenters were very insightful and presented the challenges of selecting this condition in the FY 2008 final rule.

We agree that the recent proliferation of ICD–9–CM codes for this condition will make it difficult to code and could present an administrative burden on hospitals. In addition, we are sensitive to the difficulty of identifying when a disease has progressed to sepsis or septicemia. Given the course of progression to septicemia, it can be very difficult for a clinician to appropriately diagnose staphylococcus aureus septicemia as present on admission.

While we acknowledge the many concerns raised by the commenters, we continue to believe that hospital acquired staphylococcus aureus septicemia remains a significant public health issue. We are aware of the continued need to prevent Staphylococcus Aureus septicemia in the hospital setting. Therefore, we plan to engage in a collaborative discussion with relevant experts to identify the circumstances when staphylococcus aureus septicemia is preventable. If we can identify when staphylococcus aureus septicemia is a reasonably preventable condition and have codes to distinguish those situations, we will consider this condition for future years. We appreciate the many comments and suggestions as we consider staphylococcus aureus septicemia for selection in the future, and look forward to receiving more public input to identify only instances when this condition is preventable.

Therefore, we are not selecting this condition in this final rule with comment period. We plan to collaborate with the public on this important public health issue and continue to consider the condition for selection in the FY 2009 final rule. We encourage and welcome public comment to further evaluate this condition.

(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.[23]

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

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 CMS DRGs and under the 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, 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 did not propose to select this condition as one of our initial hospital-acquired conditions. However, we welcomed public comments on how to create an ICD–9–CM code that identifies ventilator-associated pneumonia, and we encouraged participation in our September 28–29, 2007 ICD–9–CM Coordination and Maintenance Committee meeting where this issue will be discussed. We indicated that we would reevaluate the selection of this condition in FY 2009.

Comment: Some commenters urged CMS to select ventilator-associated pneumonia at this time. Most commenters recommended that CMS delay selecting this condition until a unique code is established.

Some commenters submitted an evidence-based peer-reviewed American Association for Respiratory Care (AARC) Clinical Practice Guideline (CPG) on strategies that should be disseminated and available to hospitals for the prevention of ventilator associated pneumonia. The CPG can be found at *http://www.rcjournal.com/cpgs/09.03.0869.html.* Concurrently, the AARC acknowledges that more research needs to be done in this area.

A majority of commenters believed this condition can be reasonably prevented through evidence-based medicine guidelines. These commenters noted that current unique codes for this condition are absent. These commenters urged CMS to consider the development of an explicit ICD–9–CM code for this ventilator-associated pneumonia and to select it at a later date.

Response: At the time of publication of this final rule with comment period, there is not a code associated with ventilator-associated pneumonia. Therefore, this condition does not currently meet the statutory criteria for being selected. However, the ICD–9–CM Coordination and Maintenance Committee will meet September 27–28, 2007, to discuss the creation of a unique ICD–9–CM code for this condition. Further information of the Committee's activities on diagnosis code issues can be found at the Web site: *http://www.cdc.gov/nchs/icd9.htm.* We believe that once this condition has a unique code, it should be further considered for selection beginning in FY 2009.

We believe that ventilator-associated pneumonia meets some of the criteria for being selected. There are guidelines for prevention of ventilator-associated pneumonia within CDC evidence based guidelines for healthcare associated pneumonia. More information can be found at: *http://www.cdc.gov/ncidod/dhqp/gl_hcpneumonia.html.* Furthermore, we are aware that the American Thoracic Society and the Infectious Disease Society of America collaborated to produce guidelines on the prevention of ventilator-associated pneumonia. As indicated above, most pneumonias are CCs. Therefore, it is reasonable to believe that ventilator-associated pneumonia will also be classified as a CC once a new code is created to identify it. At that time, we can further consider whether the condition is reasonably preventable and should be subject to this provision.

We appreciate all the public comment on this condition, and considered all of the respondents' point of view. While we acknowledge the clinical challenge of clearly identifying ventilator-associated pneumonia, we believe that once this condition has a unique ICD–9–CM code, coupled with well-known prevention guidelines that are the result of evidence-based medicine, we will give strong consideration for selecting this condition for FY 2009, and including it in the FY 2009 IPPS proposed rule.

(h) Vascular Catheter-Associated Infections

Coding—The proposed rule noted that 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 vascular catheter associated infections. Therefore, there was not a unique ICD–9–CM code for this infection at the time of the proposed rule. 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.* In the proposed rule, we indicated that coders would have to assign code 996.62 plus an additional code for the infection such as septicemia to identify vascular catheter-associated infections. Therefore, a list of specific infection codes would have to be developed to go along with code 996.62 if CDC did not create a code for vascular catheter-associated infections. 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. However, even if these actions were taken, we were concerned that code 996.62 is not specific to vascular catheter-associated infections.

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 CMS DRGs and the MS–DRGs. However, as stated earlier, this code is broader than vascular catheter associated infections. Therefore, at the time of the

proposed rule, there was not a unique ICD–9–CM code to identify the condition, and it did not meet the statutory criteria to be selected. However, the proposed rule indicated that we will be seeking to create a code(s) to identify this condition and may select it as a condition under the provision beginning in FY 2009.

