our initiative to update and revise the hospital cost report. Under an effort initiated by CMS to update the Medicare hospital cost report to eliminate outdated requirements in conjunction with the Paperwork Reduction Act, we plan to propose the actual changes to the cost reporting form, the attending cost reporting software, and the cost report instructions in Chapter 36 of the Medicare Provider Reimbursement Manual (PRM), Part II. We expect the proposed revision to the Medicare hospital cost report to be issued after publication of this IPPS proposed rule. If we were to adopt as final our proposal to create one cost center for Medical Supplies Charged to Patients and one cost center for Implantable Devices Charged to Patients in the FY 2009 IPPS final rule, the cost report forms and instructions would reflect those changes. We expect the revised cost report would be available for hospitals to use when submitting cost reports during FY 2009 (that is, for cost reporting periods beginning on or after October 1, 2008). Because there is approximately a 3-year lag between the availability of cost report data for IPPS and OPPS ratesetting purposes and a given fiscal year, we may be able to derive two distinct CCRs, one for medical supplies and one for devices, for use in calculating the FY 2012 IPPS relative weights and the CY 2012 OPPS relative weights.

4. Revenue Codes Used in the MedPAR File

An important first step in RTI's study (as explained in its draft interim March 2007 report) was determining how well the cost report charges used to compute CCRs matched to the charges in the MedPAR file. This match (or lack thereof) directly affects the accuracy of the DRG cost estimates because MedPAR charges are multiplied by CCRs to estimate cost. RTI found inconsistent reporting between the cost reports and the claims data for charges in several ancillary departments (Medical Supplies, Operating Room, Cardiology, and Radiology). For example, the data suggested that some hospitals often include costs and charges for devices and other medical supplies within the Medicare cost report cost centers for Operating Room, Radiology, or Cardiology, while other hospitals include them in the Medical Supplies Charged to Patients cost center. While the educational initiative undertaken by the national hospital associations is encouraging hospitals to consistently report costs and charges for devices and other medical supplies only in the Medical Supplies Charged to Patients cost center, equal attention must be paid to the way in which charges are grouped by hospitals in the MedPAR file. Several commenters on the FY 2008 IPPS proposed rule supported RTI's recommendation of including additional fields in the MedPAR file to disaggregate certain cost centers. One commenter stated that the assignment of revenue codes and charges to revenue centers in the MedPAR file should be reviewed and changed to better reflect hospital accounting practices as reflected on the cost report (72 FR 47198).

In an effort to improve the match between the costs and charges included on the cost report and the charges in the MedPAR file, we are recommending that certain revenue codes be used for items reported in the proposed Medical Supplies Charged to Patients cost center and the proposed Implantable Devices Charged to Patients cost center, respectively. Specifically, under the proposal to create a cost center for implantable devices that remain in the patient upon discharge, revenue codes 0275 (Pacemaker), 0276 (Intraocular Lens), and 0278 (Other Implants) would correspond to implantable devices reported in the proposed Implantable Devices Charged to Patients cost center. Items for which a hospital may have previously used revenue code 0270 (General Classification), but actually meet the proposed definition of an implantable device that remains in the patient upon discharge should instead be billed with the 0278 revenue code. Conversely, relatively inexpensive items and supplies that are not implantable and do not remain in the patient at discharge would be reported in the proposed Medical Supplies Charged to Patients cost center on the cost report, and should be billed with revenue codes 0271 (nonsterile supply), 0272 (sterile supply), and 0273 (take-home supplies), as appropriate. Revenue code 0274 (Prosthetic/Orthotic devices) and revenue code 0277 (Oxygen—Take Home) should be associated with the costs reported on lines 66 and 67 for DME—Rented and DME—Sold on the cost report. Charges associated with supplies used incident to radiology or to other diagnostic services (revenue codes 0621 and 0622 respectively) should match those items used incident to those services on the Medical Supplies Charged to Patients cost center of the cost report, because, under this proposal, supplies furnished incident to a service would be reported in the Medical Supplies Charged to Patients cost center (see item b. listed above, in the proposed definition of a device). A revenue code of 0623 for surgical dressings would similarly be associated with the costs and charges of items reported in the proposed Medical Supplies Charged to Patients cost center, while a revenue code of 0624 for FDA investigational device, if that device does *not* remain in the patient upon discharge, could be associated with items reported on the Medical Supplies Charged to Patients cost center as well.

In general, if an item is reported as an implantable device on the cost report, the associated charges should be recorded in the MedPAR file with either revenue codes 0275 (Pacemaker), 0276 (Intraocular Lens), or 0278 (Other Implants). Likewise, items reported as Medical Supplies should receive an appropriate revenue code indicative of supplies. We understand that many of these revenue codes have been in existence for many years and have been added for purposes unrelated to the goal of refining the calculation of cost-based weights. Accordingly, we acknowledge that additional instructions relating to the appropriate use of these revenue codes may need to be issued. In addition, CMS or the hospital associations may need to request new revenue codes from the National Uniform Billing Committee (NUBC). In either case, we do not believe either should delay use of the new Medical Supplies and Implantable Devices CCRs in setting payment rates. However, in light of our proposal to create two separate cost centers for Medical Supplies Charged to Patients and Implantable Devices Charged to Patients, respectively, we are soliciting comments on how the existing revenue codes or additional revenue codes could best be used in conjunction with the revised cost centers on the cost report.

F. Preventable Hospital-Acquired Conditions (HACs), Including Infections

1. General

In its landmark 1999 report ''To Err is Human: Building a Safer Health System,'' the Institute of Medicine found that medical errors, particularly hospital-acquired conditions (HACs) caused by medical errors, are a leading cause of morbidity and mortality in the United States. The report noted that the number of Americans who die each year as a result of medical errors that occur in hospitals may be as high as 98,000. The cost burden of HACs is also high. Total national costs of these errors due to lost productivity, disability, and health care costs were estimated at $17

billion to $29 billion.[2] In 2000, the CDC estimated that hospital-acquired infections added nearly $5 billion to U.S. health care costs every year.[3] A 2007 study found that, in 2002, 1.7 million hospital-acquired infections were associated with 99,000 deaths[4] Research has also shown that hospitals are not following recommended guidelines to avoid preventable hospital-acquired infections. A 2007 Leapfrog Group survey of 1,256 hospitals found that 87 percent of those hospitals do not follow recommendations to prevent many of the most common hospital-acquired infections.[5]

As one approach to combating HACs, including infections, in 2005 Congress authorized CMS to adjust for Medicare IPPS hospital payments to encourage the prevention of these conditions. The preventable HAC provision at section 1886(d)(4)(D) of the Act is part of an array of Medicare value-based purchasing (VBP) tools that CMS is using to promote increased quality and efficiency of care. Those tools include measuring performance, using payment incentives, publicly reporting performance results, applying national and local coverage policy decisions, enforcing conditions of participation, and providing direct support for providers through Quality Improvement Organization (QIO) activities. CMS' application of VBP tools through various initiatives, such as this HAC provision, is transforming Medicare from a passive payer to an active purchaser of higher value health care services. We are applying these strategies for inpatient hospital care and across the continuum of care for Medicare beneficiaries.

The President's FY 2009 Budget outlines another approach for addressing serious preventable adverse events (''never events''), including HACs. The President's Budget proposal would: (1) Prohibit hospitals from billing the Medicare program for ''never events'' and prohibit Medicare payment for these events; and (2) require hospitals to report occurrence of these events or receive a reduced annual payment update.