Considerations—There was not yet a unique ICD–9–CM code to identify this condition at the time of the proposed rule. In the proposed rule, we indicated that if a code were created prior to 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 did not propose to include it as one of our initial hospital-acquired conditions. However, we believed it showed merit for inclusion in future lists of hospital acquired conditions once we had resolved the coding issues and were able to better identify the condition in the Medicare data. We indicated that we would reevaluate the selection of this condition in FY 2009.

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

Comment: Some commenters stated there was not a unique ICD–9–CM code for vascular catheter-associated infection. Therefore, the condition does not meet the criteria for being selected. These commenters requested that CMS consider creating an explicit code for catheter-associated infections and selecting the condition at that time. One commenter recommended that CMS examine selecting vascular-catheter associated infections and identify the condition using the CPT codes for insertion of a central venous catheter. Other commenters recommend selecting the condition and rely on the use of specific codes for the insertion of catheters to supplement the existing code 996.62 (Infection and inflammatory reaction due to other vascular device, implant, and graft). The commenters believed that this alternative approach may reduce the need to rely on a unique code for catheter associated blood stream infection (CA–BSI). Some commenters noted that it is possible to screen for bloodstream infections upon admission. Other commenters suggested that CMS exempt vascular surgery, implantable device codes, and other obvious sources of existing conditions that cause blood stream infection prior to catheter placement. Finally, the commenters suggested that CMS exclude long-term catheter insertions such as the tunneled central venous catheter using codes 365.57 through 365.66.

Response: Since the publication of the FY 2008 IPPS proposed rule, CDC has created a new code for vascular catheter-associated infection. The new code 999.31, (Infection due to central venous catheter) will become effective on October 1, 2007. It is available for public viewing along with other new codes listed on the CMS Web site at: *http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/Downloads/new_diagnosis_codes_2007.pdf.* This new code will address commenters concerns regarding coding for this condition.

We appreciate all the public comment on this condition, and have considered all of these points of view. For the proposed rule, our only barrier to selecting vascular catheter-associated infections was the absence of a unique code to identify the condition. As CDC has since created a code to identify vascular catheter-associated infections, we believe the condition meets the criteria for being selected:

- There are unique codes that identify vascular catheter-associated infections as a CC under the MS–DRGs;
- Prevention guidelines exist to avoid vascular catheter-associated infections; and
- As shown above, vascular catheter-associated infections are high-volume conditions.

At this time, we have not decided whether there are specific clinical situations where a vascular catheter associated infection would not be considered preventable. We will consider exceptions to the policy in the circumstances provided in the public comments. We will consider these suggestions before the provision becomes effective in FY 2009.

(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-cost and 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 CMS DRGs and the 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 did not propose to include CDAD as one of our initial hospital acquired conditions at this time, given the lack of prevention guidelines. We welcomed 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 indicated that we would reevaluate the selection of this condition in FY 2009.

Comment: Commenters noted the current clinical debate surrounding this condition reveals that it is very difficult to prevent in all cases; it can be prevalent within the hospital setting. In addition, some commenters noted this condition may be caused by the treatment protocol prescribed for a principal diagnosis; it can also occur if the patient is immune-compromised. Finally, some commenters stated that a significant percentage of CDAD is unavoidable, and it is difficult to distinguish community acquired from hospital acquired CDAD. Commenters

also urged CMS to delay selection of this condition because there is a lack of unique codes, complication codes, and guidelines for prevention of this condition.

Response: This condition meets two of the three statutory criteria. There is an ICD–9–CM code for CDAD. The code is 008.45 (Clostridium difficile). Therefore, the condition can be clearly identified through the use of ICD–9–CM codes. Code 008.45 is also a CC under the CMS DRGs and the MS–DRGs. Also, as shown above, CDAD occurs with significant frequency in the Medicare population and is a high cost condition. However, prevention guidelines for this condition are currently unavailable. As suggested by the commenters, leading clinicians believe this condition may not be reasonably preventable because it can occur as a result of broad spectrum antibiotic administration, which is often unavoidable. Although we agree with these commenters, we are also aware of the public interest in this issue and will continue to be interested in selecting this condition if treatment protocols evolve to the point where CDAD is a preventable condition and prevention guidelines are developed.

We are not selecting this condition for implementation in the FY 2008 final rule. It does not currently meet the statutory guidelines for being selected because there are no prevention guidelines. Nevertheless, we will consider adopting this condition in the future if prevention guidelines to avoid CDAD are developed.

(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 bacterium 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 CMS DRGs and the 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 have 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 did not propose 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. In the proposed rule, we welcomed comments on the proposal not to include this condition. Should there be support for including this condition, we requested recommendations on what codes might be selected to identify the specific types of infections associated with MRSA.

Comment: Commenters displayed a high level of interest in this condition, not only as a hospital-acquired condition, but also as a broader public health problem that continues to affect Medicare beneficiaries. Commenters noted that MRSA is both high volume and high cost, referring to the language in the proposed rule. For this reason, many commenters believed this condition should be given a unique ICD–9–CM code to be tracked in FY 2008. Furthermore, the commenters urged CMS to include it on the list of conditions for FY 2009 for which reimbursement may be withheld. Medical device companies that provide products to screen for MRSA commented in support of selecting the condition.

However, a large number of commenters had reservations about selecting this condition because MRSA is not a CC or MCC under the new MS–DRGs. Most commenters acknowledged the clear prevention guidelines for MRSA. However, they contend that there remains debate on whether MRSA is reasonably preventable. These commenters indicated MRSA is ubiquitous and may be colonizing in so many potential patients that it is difficult to determine if it is acquired in a hospital. The commenters also noted current literature reveals a strain of community acquired MRSA that may be difficult to detect upon admission to the hospital.

Response: We acknowledge the strong public health interest in reducing the number of MRSA related infections. However, MRSA does not currently meet the statutory criteria to be selected. Although there is an ICD–9–CM code to identify MRSA and CDC has prevention guidelines to reduce its incidence, we do not believe that there is a consensus among public health experts that MRSA is preventable. The public comments and the literature on this condition reveal a vigorous debate over whether MRSA is really community-acquired rather than hospital acquired given the significant potential number of patients that can be colonized with MRSA prior to admission. While this concern may be possible to address through screening patients for MRSA upon admission, the condition is not currently identified as a CC or MCC under the MS–DRGs. If present as a secondary diagnosis, the presence of MRSA alone does not lead to higher Medicare payment. Our data do not suggest that presence of MRSA alone will lead to higher hospital costs that would justify classifying it as a CC or MCC. Therefore, as the condition is not an MCC or CC, it does not meet the statutory criteria for being selected at this time.

Although we are not selecting MRSA at this time, we believe it is a precursor to several other conditions that we have selected. MRSA may be a precursor to catheter associated urinary tract infections, vascular catheter-associated infections, and mediastinitis after coronary artery bypass graft (CABG) surgery—a surgical site infection that we have selected and is discussed in more detail below.

(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 site 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 CMS DRGs and the 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 did not propose to select surgical site infections as one of our proposed hospital-acquired conditions at this time. However, we welcomed 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 indicated that we were exploring ways to identify surgical site infections and would reevaluate this condition in FY 2009.

Comment: A number of commenters specifically requested that CMS consider selecting mediastinitis after coronary artery bypass graft (CABG) surgery. Commenters noted that mediastinitis is a postoperative infection that can arise after CABG.

Commenters stated that the condition meets the criteria set forth in the DRA. According to the comments, mediastinitis is a frequently occurring and costly infection that will develop after CABG surgery. The commenters noted that there are unique codes to identify mediastinitis and prevention guidelines that are backed by evidence based medicine have been developed.

Response: We agree that mediastinitis meets the statutory criteria for being selected.

Coding—There are unique ICD–9–CM codes to identify the condition. The ICD–9–CM code for mediastinitis is 519.2.

Burden (High Cost/High Volume)—We examined Medicare data on patients who received a CABG operation (with codes 36.10–36.19) and also had mediastinitis (ICD–9–CM code 519.2) as a secondary diagnosis. For FY 2006, there were 108 reported cases of Medicare patients who had this postoperative infection after CABG. These patients had average charges for the hospital stay of $304,747. Therefore, mediastinitis is a high-cost condition.

Prevention guidelines—The CDC surgical site infection prevention guidelines are backed by evidence based medicine. Further information can be found at: *http://www.cdc.gov/ncidod/dhqp/gl_surgicalsite.html.*

We are selecting this condition because it meets the statutory criteria and was suggested in the public comments. We would identify the coronary artery bypass graft procedures through procedure codes 36.10 through 36.19. Therefore, when a patient has a coronary artery bypass graft performed (code 36.10 through 36.19), and a secondary diagnosis of mediastinitis (code 519.2) is reported that was not present on admission, we will not count mediastinitis as an MCC beginning October 1, 2008.

''Surgical site infections'' is a broad category, and we were looking for assistance from the public for ways to identify specific surgical site infections. We appreciate the suggestion to select mediastinitis after CABG surgery when it is a hospital acquired condition. We are selecting this condition for implementation in this FY 2008 final rule. We welcome additional recommendations for other types of surgical site infections that could also be selected and look forward to working with stakeholders and the public as we consider additional surgical site infections in the future.

(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 guidelines to ensure that the correct surgery was performed on the correct patient or correct patient's body part. This event should not occur. Further information and prevention guidelines can be found at: *http://www.ahrq.gov/clinic/ptsafety/.*

CC—This code is not a CC under the CMS DRGs and the 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.

Comment: A majority of commenters agreed that there are not unique codes to identify wrong surgery. In addition, these commenters pointed out that there are guidelines to ensure that the correct surgery is being performed on the correct patient or correct patient's body part. These commenters stated that wrong surgery is a serious preventable event that should not occur.

One commenter urged CMS to rank the condition—surgery on wrong body part, wrong patient, or wrong surgery (wrong site surgery)—higher in our list of hospital-acquired conditions. This commenter stated that wrong site surgery may not be rare, but rather may be quite prevalent. The commenter disagreed with CMS' belief that wrong

site surgery should not be considered as a complication because it is a risk of being in a hospital. The commenter recommended the development of specific codes for wrong site surgery.

Response: With respect to this latter comment, the commenter may have misunderstood our discussion of this issue in the proposed rule. We never asserted wrong site surgery is not a complication because it is a risk of being in a hospital. Rather, we stated the event itself is wrong and should never occur. Unlike CCs and MCCs, wrong surgery is not a complication of a prior medical event that was medically necessary. Wrong surgery is not a CC or an MCC because the entire event itself should never occur, is not reasonable and necessary and should not result in any payment to the hospital or physician. We are not selecting wrong surgery because it is not an event for which Medicare should pay less; it is an event for which Medicare should pay nothing at all.