Medicare's IPPS encourages hospitals to treat patients efficiently. Hospitals receive the same DRG payment for stays that vary in length and in the services provided, which gives hospitals an incentive to avoid unnecessary costs in the delivery of care. In many cases, complications acquired in the hospital do not generate higher payments than the hospital would otherwise receive for uncomplicated cases paid under the same DRG. To this extent, the IPPS encourages hospitals to avoid complications. However, complications, such as infections, acquired in the hospital can generate higher Medicare payments in two ways. First, the treatment of complications can increase the cost of a hospital stay enough to generate an outlier payment. However, the outlier payment methodology requires that a hospital experience a large loss on an outlier case, which serves as an incentive for hospitals to prevent outliers. Second, under the MS–DRGs that took effect in FY 2008, there are currently 258 sets of MS–DRGs that are split into 2 or 3 subgroups based on the presence or absence of a CC or an MCC. If a condition acquired during a hospital stay is one of the conditions on the CC or MCC list, the hospital currently receives a higher payment under the MS–DRGs (prior to the October 1, 2008 effective date of the HAC payment provision). (We refer readers to section II.D. of the FY 2008 IPPS final rule with comment period for a discussion of DRG reforms (72 FR 47141).) The following is an example of how an MS–DRG may be paid.

Service: MS–DRG Assignment* (Examples below with CC/MCC indicate a single secondary diagnosis only)	Present on admission (status of secondary diagnosis)	Average payment (based on 50th percentile)
Principal Diagnosis		$5,347.98
• Intracranial hemorrhage or cerebral infarction (stroke) without CC/MCC—MS–DRG 066.		
Principal Diagnosis	Y	6,177.43
• Intracranial hemorrhage or cerebral infarction (stroke) with CC—MS–DRG 065.		
Example Secondary Diagnosis		
• Dislocation of patella-open due to a fall (code 836.4 (CC)).		
Principal Diagnosis	N	5,347.98
• Intracranial hemorrhage or cerebral infarction (stroke) with CC—MS–DRG 065.		
Example Secondary Diagnosis		
• Dislocation of patella-open due to a fall (code 836.4 (CC)).		
Principal Diagnosis	Y	8,030.28
• Intracranial hemorrhage or cerebral infarction (stroke) with MCC—MS–DRG 064.		
Example Secondary Diagnosis		
• Stage III pressure ulcer (code 707.23 (MCC)).		
Principal Diagnosis	N	5,347.98
• Intracranial hemorrhage or cerebral infarction (stroke) with MCC—MS–DRG 064.		
Example Secondary Diagnosis		
• Stage III pressure ulcer (code 707.23 (MCC)).		

* Operating amounts for a hospital whose wage index is equal to the national average.

2. Statutory Authority

Section 1886(d)(4)(D) of the Act required the Secretary to select at least two conditions by October 1, 2007, that are: (a) High cost, high volume, or both; (b) assigned to a higher paying DRG when present as a secondary diagnosis; and (c) could reasonably have been prevented through the application of evidence-based guidelines. Beginning October 1, 2008, Medicare can no longer assign an inpatient hospital discharge to

[2] Institute of Medicine: To Err Is Human: Building a Safer Health System, November 1999. Available at: *http://www.iom.edu/Object.File/Master/4/117/ToErr–8pager.pdf.*

[3] Centers for Disease Control and Prevention: Press Release, March 2000. Available at: *http://www.cdc.gov/od/oc/media/pressrel/r2k0306b.htm.*

[4] Klevens et al. Estimating Health Care-Associated Infections and Deaths in U.S. Hospitals, 2002. *Public Health Reports.* March–April 2007. Volume 122.

[5] 2007 Leapfrog Group Hospital Survey. The Leapfrog Group 2007. Available at: *http://www.leapfroggroup.org/media/file/Leapfrog_hospital_acquired_infections_release.pdf*

a higher paying MS–DRG if a selected HAC was not present on admission. That is, the case will be paid as though the secondary diagnosis was not present. (Medicare will continue to assign a discharge to a higher paying MS–DRG if the selected condition was present on admission.) Section 1886(d)(4)(D) of the Act provides that the list of conditions can be revised from time to time, as long as the list contains at least two conditions. Beginning October 1, 2007, we required hospitals to begin submitting information on Medicare claims specifying whether diagnoses were present on admission (POA).

The POA indicator reporting requirement and the HACs payment provision apply to IPPS hospitals only. At this time, non-IPPS hospitals such as CAHs, LTCHs, IRFs, and hospitals in Maryland operating under waivers, among others, are exempt from POA reporting and the HAC payment provision. Throughout this section, ''hospital'' refers to IPPS hospitals.

3. Public Input

In the FY 2007 IPPS proposed rule (71 FR 24100), we sought public input regarding conditions with evidence-based prevention guidelines that should be selected in implementing section 1886(d)(4)(D) of the Act. The public comments 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. In the FY 2008 IPPS final rule with comment period (72 FR 47200 through 47218), we summarized the public comments we received on the FY 2008 IPPS proposed rule, presented our responses, selected eight conditions to which the HAC provision will initially apply, and noted that we would be seeking comments on additional HAC candidates in this proposed rule.

4. Collaborative Process

CMS experts worked with public health and infectious disease professionals from the CDC to identify the candidate preventable HACs. CMS and CDC staff also collaborated on the process for hospitals to submit a POA indicator for each diagnosis listed on IPPS hospital Medicare claims.

On December 17, 2007, CMS and CDC hosted a jointly sponsored HAC and POA Listening Session to receive input from interested organizations and individuals. The agenda, presentations, audio file, and written transcript of the listening session are available on the Web site at: *http://www.cms.hhs.gov/HospitalAcqCond/07_EducationalResources.asp*. CMS and CDC also received informal comments during the listening session and subsequently received numerous written comments.

5. Selection Criteria for HACs

CMS and CDC staff evaluated each candidate condition against the criteria established by section 1886(d)(4)(D)(iv) of the Act.

- Cost or Volume—Medicare data [6] must support that the selected conditions are high cost, high volume, or both. At this point, there are no Medicare claims data indicating which secondary diagnoses were POA because POA indicator reporting began only recently; therefore, the currently available data for candidate conditions includes all secondary diagnoses.

[6] For this FY 2009 IPPS proposed rule, the DRG analysis is based on data from the September 2007 update of the FY 2007 MedPAR file, which contains hospital bills received through September 30, 2007, for discharges through September 30, 2007.

- Complicating Condition (CC) or Major Complicating Condition (MCC)—Selected conditions must be represented by ICD–9-CM diagnosis codes that clearly identify the condition, are designated as a CC or an MCC, and result in the assignment of the case to an MS-DRG that has a higher payment when the code is reported as a secondary diagnosis. That is, selected conditions must be a CC or an MCC that would, in the absence of this provision, result in assignment to a higher paying MS-DRG.

- Evidence-Based Guidelines—Selected conditions must be reasonably preventable through the application of evidence-based guidelines. By reviewing guidelines from professional organizations, academic institutions, and entities such as the Healthcare Infection Control Practices Advisory Committee (HICPAC), we evaluated whether guidelines are available that hospitals should follow to prevent the condition from occurring in the hospital.

- Reasonably Preventable—Selected conditions must be reasonably preventable through the application of evidence-based guidelines.

6. HACs Selected in FY 2008 and Proposed Changes to Certain Codes

The HACs that were selected for the HAC payment provision through the FY 2008 IPPS final rule with comment period are listed below. The payment provision for these selected HACs will take effect on October 1, 2008. We refer readers to section II.F.6. of the FY 2008 IPPS final rule with comment period (72 FR 47202 through 47218) for a detailed analysis supporting the selection of each of these HACs.