As stated in the proposed rule, there is not a unique ICD–9–CM code that identifies surgery performed on the wrong body part or the wrong patient, or the wrong surgery. Code E876.5 (Performance of inappropriate operation) does not describe what specifically was wrong with the surgery, such as whether it was performed on the wrong side, the wrong patient, or if the wrong surgery were performed. In examining Medicare data on the code for performance of an inappropriate operation, we found only one case reported in FY 2006. We agree this is a serious issue that requires close examination and monitoring.

The proposed rule indicated that wrong surgery (right patient, wrong surgery, right surgery, wrong patient, etc.) is not a reasonable and necessary service. Therefore, it is not covered by Medicare and should not be paid. Wrong surgery is not a CC and does not meet the criteria of the statute. As stated above, there are generally recognized guidelines hospitals and physicians must follow to ensure that the correct surgery was performed on the correct patient or correct patient's body part. This event should not occur. If hospitals fail to ensure the correct surgery is performed, there are other provisions in the regulations to address this alarming event. For instance, a hospital must meet the CoPs in order to participate in Medicare. If wrong surgery was performed, the hospital could be out of compliance with the Surgical Services CoP, the Quality Assessment and Performance Improvement CoP, or potentially others. Performance of wrong surgery may suggest a systems failure or systems that do not comply with the CoPs that should be further investigated. We are interested in promoting a culture of safety and are interested in helping hospitals improve their performance. The hospital would have an opportunity to develop and present a plan of correction to avoid termination of its participation in Medicare by addressing the deficiencies that resulted in an incorrect surgery being performed. The final action that would be taken would depend on the individual circumstances and whether the hospital has addressed the problem to reduce the chance of a similar occurrence in the future. In any event, we reiterate that the way for Medicare to address wrong surgery is not through this provision that does not pay extra for preventable hospital complications when we should be paying nothing at all, but instead through Medicare's regulations that ensure that every Medicare provider meets basic quality of care standards.

(m) Falls and Fractures, Dislocations, Intracranial Injury, Crushing Injury, and Burns

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 identify all types of falls. Therefore, in the FY 2008 IPPS proposed rule, 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 CMS DRGs or the 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 did not propose the inclusion of falls as one of our initial hospital-acquired conditions because we could only identify a limited number of these cases, and they were not classified as CCs. However, we welcomed 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.

Comment: Several commenters stated that the category of falls is not appropriate for inclusion as one of the hospital-acquired conditions. Specifically, the commenters noted that it is impossible to prevent all falls, and the definition of what constitutes a ''preventable fall'' is not well-defined. Several commenters strongly recommended the inclusion of falls for the final rule because falls and their resulting injuries are an important public health safety issue. However, these commenters did not give further details or recommendations to CMS regarding how to identify falls and related injuries as a hospital-acquired condition that would be subject to this provision.

Response: With respect to the comment that not all falls are preventable, we reiterate that the statutory provision authorizes the Secretary to select conditions that ''could reasonably have been prevented through the application of evidence based guidelines.'' We believe that injuries that occur in the hospital due to falls are preventable. As discussed earlier, we received a couple of comments urging us to include falls as one of our hospital acquired conditions. We recognize that preventable injuries are an important patient safety issue. Therefore, we considered additional ways to identify patients who had preventable injuries that occurred in the hospital. We examined the use of a combination of External cause of injury codes and the specific injury to identify these cases. We identified five external causes of injury codes that would identify falls in a hospital. These include:

- E884.2 Fall from chair
- E884.3 Fall from wheelchair
- E884.4 Fall from bed
- E884.5 Fall from other furniture
- E884.6 Fall from commode

These codes clearly identify certain types of falls. If coded for an inpatient, they could identify that the fall occurred in the hospital. If these codes appeared

on a claim along with a fracture or trauma code that did not reflect that the condition was present on admission, we could conclude that the injury was a result of a fall in the hospital that should not be counted as an MCC or CC. However, we identified potential problems in using the external cause of injury codes. There is a separate field on the electronic claim to report one external cause of injury code. However, hospitals do not report the POA indicator with this field. Therefore, we will not be able to tell if the external cause of injury code is identifying an event that occurred before or after admission.

Hospitals can also report external cause of injury codes as a secondary diagnosis. If the hospital lists the external cause of injury code among the secondary diagnoses, the hospital would be assigning a Present on Admission indicator to the external cause of injury code. In these cases, we would be able to identify that one of the five types of falls indicated above occurred after admission. We could use this information along with the ICD–9–CM diagnosis code for the specific type of injury, such as a fracture, to not allow the specific injury to count as a MCC or CC, since it would be the result of a preventable injury. In our analysis of the use of an external cause of injury code, we believe this approach is too complicated to identify preventable injuries. Therefore, we focused on simply identifying injuries that should not occur during a hospitalization. If a preventable injury occurs during a hospitalization, it should be included on our list of hospital acquired conditions.

We reviewed diagnosis codes contained in the Injury and Poisoning Chapter of ICD–9–CM and attempted to develop a list of codes that could identify potential adverse events that may or may not have been the result of a fall occurring in the hospital setting. After reviewing each category of diagnosis codes, we identified the following injuries that should not occur during a patient's hospitalization. The generic categories of injuries are as follows:

- Fractures—ICD–9–CM code range 800 through 829
- Dislocations—ICD–9–CM code range 830 through 839
- Intracranial injury—ICD–9–CM code range 850 through 854
- Crushing injury—ICD–9–CM code range 925 through 929
- Burns—ICD–9–CM code range 940 through 949
- Other and unspecified effects of external causes—ICD–9–CM code range 991 through 994

In our view, the above conditions should not occur after admission to the hospital. That is, if the patient is admitted to the hospital without a crushing injury, a burn, fracture, dislocation, among others, we can see no reason why such an event would not be preventable while the patient is in the hospital. None of these injuries should occur after admission. We believe this range of conditions offers a relatively uncomplicated method to determine if an injury or trauma is acquired in the hospital. This range of conditions meets the statutory criteria for being selected when they are MCCs or CCs. First, they are identifiable with ICD–9–CM codes. Second, injuries that occur as a result of a fall in the hospital complicate the care and treatment of the patient. Fractures and dislocations and other injuries are common in the Medicare population. There were more than 175,000 fractures and other traumatic injuries in the above range of codes for FY 2006. Third, hospital acquired injuries included in this range of codes should not occur and are preventable. Although we have not identified specific prevention guidelines for the conditions described by the above range of codes, we believe these types of injuries and trauma should not occur in the hospital, and we look forward to working with CDC and the public in identifying research that has or will occur that will assist hospitals in following the appropriate steps to prevent these conditions from occurring after admission.

We welcome public comments on additions and deletions to this injury list as well as our findings on the use of a combination of external cause of injury codes and injury codes to identify patients that acquired an injury in the hospital due to a fall. We also welcome any additional suggestions to identify cases where preventable injuries, such as falls, occur during hospitalization. We will review all recommendations in the FY 2009 IPPS rule in order to further refine our policy to identify preventable injuries and ensure that Medicare does not pay extra by counting them as MCC or CCs.

(n) Other Conditions Suggested Through Comment: Deep Vein Thrombosis (DVT)/ Pulmonary Embolism (PE)

Comment: A number of commenters encouraged CMS to select Venous Thromboembolism (VTE), which includes both Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE), as a preventable condition. The commenters noted that prophylactic measures exist to avoid these conditions and they are preventable if these steps are followed.

The commenters asserted that this condition meets the DRA criteria requirements for a condition eligible for a payment adjustment in that it involves high cost and high volume (according to the 2006 MedPAR data, DVT resulted in more than 180,000 discharges with a mean standardization cost of $17,410 and PE in more than 100,000 discharges with a mean standardization cost of $20,742), and results in assignment to a higher paying DRG if present as a secondary diagnosis. The commenters also noted that both DVT and PE have ICD–9–CM codes that are on the MCC and CC lists. In addition, this condition can be prevented in accordance with evidence-based guidelines. These commenters cited Geerts, et al., Prevention of Venous Thromboembolism: The Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy, Chest, 126: 338S–400S (2004). The commenters acknowledged DVT and PE are identified by multiple codes, but asserted that administrative issues surrounding the selection of this condition could be resolved. They requested that CMS consider selecting DVT and PE as preventable complications for which hospitals will not receive additional payments.

Response: We appreciate these comments suggesting that we add DVT and PE to our list of conditions that would be subject to the hospital acquired conditions provision. A DVT is a blood clot that forms in a vein, most commonly in the lower extremity. It can arise secondary to a number of clinical circumstances, including prolonged inactivity or bedrest, or from extended periods of time with the lower extremity in a bent position. It can also arise in the setting of a hypercoagulable state such as that which occurs with a number of malignancies, where the blood has an increased propensity to form clots, and it is also more common in patients taking oral contraceptives, particularly in conjunction with regular tobacco use. A PE is a clot that occurs in one of the pulmonary arteries that supplies a portion of the lung, most commonly when part or all of a DVT migrates to the pulmonary vessels from its original location, although it can also occur in the absence of a DVT, and it is a particularly serious event that is often life threatening. We refer readers to the current medical literature to further define DVT and PE.

We agree that there are circumstances where these conditions are preventable,

and where the condition meets the statutory criteria to be selected. These conditions can be identified by unique ICD–9–CM codes. DVT can be identified through codes 453.40 (Venous embolism and thrombosis of unspecified deep vessels of lower extremity), 453.41 (Venous embolism and thrombosis of deep vessels of proximal lower extremity), and 453.42 (Venous embolism and thrombosis of deep vessels of distal lower extremity). All three codes are on the CC list. PE is identified through codes 415.10 (Iatrogenic pulmonary embolism and infarction) and 415.19 (Other pulmonary embolism and infarction). Both of these codes are on the MCC list. The commenters provided Medicare data showing that these conditions are both frequent and high cost in the Medicare population. Finally, the commenters have identified prevention guidelines backed by evidence based medicine to avoid DVTs and PEs. Therefore, at least in some circumstances, these conditions meet the statutory criteria for being selected.