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Selected HAC	Medicare Data (FY 2007)	CC/MCC (ICD-9-CM Codes)	Selected Evidence-Based Guidelines
Foreign Object Retained After Surgery	• 750 cases* • $63,631/hospital stay**	998.4 (CC) 998.7 (CC)	NQF Serious Reportable Adverse Event NQF's Safe Practices for Better Healthcare available at the Web site: http://www.ahrq.gov/qual/nqfpract.htm
Air Embolism	• 57 cases • $71,636/hospital stay	999.1 (MCC)	NQF Serious Reportable Adverse Event NQF's Safe Practices for Better Healthcare available at the Web site: http://www.ahrq.gov/qual/nqfpract.htm
Blood Incompatibility	• 24 cases • $50,455/hospital stay	999.6 (CC)	NQF Serious Reportable Adverse Event NQF's Safe Practices for Better Healthcare available at the Web site: http://www.ahrq.gov/qual/nqfpract.htm
Stage III & IV Pressure Ulcers	• 257,412 cases*** • $43,180/hospital stay	New codes (to replace 707.00–707.09) 707.23 (MCC) 707.24 (MCC) All other pressure ulcer codes will not be a CC.	NQF Serious Reportable Adverse Event Available at the Web site: http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat2.chapter.4409
Falls and Trauma: - Fractures - Dislocations - Intracranial Injuries - Crushing Injuries - Burns	• 193,566 cases**** • $33,894/hospital stay	Codes within the these ranges on the CC/MCC list: 800-829 830-839 850-854 925-929 940-949 991-994	NQF Serious Reportable Adverse Events address falls, electric shock, and burns. NQF's Safe Practices for Better Healthcare available at the Web site: http://www.ahrq.gov/qual/nqfpract.htm

Selected HAC	Medicare Data (FY 2007)	CC/MCC (ICD-9-CM Codes)	Selected Evidence-Based Guidelines
Catheter-Associated Urinary Tract Infection (UTI)	• 12,185 cases • $44,043/hospital stay	996.64 (CC) Also excludes the following from acting as a CC/MCC: 112.2 (CC) 590.10 (CC) 590.11 (MCC) 590.2 (MCC) 590.3 (CC) 590.80 (CC) 590.81 (CC) 595.0 (CC) 597.0 (CC) 599.0 (CC)	Available at the Web site: http://www.cdc.gov/ncidod/dhqp/gl_catheter_assoc.html
Vascular Catheter-Associated Infection	• 29,536 cases • $103,027/hospital stay	999.31 (CC)	Available at the Web site: http://www.cdc.gov/ncidod/dhqp/gl_intravascular.html
Surgical Site Infection-Mediastinitis after Coronary Artery Bypass Graft (CABG)	• 69 cases • $299,237/hospital stay	519.2 (MCC) And one of the following procedure codes: 36.10–36.19	Available at the Web site: http://www.cdc.gov/ncidod/dhqp/gl_surgicalsite.html

*A case represents a patient discharge identified from the MedPAR database that met the associated HAC diagnosis/procedure criteria (a secondary diagnosis on the HAC list and, where appropriate, a procedure code described in conjunction with a specific HAC).

**Standardized charge is the total charge for a patient discharge record based on the CMS standardization file. The average standardized charge for the HAC is the average charge for all patient discharge records that met the associated HAC criteria.

***The number of cases of pressure ulcers reflects CC/MCC assignments for codes 707.00 through 707.07 and 707.09, which are currently being reported. New proposed MCC codes 707.23 and 707.24 will be implemented on October 1, 2008.

****Note: The number of cases for the falls and trauma HAC is significantly higher for this FY 2009 IPPS proposed rule than for the FY 2008 IPPS final rule with comment period. The FY 2008 IPPS final rule with comment period only included cases in which patients fell out of bed. This FY 2009 IPPS proposed rule includes all cases within the CC/MCC code range listed.

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We are seeking public comments on the following refinements to two of the previously selected HACs:

a. Foreign Object Retained After Surgery: Proposed Inclusion of ICD–9–CM Code 998.7 (CC)

In the FY 2008 IPPS final rule with comment period (72 FR 47206), we indicated that a foreign body accidentally left in the patient during a procedure (ICD–9–CM code 998.4) was one of the conditions selected. It has come to our attention that ICD–9–CM diagnosis code 998.7 (Acute reaction to foreign substance accidentally left during a procedure) should also be included. ICD–9–CM code 998.7 describes instances in which a patient developed an acute reaction due to a retained foreign substance. Therefore, we are proposing to make this code subject to the HAC payment provision.

b. Pressure Ulcers: Proposed Changes in Code Assignments

As discussed in the FY 2008 IPPS final rule with comment period (72 FR 47205–47206), we referred the need for more detailed ICD–9–CM pressure ulcer codes to the CDC. The topic of expanding pressure ulcer codes to capture the stage of the ulcer was addressed at the September 27–28, 2007, meeting of the ICD–9–CM Coordination and Maintenance Committee. A summary report of this meeting is available on the Web site at: *http://www.cdc.gov/nchs/about/otheract/icd9/maint/maint.htm.*

Numerous wound care professionals supported modifying the pressure ulcer codes to capture staging information. The stage of the pressure ulcer is a powerful predictor of severity and resource utilization. At its September 27–28, 2007 meeting, the ICD–9–CM Coordination and Maintenance Committee discussed the creation of pressure ulcer codes to capture this information. The new codes, along with their proposed CC/MCC classifications, are shown in Table 6A of the Addendum to this proposed rule. The new codes are as follows:

- 707.20 (Pressure ulcer, unspecified stage).
- 707.21 (Pressure ulcer stage I).
- 707.22 (Pressure ulcer stage II).
- 707.23 (Pressure ulcer stage III).
- 707.24 (Pressure ulcer stage IV).

While the code titles are final, we are soliciting comment on the proposed MS–DRG classifications of these codes, as indicated in Table 6A of the Addendum to this proposed rule. We are proposing to remove the CC/MCC classifications from the current pressure ulcer codes that show the site of the ulcer (ICD–9–CM codes 707.00 through 707.09). Therefore, the following codes would no longer be a CC:

- 707.00 (Decubitus ulcer, unspecified site).
- 707.01 (Decubitus ulcer, elbow).
- 707.09 (Decubitus ulcer, other site).

The following codes would no longer be an MCC:

- 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).

We are proposing to instead assign the CC/MCC classifications to the stage of the pressure ulcer as shown in Table 6A of the Addendum to this proposed rule. We are proposing to classify ICD–9–CM codes 707.23 and 707.24 as MCCs. We are proposing to classify codes 707.20, 707.21, and 707.22 as non-CCs.

Therefore, we are proposing that, beginning October 1, 2008, the codes used to make MS–DRG adjustments for pressure ulcers under the HAC provision would include the proposed MCC codes 707.23 and 707.24.

7. HACs Under Consideration as Additional Candidates

CMS and CDC have diligently worked together and with other stakeholders to identify additional HACs that might appropriately be subject to the HAC payment provision. If the additional candidate HACs are selected in the FY 2009 IPPS final rule, the payment provision will take effect for these candidate HACS on October 1, 2008. The statutory criteria for each HAC candidate are presented in tabular format. Each table contains the following:

- HAC Candidate—We are seeking public comment on all HAC candidates.
- Medicare Data—We are seeking public comment on the statutory criterion of high cost, high volume, or both as it applies to the HAC candidate.
- CC/MCC—We are seeking public comment on the statutory criterion that an ICD–9–CM diagnosis code(s) clearly identifies the HAC candidate.
- Selected Evidence-Based Guidelines—We are seeking public comment on the degree to which the HAC candidate is reasonably preventable through the application of the identified evidence-based guidelines.

a. Surgical Site Infections Following Elective Surgeries

HAC Candidate	Medicare Data (FY 2007)	CC/MCC (ICD-9-CM Codes)	Selected Evidence-Based Guidelines
Surgical Site Infections Following Elective Procedures: - Total Knee Replacement - Laparoscopic Gastric Bypass and Gastroenterostomy - Ligation and Stripping of Varicose Veins	Total Knee Replacement • 539 cases • $63,135/hospital stay Laparoscopic Gastric Bypass and Gastroenterostomy • 208 cases • $180,142/hospital stay Ligation and Stripping of Varicose Veins • 3 cases • $66,355/hospital stay	Total Knee Replacement (81.54): 996.66 (CC) and 998.59 (CC) Laparoscopic Gastric Bypass (44.38) and Gastroenterostomy (44.39): 998.59 (CC) Varicose Veins (38.59): 998.59 (CC)	Available at theWeb site: http://www.cdc.gov/ncidod/dhqp/gl_surgicalsite.html Available at the Web site: http://www.cdc.gov/ncidod/dhqp/gl_isolation.html

In the FY 2008 IPPS final rule with comment period (72 FR 47213), surgical site infections were identified as a broad category for consideration, and we selected mediastinitis after coronary artery bypass graft (CABG) as one of the initial eight HACs for implementation. We are now considering the addition of other surgical site infections, particularly those following elective procedures. In most cases, patients selected as candidates for elective surgeries should have a relatively low-risk profile for surgical site infections.

The following elective surgical procedures are under consideration:

- Total Knee Replacement (81.54): ICD–9–CM codes 996.66 (CC) and 998.59 (CC)
- Laparoscopic Gastric Bypass (44.38) and Laparoscopic Gastroenterostomy (44.39): ICD–9–CM code 998.59 (CC)
- Ligation and Stripping of Varicose Veins (38.50 through 38.53, 38.55, 38.57, and 38.59): ICD–9–CM code 998.59 (CC)

Evidence-based guidelines for preventing surgical site infections emphasize the importance of appropriately using prophylactic antibiotics, using clippers rather than razors for hair removal and tightly controlling postoperative glucose.

While we are seeking public comments on the applicability of each of the statutory criteria to surgical site infections following elective procedures, we are particularly interested in receiving comments on the degree of preventability of surgical site infections following elective procedures generally, as well as specifically for those listed above. We also are seeking public comments on additional elective surgical procedures that would qualify for the HAC provision by meeting all of the statutory criteria. Based on the public comments we receive, we may select some combination of the four procedures presented here along with additional conditions that qualify and are supported by the comments.

b. Legionnaires' Disease

HAC Candidate	Medicare Data (FY 2007)	CC/MCC (ICD-9-CM Code)	Selected Evidence-Based Guidelines
Legionnaires' Disease	• 351 cases • $86,014/hospital stay	482.84	Available at the Web site: http://www.cdc.gov/ncidod/dbmd/diseaseinfo/legionellosis_g.htm Available at the Web site: http://www.legionella.org/

We discussed Legionnaires' Disease in the FY 2008 IPPS final rule with comment period (72 FR 47216). Legionnaires' Disease is a type of pneumonia caused by the bacterium *Legionella pneumophila*. It is contracted

by inhaling contaminated water vapor or droplets. It is not spread person to person. Individuals at risk include those who are elderly, immunocompromised, smokers, or persons with underlying lung disease. The bacterium thrives in warm aquatic environments and infections have been linked to large industrial water systems, including hospital water systems such as air conditioning cooling towers and potable water plumbing systems. Prevention depends primarily on regular monitoring and decontamination of these water systems. While we are seeking public comments regarding the applicability of each of the statutory criteria to Legionnaires' Disease, we are particularly interested in receiving comments on the degree of preventability of Legionnaires' Disease through the application of hospital water system maintenance guidelines.

Legionnaires' Disease is typically acquired outside of the hospital setting and may be difficult to diagnose as present on admission. We are seeking comments on the degree to which hospital-acquired Legionnaires' Disease can be distinguished from community-acquired cases.

We also are seeking public comments on additional water-borne pathogens that would qualify for the HAC provision by meeting the statutory criteria. Based on the public comments we receive, we may finalize some combination of Legionnaires' Disease and additional conditions that qualify and are supported by the public comments.

c. Glycemic Control

HAC Candidate	Medicare Data (FY 2007)	CC/MCC (ICD-9-CM Code)	Selected Evidence-Based Guidelines
Glycemic Control: - Diabetic Ketoacidosis - Nonketotic Hyperosmolar Coma - Diabetic coma - Hypoglycemic Coma	Diabetic Ketoacidosis • 11,469 cases • $42,974/hospital stay Nonketotic Hyperosmolar Coma • 3,248 cases • $35,215/hospital stay Diabetic Coma • 1,131 cases • $45,989/hospital stay Hypoglycemic Coma • 212 cases • $36,581/hospital stay	Diabetic Ketoacidosis: 250.10 – 250.13 (CC) Nonketotic Hyperosmolar Coma: 250.20 – 250.23 (CC) Diabetic coma: 250.30 - 250.33 (CC) Hypoglycemic Coma: 251.0 (CC)	NQF Serious Reportable Adverse Events addresses hypoglycemia. Available at the Web site: http://www.diabetes.org/uedocuments/InpatientDMGlycemicControlPositionStmt02.01.06.REV.pdf

During the December 17, 2007 HAC and POA Listening Session, one of the commenters suggested that we explore hyperglycemia and hypoglycemia as HACs for selection. NQF's list of Serious Reportable Adverse Events includes death or serious disability associated with hypoglycemia that occurs during hospitalization.

Hyperglycemia and hypoglycemia are extremely common laboratory findings in hospitalized patients and can be complicating features of underlying diseases and some therapies. However, we believe that extreme forms of poor glycemic control should not occur while under medical care in the hospital setting. Thus, we are considering whether the following forms of extreme glucose derangement should be subject to the HAC payment provision:

- Diabetic Ketoacidosis: ICD–9–CM codes 250.10–250.13 (CC)
- Nonketotic Hyperosmolar Coma: ICD–9–CM code 251.0 (CC)
- Diabetic Coma: ICD–9–CM codes 250.30–250.33 (CC)
- Hypoglycemic Coma: ICD–9–CM codes 250.30–251.0 (CC)

While we are seeking public comments regarding the applicability of each of the statutory criteria to these extreme aberrations in glycemic control, we are particularly interested in receiving comments on the degree to which these extreme aberrations in glycemic control are reasonably preventable, in the hospital setting, through the application of evidence-based guidelines. Based on the public comments we receive, we may select some combination of these glycemic control-related conditions as HACs.

d. Iatrogenic Pneumothorax

HAC Candidate	Medicare Data (FY 2007)	CC/MCC (ICD-9-CM Code)	Selected Evidence-Based Guidelines
Iatrogenic Pneumothorax	• 22,665 cases • $75,089/hospital stay	512.1 (CC)	Available at the Web site: http://www.ncbi.nlm.nih.gov/pubmed/1485006

Iatrogenic pneumothorax refers to the accidental introduction of air into the pleural space, which is the space between the lung and the chest wall. When air is introduced into this space it partially or completely collapses the lung. Iatrogenic pneumothorax can occur during any procedure where there is the possibility of air entering pleural space, including needle biopsy of the lung, thoracentesis, central venous catheter placement, pleural biopsy, tracheostomy, and liver biopsy. Iatrogenic pneumothorax can occur secondary to positive pressure mechanical ventilation when an air sac in the lung ruptures allowing air into the pleural space.

While we are seeking public comments on the applicability of each of the statutory criteria to iatrogenic pneumothorax, we are particularly interested in receiving comments on the degree to which iatrogenic pneumothorax is reasonably preventable through the application of evidence-based guidelines. Based on the public comments we receive, we may select iatrogenic pneumothorax as an HAC.

e. Delirium

HAC Candidate	Medicare Data (FY 2007)	CC/MCC (ICD-9-CM Code)	Selected Evidence-Based Guidelines
Delirium	• 480 cases • $23,290/hospital stay	293.1 (CC)	Available on the Web site: http://www.ahrq.gov/clinic/ptsafety/chap28.htm

Delirium is a relatively abrupt deterioration in a patient's ability to sustain attention, learn, or reason. Delirium is strongly associated with aging and treatment of illnesses that are associated with hospitalizations. Delirium affects nearly half of hospital patient days for individuals age 65 and older, and approximately three-quarters of elderly individuals in intensive care units have delirium. About 14 to 24 percent of hospitalized elderly individuals have delirium at the time of admission. Having delirium is a very serious risk factor, with 1-year mortality of 35 to 40 percent, a rate as high as those associated with heart attacks and sepsis. The adverse effects of delirium routinely last for months. Delirium is a clinical diagnosis, commonly assisted by screening tests such as the Confusion Assessment Method.