We appreciate the collaborative efforts of other organizations to further define the prevention guidelines for this condition. We recognize that routine admission physical examinations should include efforts to detect a DVT. Although we believe DVTs and PEs may be preventable in certain circumstances (such as when an otherwise healthy patient is having elective surgery on a lower extremity), it is possible that a patient may have a DVT upon admission that goes unidentified, and it is also possible that DVT may occur because of other circumstances, such as an occult malignancy. If a DVT is clinically suspected upon admission to the hospital, the definitive diagnosis of a DVT can be made with a Doppler ultrasound examination or intravenous venogram, or both. We anticipate that it is not feasible to perform these studies on every hospitalized patient. In the case of a patient who is admitted with a clinically unapparent DVT that is not detected, the hospital will have followed all typical patient care protocols yet the DVT went undiagnosed upon admission. It may remain undetected until the patient exhibits symptoms of either the DVT or a PE that is unrelated to the patient's principal diagnosis. In these circumstances, we believe the DVT or PE should continue to be counted as an MCC or CC because, in our view, the condition either was unidentifiable prior to admission or did not likely occur as a result of poor management of the patient while they were in the hospital. We believe it is very important to select DVTs and PEs only when they are preventable through following standard prevention guidelines. We will seek to identify clearly defined instances of preventable DVT and PE that should not occur in the hospital setting which will help to further increase hospital quality of care.

We appreciate suggestions on how to identify DVTs and PEs that are preventable hospital acquired conditions. If we can identify only those circumstances where DVTs and PEs are preventable and meet the statutory criteria for being selected, we likely would make them subject to the provision in the FY 2009 IPPS final rule. We welcome comments on this issue and look forward to working with stakeholders to identify instances of preventable DVTs and PEs prior to implementation of this provision on October 1, 2008.

(o) Other Conditions Suggested Through Public Comment: Legionnaires' Disease

Comment: One commenter suggested that CMS select Legionnaire's disease. The commenter asserted that this condition is high cost/high volume: CDC estimates between 8,000 and 18,000 cases per year. Due to underreporting and underdiagnosis, only 2 to 10 percent of cases are reported. Death occurs in 10 to 15 percent of cases. In addition, the commenter cited established prevention guidelines: CDC prevention guidelines are available and widely distributed. Finally, the commenter stated that Legionnaires' disease is identified by ICD–9–CM code 482.84.

Response: While there may be a discrete ICD–9–CM code to identify Legionnaires' disease, it is not typically a hospital acquired condition. Legionnaires' disease is usually acquired outside of a hospital from a contaminated water supply that may or may not have any relation to a particular institution. Any outbreak of Legionnaires' disease suggests a significant public health emergency that should be addressed by public health resources rather than by a particular Medicare payment policy.

(p) CMS Response to Additional Comments

We welcomed any comments on the clinical aspects of the conditions and on which conditions should be selected for implementation on October 1, 2008. We also solicited comments on any problematic issues for specific conditions that may support not selecting them as one of the initial conditions. We encouraged comments on how some of the administrative problems can be overcome if there is support for a particular condition.

Commenters did not raise any general administrative concerns. Rather, a number of commenters addressed the potential for an appeals process and POA coding issues. We have included the comment and response for each issue below:

- Appeals Process:

Comment: A large number of commenters requested clarification from CMS on how hospitals appeal CMS decisions that a particular patient may fall under the hospital-acquired conditions policy and, therefore, is not eligible for higher payment through assignment to the higher CC/MCC level of the MS-DRG. They asked CMS to provide specific instructions for hospitals to follow for appealing a decision.

Response: We do not believe a separate appeals process is necessary for the payment adjustment for hospital-acquired conditions because existing procedures provide adequate opportunity for review. Under 42 CFR § 412.60(d), a hospital has 60 days after the date of the notice of the initial assignment of a discharge to a DRG to request a review of that assignment. The hospital may submit additional information as a part of its request. A hospital that believes a discharge was assigned to the incorrect DRG as a result of the payment adjustment for hospital-acquired conditions may request review of the DRG assignment by its fiscal intermediary or MAC.

However, we note that section 1886(d)(7)(B) of the Act, as amended by section 5001(c)(2) of the DRA, provides that there shall be no administrative or judicial review of the establishment of DRGs, including the selection and revision of codes under the payment adjustment for hospital acquired conditions. Therefore, although a hospital may request review of a DRG assignment in a particular case, the statute does not provide for review of the codes we select to be subject to the payment adjustment for hospital-acquired conditions.

- POA Coding

Comment: Commenters suggested that all secondary diagnoses coded as present on admission be used to support the development of new complication rate measures and other quality indicators in the future. They suggested that CMS should develop special Grouper logic to exclude similar ICD–9-CM codes. The commenters stated that reducing hospital payments for a condition present upon admission, but not documented, is too punitive.

Many commenters submitted the experiences of two States that already use present-on-admission coding. They believed it takes several years and intense educational efforts to achieve reliable data and therefore there must be a strong clinical training component.

The commenters recommended that CMS implement the collection of the POA indicator but delay the implementation of any conditions that are dependent on its use until physicians and hospitals have an appropriate level of experience.

Response: We refer commenters to the Change Request No. 5499 released on May 11, 2007, for answers to additional questions regarding present-on-admission coding. We remind commenters that the DRG payment adjustment based on the POA indicator is not applicable until October 1, 2008. It is important to note that hospitals will gain experience in reporting POA information during FY 2008 prior to it having a payment impact in FY 2009.