Well-established practices, such as reducing certain medications, reorienting the patient, assuring sensory input and sleep, and avoiding malnutrition and dehydration, prevent 30 to 40 percent of the possible cases. While we are seeking public comments on the applicability of each of the statutory criteria to delirium, we are particularly interested in receiving comments on the degree to which delirium is reasonably preventable through the application of evidence-based guidelines. Based upon the public comments we receive, we may select delirium as an HAC.

f. Ventilator-Associated Pneumonia (VAP)

HAC Candidate	Medicare Data (FY 2007)	CC/MCC (ICD-9-CM Code)	Selected Evidence-Based Guidelines
Ventilator-Associated Pneumonia (VAP)	• 30,867 cases* • $135,795/hospital stay	The new code for VAP is 997.31. To identify cases in current Medicare data, use a ventilator code (96.70 – 96.72), plus one of the following: 073.0 (MCC) 112.4 (MCC) 136.3 (MCC) 480.0-480.4 (MCCs) 480.8-480.9 (MCCs) 481 (MCC) 482.0-482.2 (MCC) 482.39-482.41 (MCCs) 482.49 (MCC) 482.81-482.84 (MCCs) 482.89 (MCC) 482.9 (MCC) 483.0 (MCC)	Available on the Web site: http://www.rcjournal.com/cpgs/09.03.0869.html

*Note: The number of cases for VAP is significantly lower for this FY 2009 IPPS proposed rule than that shown in the FY 2008 IPPS final rule with comment period. The FY 2008 IPPS final rule with comment period included all pneumonia cases. This FY 2009 IPPS proposed rule includes only cases with a diagnosis of VAP and where a ventilator code was also included.

We discussed ventilator-associated pneumonia (VAP) in the FY 2008 IPPS final rule with comment period (72 FR 47209–47210). VAP is a serious hospital-acquired infection associated with high mortality, significantly increased hospital length of stay, and high cost. It is typically caused by the aspiration of contaminated gastric and/or oropharyngeal secretions. The presence of an endotracheal tube facilitates both the contamination of secretions as well as aspiration.

During the past year, the ICD–9–CM Coordination and Maintenance Committee discussed the creation of a new ICD–9–CM code 997.31 to identify VAP. This new code is shown in Table 6A of the Addendum to this proposed rule. The lack of a specific code was one of the barriers to including VAP as an HAC that we discussed in the FY 2008 IPPS final rule with comment period. We also discussed the degree to which VAP may be reasonably preventable through the application of evidence-based guidelines. Specifically, the FY 2008 IPPS final rule with comment period referenced the American Association for Respiratory Care's Clinical Practice Guidelines at the Web site: *http://www.rcjournal.com/cpgs/09.03.0869.html.*

To further investigate the extent to which VAP is reasonably preventable, we reviewed published clinical research. The literature, including recommendations by CDC and the HICPAC, from 2003 shows numerous prevention guidelines that can significantly reduce the incidence of VAP in the hospital setting. These guidelines include interventions such as educating staff, hand washing, using gowns and gloves, properly positioning the patient, elevating the head of the bed, changing ventilator tubing, sterilizing reusable equipment, applying chlorhexadine solution for oral decontamination, monitoring sedation daily, administering stress ulcer prophylaxis, and administering pneumococcal vaccinations. Further review of the literature, specifically regarding the proportion of VAP cases that might be preventable, revealed two large-scale analyses that were completed recently. One study concluded that an estimated 40 percent of VAP cases are preventable. A second study concluded that at least 20 percent of nosocomial infections in general (not just VAP) are preventable.[7]

During the December 17, 2007 HAC and POA Listing Session, we also received comments on evidence-based guidelines for preventing VAP. Commenters referenced two articles[8 9] that both state there is a high degree of risk associated with endotracheal tube insertions, suggesting that VAP may not always be preventable.

While we are seeking public comments on the applicability of each of the statutory criteria to VAP, we are particularly interested in receiving comment on the degree to which VAP

[7] *American Association for Respiratory Care Clinical Practice:* Guideline: Care of the Ventilator Circuit and Its Relation to Ventilator Associated Pneumonia. *Available at the Web site: http://www.rcjournal.com/cpgs/09.03.0869.html.*

[8] Ramirez et al.: Prevention Measures for Ventilator-Associated Pneumonia: A New Focus on the Endotracheal Tube. *Current Opinion in Infectious Disease,* April 2007, Vol.20 (2), pp. 190–197.

[9] Safdar et al.: The Pathogenesis of Ventilator-Associated Pneumonia: Its Relevance to Developing Effective Strategies for Prevention. *Respiratory Care,* June 2005, Vol. 50, No. 6, pp.725–741.

is reasonably preventable through the application of evidence-based guidelines. Based on the public comments we receive, we may select VAP as an HAC.

g. Deep Vein Thrombosis (DVT)/ Pulmonary Embolism (PE)

HAC Candidate	Medicare Data (FY 2007)	CC/MCC (ICD-9-CM Codes)	Selected Evidence-Based Guidelines
Deep Vein Thrombosis (DVT)/Pulmonary Embolism (PE)	• 149,010 cases • $50,937/hospital stay	453.40 – 453.42 415.11 415.19	Available on the Web site: http://www.chestjournal.org/cgi/reprint/126/3_suppl/172S Available on the Web site: http://orthoinfo.aaos.org/topic.cfm?topic=A00219

We discussed deep vein thrombosis (DVT) and pulmonary embolism (PE) in the FY 2008 IPPS final rule with comment period (72 FR 47215). DVT and PE are common events. DVT occurs when a blood clot forms in the deep veins of the leg and causes local swelling and inflammation. PE occurs when a clot or a piece of a clot migrates from its original site into the lungs, causing the death of lung tissue, which can be fatal. Risk factors for DVTs and PEs include inactivity, smoking, use of oral contraceptives, prolonged bed rest, prolonged sitting with bent knees, certain types of cancer and other disease states, certain blood clotting disorders, and certain types of orthopedic and other surgical procedures. DVT is not always clinically apparent because the manifestations of pain, redness, and swelling may develop some time after the venous clot forms.

As we discussed in the FY 2008 IPPS final rule with comment period, DVTs and PEs may be preventable in certain circumstances, but it is possible that a patient may have a DVT that is difficult to detect on admission. We also received comments during the December 17, 2007 HAC and POA Listening Session reiterating that not all cases of DVTs and PEs are preventable. For example, common patient characteristics such as immobility, obesity, severe vessel trauma, and venous stasis put certain trauma and joint replacement surgery patients at high risk for these conditions.

In our review of the literature, we found that there are definite pharmacologic and nonpharmacologic interventions that may reduce the likelihood of developing DVTs and PEs, including exercise, compression stockings, intermittent pneumatic boots, aspirin, enoxaparin, dalteparin, heparin, coumadin, clopidogrel, and fondaparinux. However, the evidence-based guidelines indicate that some patients may still develop clots despite these therapies.

While we are seeking public comments on the applicability of each of the statutory criteria to DVTs and PEs, we are particularly interested in receiving comments on the degree of preventability of DVTs and PEs. We are also interested in comments on determining the presence of DVT and PE at admission. Based on the public comments we receive, we may select DVTs and PEs as HACs.

h. *Staphylococcus aureus* Septicemia

HAC Candidate	Medicare Data (FY 2007)	CC/MCC (ICD-9-CM Codes)	Selected Evidence-Based Guidelines
Staphylococcus aureus Septicemia	• 27,737 cases • $84,976/hospital stay	038.11(MCC) 995.91 (MCC) 995.92 (MCC) 998.59 (CC) 999.3 (CC)	Available on the Web site: http://www.cdc.gov/ncidod/dhqp/gl_isolation.html Available on the Web site: http://www.cdc.gov/ncidod/dhqp/gl_intravascular.html (Intravascular catheter-associated *Staphylococcus aureus* Septicemia only)

We discuss *Staphylococcus aureus* Septicemia in the FY 2008 IPPS final rule with comment period (72 FR 47208). *Staphylococcus aureus* is a bacterium that lives in the nose and on the skin of a large percentage of the population. It usually does not cause physical illness, but it can cause infections ranging from superficial boils to cellulitis to pneumonia to life threatening bloodstream infections (septicemia). It usually enters the body through traumatized tissue, such as cuts or abrasions, or at the time of invasive procedures. *Staphylococcus aureus* Septicemia can also be a late effect of an injury or a surgical procedure. Risk factors for developing *Staphylococcus aureus* Septicemia include advanced age, debilitated state, immunocompromised status, and a history of an invasive medical procedure.