• Prevention Guidelines

Comment: A small number of commenters questioned the feasibility and reliability of current prevention guidelines. The commenters supported CMS' goal of encouraging improvements in health care and reducing the number of preventable infections, but believed that hospitals must be reimbursed appropriately for providing the care patients need. The commenters believed that CMS should be sure that hospitals are not penalized for infections that originated outside the hospital or that are caused by factors beyond the hospital's control.

The commenters suggested that CMS should recognize that, even with the best infection control practices, some infections will occur anyway. They added that reducing payments for all cases in which those infections occur could harm hospitals' ability to purchase and provide advanced drugs and treatment modalities or invest in other infection control technologies.

Response: We address each concern regarding prevention guidelines in the respective response for each condition. We are committed to improving quality and decreasing the number of hospital-acquired conditions. In that goal, we have chosen these specific conditions because they fulfill the criteria outlined in the DRA: the conditions have unique codes that are MCCs or CCs; the conditions are high volume, high cost or both; and the conditions can be reasonably prevented through the application of evidence-based guidelines.

• Academic Centers/Hospitals with high risk patients:

Comment: Commenters representing academic centers and hospitals with high risk patient populations urged CMS to consider excluding patients considered to be high risk such as those that are more susceptible to infections.

Response: As indicated above, we are selecting conditions that are ''reasonably preventable'' through application of evidence-based guidelines and meet the other statutory criteria. In response to comments on each of the conditions considered, we indicated that we are researching whether to establish exceptions to the conditions for specific clinical circumstances where the condition may not be preventable. The determination of whether a patient is ''high risk'' will depend on the specific circumstances of the patient and the condition under consideration. We do not believe it is possible to classify a patient generally as ''high risk'' in all the circumstances where the provision could potentially apply. As we indicated above, we welcome public comments on clinical scenarios where a specific condition may not be reasonably preventable in the hospital and how to identify and distinguish those circumstances from other situations where the condition is preventable.

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 cases that includes a hospital-acquired 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.

To summarize, we appreciate all of the comments on hospital-acquired conditions and look forward to continued input as we plan to implement these hospital-acquired conditions. Below is the list of conditions that we are selecting in this FY 2008 final rule. These conditions will be made subject to the provision beginning on October 1, 2008 (FY 2009).

• Serious Preventable Event—Object Left in Surgery

• Serious Preventable Event—Air Embolism

• Serious Preventable Event—Blood incompatibility

• Catheter-Associated Urinary Tract Infections

• Pressure Ulcers (Decubitus Ulcers)

• Vascular Catheter-Associated Infection

• Surgical Site Infection—Mediastinitis After Coronary Artery Bypass Graft (CABG) Surgery

• Hospital Acquired Injuries—Fractures, Dislocations, Intracranial Injury, Crushing Injury, Burn, and Other Unspecified Effects of External Causes

We will also propose the following conditions for consideration in the FY 2009 IPPS proposed rule. We will work diligently to address issues surrounding these conditions and propose to select these conditions in the FY 2009 IPPS final rule.

• Ventilator Associated Pneumonia (VAP)

• Staphylococcus Aureus Septicemia

• Deep Vein Thrombosis (DVT)/Pulmonary Embolism (PE)

Finally, we list below the set of conditions that signal further analysis for future implementation.

• Methicillin Resistant Staphylococcus Aureus (MRSA)

• Clostridium Difficile-Associated Disease (CDAD)

• Wrong Surgery—Provision not applicable because Medicare should not pay less; it should not pay at all.

TABLE 1.—HOSPITAL-ACQUIRED CONDITIONS
(in rank order)

Condition	Considered in NPRM	Proposed in NPRM	Selected in FY 2008 final rule	May be considered in future rulemaking
1. Serious Preventable Event—Object left in surgery.	Yes	Yes	Yes	N/A.
2. Serious Preventable Event—Air embolism.	Yes	Yes	Yes	N/A.
3. Serious Preventable Event—Blood incompatibility.	Yes	Yes	Yes	N/A.
4. Catheter-Associated Urinary Tract Infections.	Yes	Yes	Yes	N/A.
5. Pressure Ulcers (Decubitus Ulcers).	Yes	Yes	Yes	N/A.
6. Vascular Catheter-Associated Infection.	Yes	No (No FY 2008 code)	Yes (Code Created for FY 2008).	N/A.
7. Surgical Site Infection—Mediastinitis after Coronary Artery Bypass Graft (CABG) surgery.	Yes (All surgical site infections, not just Mediastinitis).	No (No unique codes)	Yes (Comments suggested Mediastinitis which has unique code).	N/A.
8. Falls	Yes	No (Coding not unique)	Yes (Operational difficulties will be overcome by FY 2009).	Expand to all hospital acquired injuries, adverse events.
9. Ventilator Associated Pneumonia (VAP).	Yes	No (Coding not unique)	No (Coding not unique)	Yes—FY 2009 IPPS final rule (Pursuing code with CDC).
10. Staphylococcus Aureus Septicemia.	Yes	Yes	No (Must identify subset where preventable).	Yes—FY 2009 IPPS final rule.
11. Deep Vein Thrombosis (DVT)/Pulmonary Embolism (PE).	No	No	No	Yes—FY 2009 IPPS final rule (Work to identify situations where it should be preventable).
12. Methicillin Resistant Staphylococcus Aureus (MRSA).	Yes	No	No	Yes.
13. Clostridium Difficile—Associated Disease (CDAD).	Yes	No	No	Yes.
Other: Medicare Does not Pay For:				
14. Wrong Surgery	Yes	No	No	Provision not Applicable. Medicare should not pay at all.