CDC has developed evidence-based guidelines for the prevention of the *Staphylococcus aureus* Septicemia. Most preventable cases of septicemia are primarily related to the presence of a central venous or vascular catheter. During the December 17, 2007 HAC and POA Listening Session, commenters noted that intravascular catheter-associated infections are only one cause of septicemia. Therefore, catheter-oriented evidence-based guidelines would not cover all cases of *Staphylococcus aureus* Septicemia.[10]

We identified evidence-based guidelines that suggest *Staphylococcus aureus* Septicemia is reasonably preventable. These guidelines emphasize the importance of effective and fastidious hand washing by both staff and visitors, using gloves and gowns where appropriate, applying proper decontamination techniques, and exercising contact isolation where clinically indicated.

While we are seeking public comments on the applicability of each of the statutory criteria to *Staphylococcus aureus* infections generally, we are particularly interested in receiving comments on the degree of preventability of *Staphylococcus aureus* infections generally, and specifically *Staphylococcus aureus* Septicemia. Based on the public comments we receive, we may select *Staphylococcus aureus* Septicemia as an HAC.

i. *Clostridium Difficile*-Associated Disease (CDAD)

HAC Candidate	Medicare Data (FY 2007)	CC/MCC (ICD-9-CM Code)	Selected Evidence-Based Guidelines
Clostridium Difficile Associated Disease (CDAD)	• 96,336 cases • $59,153/hospital stay	008.45 (CC)	Available on the Web site: http://www.cdc.gov/ncidod/dhqp/gl_isolation.html Available on the Web site: http://www.cdc.gov/ncidod/dhqp/id_CdiffFAQ_HCP.html#9

We discussed *Clostridium difficile*-associated disease (CDAD) in the FY 2008 IPPS final rule with comment period. *Clostridium difficile* is a bacterium that colonizes the gastrointestinal (GI) tract of a certain number of healthy people. Under conditions where the normal flora of the gastrointestinal tract is altered, *Clostridium difficile* can flourish and release large enough amounts of a toxin to cause severe diarrhea or even life threatening colitis. Risk factors for CDAD include prolonged use of broad spectrum antibiotics, gastrointestinal surgery, prolonged nasogastric tube insertion, and repeated enemas. CDAD can be acquired in the hospital or in the community. Its spores can live outside of the body for months and thus can be spread to other patients in the absence of meticulous hand washing by care providers and others who contact the infected patient.

We continue to receive strong support in favor of selecting CDAD as an HAC. During the December 17, 2007 HAC and POA Listening Session, representatives of consumers and purchasers advocated to include CDAD as an HAC.

The evidence-based guidelines for CDAD prevention emphasize that hand washing by staff and visitors and effective decontamination of environmental surfaces prevent the spread of *Clostridium difficile.* While we are seeking public comments on the applicability of each of the statutory criteria to CDADs, we are particularly interested in receiving comments on the degree of preventability of CDAD. Based on the public comments we receive, we may select CDAD as an HAC.

j. Methicillin-Resistant *Staphylococcus aureus* (MRSA)

[10] Jensen, A.G. Importance of Focus Identification in the Treatment of *Staphylococcus aureus* Bacteremia. 2002. Vol. 52, pp. 29–36.

HAC Candidate	Medicare Data (FY 2007)	CC/MCC (ICD-9-CM Code)	Selected Evidence-Based Guidelines
Methicillin-Resistant *Staphylococcus aureus* (MRSA) (Code V09.0 includes infections with microorganisms resistant to penicillins	• 88,374 (V09.0) cases • $32,049/hospital stay	No CC/MCC	Available at the Web site: http://www.cdc.gov/ncidod/dhqp/gl_isolation.html

We discussed the special case of methicillin-resistant *Staphylococcus aureus* (MRSA) in the FY 2008 IPPS final rule with comment period (72 FR 47212). In October 2007, the CDC published in the *Journal of the American Medical Association* an article citing high mortality rates from MRSA, an antibiotic-resistant ''superbug.'' The article estimates 19,000 people died from MRSA infections in the United States in 2005. The majority of invasive MRSA cases are health care-related—contracted in hospitals or nursing homes—though community-acquired MRSA also poses a significant public health concern. Hospitals have been focused for years on controlling MRSA through the application of CDC's evidence-based guidelines outlining best practices for combating the bacterium in that setting.

MRSA is currently addressed by the HAC payment provision. For every infectious condition selected, MRSA could be the etiology of that infection. For example, if MRSA were the cause of a vascular catheter-associated infection (one of the eight conditions selected in the FY 2008 IPPS final rule with comment period), the HAC payment provision would apply to that MRSA infection.

As we noted in the FY 2008 IPPS final rule with comment period, colonization by MRSA is not a reasonably preventable HAC according to the current evidence-based guidelines; therefore, MRSA does not meet the reasonably preventable statutory criterion for an HAC. An estimated 32.4 percent of Americans are colonized with MRSA, which may reside in the nose or on the skin of asymptomatic carriers.[11] In addition, in last year's final rule with comment period, we noted that there is no CC/MCC code available for MRSA, and therefore it also does not meet the codeable CC/MCC statutory criterion for an HAC. Only when MRSA causes an infection does a codeable condition occur. However, we referenced the possibility that new codes for MRSA were being considered by the ICD–9–CM Coordination and Maintenance Committee. The creation of unique codes to capture MRSA was discussed during the March 19–20, 2008 Committee meeting. While these codes will enhance the data available and our understanding of MRSA, the availability and use of these codes will not change the fact that the mere presence of MRSA as a colonizing bacterium does not constitute an HAC.

Because MRSA as a bacterium does not meet two of our statutory criteria, codeable CC/MCC and reasonably preventable through evidence-based guidelines, we are not proposing MRSA as an HAC. However, we recognize the significant public health concerns that were raised by representatives of consumers and purchasers at the HAC and POA Listening Session, and we are committed to reducing the spread of multi-drug resistant organisms, such as MRSA.

In addition, we are pursuing collaborative efforts with other HHS agencies to combat MRSA. The Agency for Healthcare Research and Quality (AHRQ) has launched a new initiative in collaboration with CDC and CMS to identify and suppress the spread of MRSA and related infections. In support of this work, Congress has appropriated $5 million to fund research, implementation, management, and evaluation practices that mitigate such infections.

CDC has carried out extensive research on the epidemiology of MRSA and effective techniques that could be used to treat the infection and reduce its spread. The following Web sites contain information that reflect CDC's commitment: (1) *http://www.cdc.gov/ncidod/dhqp/ar_mrsa.html* (health care-associated MRSA); (2) *http://www.cdc.gov/ncidod/dhqp/ar_mrsa_ca_public.html* (community-acquired MRSA); (3) *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4908a1.htm;* and (4) *http://www.cdc.gov/handhygiene/.*

AHRQ has made previous investments in systems research to help monitor MRSA and related infections in hospital settings, as reflected in material on the Web site at: *http://www.guideline.gov/browse/guideline_index.aspx* and *http://www.ahrq.gov/clinic/ptsafety/pdf/ptsafety.pdf.*

8. Present on Admission (POA) Indicator Reporting

POA indicator information is necessary to identify which conditions were acquired during hospitalization for the HAC payment provision and for broader public health uses of Medicare data. Through Change Request No. 5679 (released June 20, 2007), CMS issued instructions requiring IPPS hospitals to submit the POA indicator data for all diagnosis codes on Medicare claims. Specific instructions on how to select the correct POA indicator for each diagnosis code are included in the ICD–9–CM Official Guidelines for Coding and Reporting, available at the Web site: *http://www.cdc.gov/nchs/datawh/ftpserv/ftpicd9/icdguide07.pdf* (POA

[11] Kuehnert, M.J., et al.: Prevalence of *Staphylococcusa aureus* Nasal Colonization in the United States, 2001-2002. The Journal of Infectious Disease, January 15, 2006; Vol. 193.

reporting guidelines begin on page 92). Additional instructions, including information regarding CMS's phased implementation of POA indicator reporting and application of the POA reporting options, are available at the Web site: *http://www.cms.hhs.gov/HospitalAcqCond*.