G. Changes to Specific DRG Classifications

1. Pre-MDCs: Intestinal Transplantation

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 did 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 section II.C. of the preamble of the FY 2008 IPPS proposed rule, we proposed to split CMS DRG 480 into two severity levels: MS–DRG 005 (Liver Transplant and/or Intestinal Transplant with MCC) and MS–DRG 006 (Liver Transplant and/or Intestinal Transplant without MCC). The following table displays our results:

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 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

be assigned to 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 22.25 days for all cases assigned to proposed MS–DRG 005. For this reason, we proposed to move all intestinal transplant cases to MS–DRG 005. As part of the proposal, we proposed to 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. We also proposed to redefine proposed MS–DRG 006 as ''Liver Transplant without MCC''.

Comment: Two commenters supported the proposed reassignment of intestinal transplants to MS–DRG 005. One commenter stated that CMS should continue to evaluate the frequency of this procedure and reassign it to an appropriate DRG reflective of its high resource utilization.

Response: We appreciate the support of the commenters and agree that when we receive sufficient data, we will again consider a separate intestinal transplant DRG.

Comment: One commenter supported separate MS–DRGs for intestinal transplants and combination liver-intestine transplants. The commenter cited that the data from the Milliman 2005 U.S. Organ and Tissue Transplant Cost Estimates and Discussion Research Report supports separate MS–DRGs. This report provided data for 58 intestine only transplants with estimated first year billed charges of $813,600 and 47 liver-intestine transplants with estimated first year billed charges of $830,200.

Response: The report submitted by the commenter does not indicate whether the patients cited in the study were Medicare. Further, it is not clear whether the identified costs were hospital inpatient only or total. For these reasons, we are not using these data to make an MS–DRG assignment. However, we are open to considering, to the extent feasible, reliable, validated data other than MedPAR data in annually recalibrating and reclassifying the DRGs.

In this final rule with comment period, we are adopting as final our proposal to reassign intestinal transplantation cases to MS–DRG 005. We are also redefining MS–DRG 005 as ''Liver Transplant with MCC or Intestinal Transplant'' and MS–DRG 006 as ''Liver Transplant without CC''.

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

a. Implantable Neurostimulators

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 manufacturers were 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 manufacturers recommended that we:

- Reroute all spinal and peripheral neurostimulator cases into a common set of base DRGs.
- Reclassify ICD–9–CM pain codes 338.0 through 338.4 currently assigned to MDC 23 into MDC 1 when reported as the principal diagnosis.
- Revise surgical CMS DRGs in MDC 1 based on whether the patient received a major device.
- Split the single surgical CMS DRG in MDC 19 (Mental Diseases and Disorders) and MDC 23 into two CMS DRGs: one CMS DRG for minor procedures as defined by CMS DRGs 477 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis) and CMS DRG 468 (Extensive O.R. Procedure Unrelated to Principal Diagnosis) and one CMS DRG for major procedures.
- Create a new CMS DRG in MDC 1 for major devices.

The manufacturers recognized that implementing a re-routing feature in the CMS DRG system would be a major undertaking and, alternatively, suggested reassigning the pain codes to MDC 1 as an interim step. In the FY 2008 IPPS proposed rule, we noted that we agreed with this suggestion. With respect to the suggestion to split the single surgical CMS DRG in MDCs 19 and 23 into two CMS DRGs and create a major device CMS DRG within MDC 1, in the FY 2008 IPPS proposed rule, we encouraged commenters to examine the assignment of neurostimulator cases under the MS–DRGs to determine whether the changes we proposed to adopt to better recognize severity in the CMS DRG system would address these concerns.

The implantation of a neurostimulator requires two types of procedures. First, the surgeons implant leads containing electrodes into the targeted section of the brain, spine, or peripheral nervous system. Second, a neurostimulator pulse generator is implanted into the pectoral region and extensions from the neurostimulator pulse generator are tunneled under the skin and connected with the proximal ends of the leads. Hospitals stage the two procedures required for a full system neurostimulator implant.

There are separate ICD–9–CM procedure codes that identify the implant of the leads and the insertion of the pulse generator. The three codes for the leads insertion are: 02.93 (Implantation or replacement of intracranial neurostimulator lead(s)); 03.93 (Implantation or replacement of spinal neurostimulator lead(s)); and code 04.92 (Implantation or replacement of peripheral neurostimulator lead(s). The five codes for the insertion of the pulse generator are: 86.94 (Insertion or replacement of single array neurostimulator pulse generator, not specified as rechargeable); 86.95 (Insertion or replacement of dual array neurostimulator pulse generator, not specified as rechargeable); 86.96 (Insertion or replacement of other neurostimulator pulse generator); 86.97 (Insertion or replacement of single array rechargeable neurostimulator pulse generator); and 86.98 (Insertion or replacement of dual array rechargeable neurostimulator pulse generator).

The patient's principal diagnosis determines the MDC assignment. Implant of a cranial, spinal or peripheral neurostimulator will result in assignment of the case to a surgical DRG within that MDC. Although the manufacturers are correct that neurostimulator cases can potentially be assigned to many different CMS DRGs