There are five POA indicator reporting options: ''Y,'' ''N,'' ''W,'' ''U,'' and ''1.'' Under the HAC payment provision, we are proposing to pay the CC/MCC MS–DRGs only for those HACs coded as ''Y'' and ''W'' indicators. The ''Y'' option indicates that the condition was present on admission. The ''W'' indicator affirms that the provider has determined, based on data and clinical judgment, that it is not possible to document when the onset of the condition occurred. We expect that this approach will encourage better documentation and promote the public health goals of POA reporting by providing more accurate data about the occurrence of HACs in the Medicare population. We anticipate that true clinical uncertainty will occur in only a very small number of cases. We plan to analyze how frequently the ''W'' indicator is used, and we leave open the possibility of proposing in future IPPS rulemaking not paying the CC/MCC MS–DRGs for HACs coded with the ''W'' indicator. In addition, we plan to analyze whether both the ''Y'' and ''W'' indicators are being used appropriately. Medicare program integrity initiatives closely monitor for inaccurate coding and coding that is inconsistent with medical record documentation. We are seeking public comments regarding the proposed treatment of the ''Y'' and ''W'' POA reporting options under the HAC payment provision.

We are proposing to not pay the CC/MMC MS–DRGs for HACs coded with the ''N'' indicator. The ''N'' option indicates that the condition was not present on admission. We are also proposing to not pay the CC/MCC MS–DRGs for HACs coded with the ''U'' indicator. The ''U'' option indicates that the medical record documentation is insufficient to determine whether the condition was present at the time of admission. Not paying for the CC/MCC MS–DRGs for HACs that are coded with the ''U'' indicator is expected to foster better medical record documentation.

Although we are proposing not paying the CC/MCC MS–DRG for HACs coded with the ''U'' indicator, we do recognize there may be some exceptional circumstances under which payment might be made. Death, elopement (leaving against medical advice), and transfers out of a hospital may preclude making an informed determination of whether an HAC was present on admission. We are seeking public comments on the potential use of the following current patient discharge status codes to identify the exceptional circumstances:

PATIENT DISCHARGE STATUS CODES

Form locator code	Code descriptor
Exception for Patient Death	
20	Expired.
Exception for Patient Elopement (Leaving Against Medical Device)	
7	Left against medical advice or discontinued care.
Exception for Transfer	
02	Discharged/transferred to a short-term general hospital for inpatient care.
03	Discharged/transferred to a skilled nursing facility (SNF) with Medicare certification in anticipation of skilled care.
04	Discharged/transferred to an intermediate care facility (ICF).
05	Discharged/transferred to a designated cancer center or children's hospital.
06	Discharged/transferred to home under care of organized home health service organization.
43	Discharged/transferred to a Federal health care facility.
50	Hospice-home.
51	Hospice-medical facility (certified) providing hospice level of care.
61	Discharged/transferred to a hospital-based Medicare approved swing bed.
62	Discharged/transferred to an inpatient rehabilitation facility (IRF) including rehabilitation distinct part units of a hospital.
63	Discharged/transferred to a Medicare certified long term care hospital (LTCH).
64	Discharged/transferred to a nursing facility certified under Medicaid but not certified under Medicare.
65	Discharged/transferred to a psychiatric hospital or psychiatric distinct part unit of a hospital.
66	Discharged/transferred to a critical access hospital (CAH).
70	Discharged/transferred to another type of health care institution not otherwise defined in this code list.

We plan to analyze whether both the ''N'' and ''U'' POA reporting options are being used appropriately. The American Health Information Management Association (AHIMA) has promulgated Standards of Ethical Coding that require accurate coding regardless of the payment implications of the diagnoses. That is, diagnoses must be reported accurately regardless of their effect on payment. Medicare program integrity initiatives closely monitor for inaccurate coding and coding inconsistent with medical record documentation. We are seeking public comments regarding the proposal to not pay the CC/MCC MS–DRGs for HACs coded with ''N'' and ''U'' indicators.

9. Enhancement and Future Issues

The preventable HAC payment provision is one of CMS' VBP initiatives, as noted earlier in this section. VBP ties payment to performance through the use of incentives based on quality measures and cost of care. The implementation of VBP is rapidly transforming CMS from being a passive payer of claims to an active purchaser of higher quality, more efficient health care for Medicare beneficiaries. Other VBP initiatives include hospital pay for reporting (the RHQDAPU program discussed in section IV.B. of the preamble of this proposed rule), physician pay for reporting (the Physician Quality Reporting Initiative), home health pay for reporting, the Hospital VBP Plan Report to Congress (discussed in section IV.C. of the preamble of this proposed rule), and various VBP demonstration

programs across payment settings, including the Premier Hospital Quality Incentive Demonstration and the Physician Group Practice Demonstration.

The success of CMS' VBP initiatives depends in large part on the validity of the performance measures and on the effectiveness of incentives in driving desired changes in behavior that will result in greater quality and efficiency. We are committed to enhancing the Medicare VBP programs, in close collaboration with stakeholders, to fulfill VBP's potential to promise of promoting higher value health care for Medicare beneficiaries. It is in this spirit that we seek public comment on enhancements to the preventable HACs payment policy and to concomitant POA indicator reporting.

We welcome all public comments presenting ideas and models for combating preventable HACs through the application of VBP principles. To stimulate reflection and creativity, we present several options:

- Risk adjustment could be applied to make the HAC payment provision more precise.
- Rates of HACs could be collected to obtain a more robust longitudinal measure of a hospital's incidence of these conditions.
- POA information could be used in various ways to decrease the incidence of preventable HACs.
- The adoption of ICD–10–PCS could facilitate more precise identification of HACs.
- The principle behind the HAC payment provision (Medicare not paying more for preventable HACs) could be applied to Medicare payments in settings of care other than the IPPS.
- CMS is using authority other than the HAC payment provision to address other events on the NQF's list of Serious Reportable Adverse Events.

We note that we are not proposing new Medicare policy in this Enhancements and Future Issues discussion, as some of these approaches may require new statutory authority.

a. Risk Adjustment

To make the HAC payment provision more precise, the adjustments to payment made when one of the selected HACs occurs during the hospitalization could be further adjusted to account for patient-specific risk factors. The expected occurrence of an HAC may be greater or lesser depending on the health status of the patient, as reflected by severity of illness, presence of comorbidities, or other factors. Rather than not paying any additional amount for the complication, the additional payment for the complication could range from zero for the lowest risk patient to the full amount for the highest risk patient. An option may be individualized adjustment for every hospitalization based on the patient's unique characteristics, but state-of-the-art risk adjustment currently precludes such individualized adjustment.

b. Rates of HACs

Given our limited capability at present for precise patient-level risk adjustment, adding a consideration of risk to the criteria for selecting HACs could be an alternative. If primarily high-risk patients are acquiring a certain condition during hospitalization, that condition could be considered a less-fit candidate for selection. Other alternatives to precise individualized risk adjustment could be adjustment for overall facility case mix or facility case-mix by condition. At the highest level, national Medicare program data could be used to make adjustments to the payment implications for the selected HACs based on expected rates of complications. Another option could be to designate certain patient risk factors as exemptions that would prohibit or mitigate the application of the HAC payment policy to the claims of patients with those risk factors.

The Medicare Hospital VBP Plan was submitted in a Report to Congress on November 21, 2007. The plan includes a performance assessment model that scores a hospital's attainment or improvement on various measures. The scores for each measure would be summed within each domain, such as the clinical process of care domain or the patient experience domain, and then the domains would be weighted and summed to yield a total performance score. The total performance score would then be translated into an incentive payment, proposed to be a certain percentage of each MS–DRG payment, using an exchange function. The plan also calls for public reporting of hospitals' performance scores by domain and in total. (Section IV.C. of this preamble included a related discussion of the Hospital VBP Plan Report to Congress.)

In accordance with this hospital VBP model, a hospital's rates of HACs could be included as a domain within each hospital's total performance score. The measurement of rates over time could be a more meaningful, actionable, and fair way to adjust a hospital's MS–DRG payments for the incidence of HACs. The consequence of a higher incidence of measured conditions would be a lower VBP incentive payment. Public reporting of the measured rates of HACs would give hospitals an additional, nonfinancial incentive to prevent occurrence of the conditions to avoid lower public ratings.

c. Use of POA Information

Information obtained from hospitals' reporting of POA data could be used in various ways to better understand and prevent the occurrence of HACs. The POA information could be provided to health services researchers to analyze factors that lead to HACs and disseminate the best practices for prevention of HACs. At least two states, New York and California, already collect POA data from their hospitals. Comparison of the State POA data with the Medicare data could fill in gaps in the databases and yield valuable insights about POA data validity.

POA data could also be used to calculate the incidence of HACs by hospital. This application of the POA data would be particularly powerful if the Medicare POA data were combined with state or private sector payer POA data. The Medicare-only or combined quality of care information could be initially shared with hospitals and thereafter publicly reported to support better healthcare decision making by Medicare beneficiaries, other health care consumers, professionals, and caregivers.

d. Transition to ICD–10–PCS

Accurate identification of HACs requires unambiguous and precise diagnosis codes. The current ICD–9–CM diagnosis coding system is three decades old. It is outdated and contains numerous instances of broad and vague codes. Attempts to add necessary detail to the ICD–9–CM system are inhibited by lack of expansion capacity. These factors negatively affect CMS' attempts to identify HAC cases.

ICD–10–PCS codes are more precise and capture information using more current medical terminology. For example, ICD–9–CM codes for pressure ulcers do not provide information about the size, depth, or exact location of the ulcer, while ICD–10–PCS has 60 codes to capture this information. ICD–10–PCS would also provide codes, beyond the current ICD–9–CM codes, that would enable the selection of additional surgical complications and adverse drug events.

e. Application of Nonpayment for HACs to Other Settings

The broad principle of Medicare not paying for preventable health care-associated conditions could potentially be applied to Medicare payment settings other than IPPS hospitals. Other

possible settings of care might include hospital outpatient departments, SNFs, HHAs, end-stage renal disease facilities, and physician practices. The implications would be different for each setting, as each payment system is different and the reasonable preventability through the application of evidence-based guidelines would vary for candidate conditions over the different settings. However, alignment of incentives across settings of care is an important goal for all of CMS' VBP initiatives, including the HAC provision.

A related application of the broad principle behind the HAC payment could be accomplished through modification to the Medicare secondary payer policy which would allow us to directly recoup from the provider that failed to prevent the occurrence of a preventable condition in one setting to pay for all or part of the necessary followup care in a second setting. This would help shield the Medicare program from inappropriately paying for the downstream effects of a preventable condition acquired in the first setting but treated in the second setting.

f. Relationship to NQF's Serious Reportable Adverse Events

CMS is applying its authority to address the events on the NQF's list of Serious Reportable Adverse Events (also known as ''never events''). In May 2006 testimony before the Senate Finance Committee, the CMS Administrator noted that paying hospitals for serious preventable events is contrary to the promise that hospital payments should support higher quality and efficiency. There is growing consensus that health care purchasers should not be paying for these events when they occur during a hospitalization. In January 2005, HealthPartners, a Minnesota-based not-for-profit HMO, announced that it would no longer reimburse hospitals for services associated with events enumerated in the Minnesota Adverse Health Care Events Reporting Act (essentially the NQF's list of Serious Reportable Adverse Events). Further, HealthPartners' contracts preclude hospitals from seeking reimbursement from the patient for these costs. During 2007, several State hospital associations adopted policies stating that their members will not bill payers or patients when these events occur in their hospitals.

In the FY 2008 IPPS final rule with comment period, we adopted several items from the NQF's list of events as HACs, including retained foreign object after surgery, air embolism, blood incompatibility, stage III and IV pressure ulcers, falls, electric shock, and burns. In this proposed rule, we are seeking public comments regarding adding hypoglycemic coma, which is closely related to NQF's listing of death or serious disability associated with hypoglycemia. However, as we discussed in the FY 2008 IPPS final rule with comment period, the HAC payment provision is not ideally suited to address every condition on the NQF's list of Serious Reportable Adverse Events. To address the events on the NQF's list beyond the effect of the HAC policy, CMS is exploring the application of Medicare authority, including other payment provisions, coverage policy, conditions of participation, and Quality Improvement Organization (QIO) retrospective review.

We note that we are not proposing new Medicare policy in this discussion of the HAC payment provision for IPPS hospitals, as some of these approaches may require new statutory authority. We are seeking public comments on these and other options for enhancing the preventable HACs payment provision and maximizing the use of POA indicator reporting data. We look forward to working with stakeholders in the fight against HACs.

G. Proposed Changes to Specific MS–DRG Classifications

1. Pre-MDCs: Artificial Heart Devices

Heart failure affects more than 5 million patients in the United States with 550,000 new cases each year, and causes more than 55,000 deaths annually. It is a progressive disease that is medically managed at all stages, but over time leads to continued deterioration of the heart's ability to pump sufficient amounts of adequately oxygenated blood throughout the body. When medical management becomes inadequate to continue to support the patient, the patient's heart failure would be considered to be the end stage of the disease. At this point, the only remaining treatment options are a heart transplant or mechanical circulatory support. A device termed an artificial heart has been used only for severe failure of both the right and left ventricles, also known as biventricular failure. Relatively small numbers of patients suffer from biventricular failure, but the exact numbers are unknown. There are about 4,000 patients approved and waiting to receive heart transplants in the United States at any given time, but only about 2,000 hearts per year are transplanted due to a scarcity of donated organs. There are a number of mechanical devices that may be used to support the ventricles of a failing heart on either a temporary or permanent basis. When it is apparent that a patient will require long-term support, a ventricular support device is generally implanted and may be considered either as a bridge to recovery or a bridge to transplantation. Sometimes a patient's prognosis is uncertain, and with device support the native heart may recover its function. However when recovery is not likely, the patient may qualify as a transplant candidate and require mechanical circulatory support until a donor heart becomes available. This type of support is commonly supplied by ventricular assist devices, (VADs), which are surgically attached to the native ventricles but do not replace them.

Devices commonly called artificial hearts are biventricular heart replacement systems that differ from VADs in that a substantial part of the native heart, including both ventricles, is removed. When the heart remains intact, it remains possible for the native heart to recover its function after being assisted by a VAD. However, because the artificial heart device requires the resection of the ventricles, the native heart is no longer intact and such recovery is not possible. The designation ''artificial heart'' is somewhat of a misnomer because some portion of the native heart remains and there is no current mechanical device that fully replaces all four chambers of the heart. Over time, better descriptive language for these devices may be adopted.

In 1986, CMS made a determination that the use of artificial hearts was not covered under the Medicare program. To conform to that decision, we placed ICD–9–CM procedure code 37.52 (Implantation of total replacement heart system) on the GROUPER program's MCE in the noncovered procedure list.

On August 1, 2007, CMS began a national coverage determination process for artificial hearts. SynCardia Systems, Inc. submitted a request for reconsideration of the longstanding noncoverage policy when its device, the CardioWest Temporary Total Artificial Heart (TAH–t) System, is used for ''bridge to transplantation'' in accordance with the FDA-labeled indication for the device. ''Bridge to transplantation'' is a phrase meaning that a patient in end-stage heart failure may qualify as a heart transplant candidate, but will require mechanical circulatory support until a donor heart becomes available. The CardioWest TAH–t System is indicated for use as a bridge to transplantation in cardiac transplant-eligible candidates at risk of imminent death from biventricular