

should be made in response to that proposed rule. The comment period for the OPPS/ASC proposed rule closes at 5:00 p.m. E.S.T. on September 2, 2008.

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

1. General Background

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 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 The costs associated with hospital-acquired infections are particularly burdensome for Medicare, as Medicare covers a greater portion

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

of patients with hospital-acquired infections than other payers. One study found that the payer mix for patients without infections was 37 percent Medicare, 28 percent commercial, 21 percent other, and 14 percent Medicaid, while the payer mix for patients with hospital-acquired infections was 57 percent Medicare, 17 percent commercial, 15 percent other, and 11 percent Medicaid.⁶

As one approach to combating HACs, including infections, in 2005 Congress authorized CMS to adjust 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.

Additionally, the President's FY 2009 Budget outlines another approach for addressing serious preventable adverse events ("never events"), including HACs (see section II.F.9. below for a discussion regarding which HACs are included in the list of Serious Reportable Adverse Events). The President's Budget proposal would:

(1) prohibit hospitals from billing the Medicare program for "never events" and prohibit

⁶ 1.6 Million Admission Analysis, MedMined, Inc. September 2006.

Medicare payment for these events and (2) require hospitals to report any 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 some 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 complicating condition (CC) or a major complicating condition (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). Medicare will continue to assign a discharge to a higher paying MS-DRG if the selected condition is present on admission. (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 under the HAC provision:

Service: MS-DRG Assignment* (Examples below with CC/MCC indicate a single secondary diagnosis only)	Present on Admission (Status of Secondary Diagnosis)	Median Payment
Principal Diagnosis • Intracranial hemorrhage or cerebral infarction (stroke) without CC/MCC - MS-DRG 066	--	\$5,347.98
Principal Diagnosis • 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))	Y	\$6,177.43
Principal Diagnosis • 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))	N	\$5,347.98
Principal Diagnosis • Intracranial hemorrhage or cerebral infarction (stroke) with MCC - MS-DRG 064 Example Secondary Diagnosis • Stage III pressure ulcer (code 707.23 (MCC))	Y	\$8,030.28
Principal Diagnosis • Intracranial hemorrhage or cerebral infarction (stroke) with MCC - MS-DRG 064 Example Secondary Diagnosis • Stage III pressure ulcer (code 707.23 (MCC))	N	\$5,347.98

*Operating amounts for a hospital whose wage index is equal to the national average. Based on FY 2008 wage index.

This example illustrates a payment scenario in which the CC/MCC indicates a single secondary diagnosis only. It is atypical for a hospitalized Medicare beneficiary to have only one secondary diagnosis.⁷

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 MS-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 a higher paying MS-DRG if a selected HAC is not present on admission. That is, the case will be paid as though the secondary diagnosis were not present. Medicare will continue to assign a discharge to a higher paying MS-DRG if the selected condition is present on admission. However, if any nonselected CC/MCC appears on the claim, the claim will be paid at the higher MS-DRG rate; to cause a lower MS-DRG payment, all CCs/MCCs on the claim must be selected conditions for the HAC payment provision. 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 HAC payment provision apply to IPPS hospitals only. At this time, non-IPPS hospitals, including CAHs, LTCHs, IRFs,

⁷ Medicare Payment for Selected Adverse Events: Building the Business Case for Investing in Patient Safety. *Health Affairs*. Zhan et al. September 2006.

IPFs, cancer hospitals, children's inpatient hospitals, and hospitals in Maryland operating under waivers, 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 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 apply, and noted that we would be seeking comments on additional HAC candidates in the FY 2009 IPPS proposed rule.

In the FY 2009 IPPS proposed rule (73 FR 23547), we proposed several candidate HACs in addition to proposing refinements to the previously selected HACs. In this FY 2009 IPPS final rule, we summarize the public comments we received on the FY 2009 IPPS proposed rule, present our responses, select additional conditions to which the HAC payment provision will apply, and note that we will be seeking comments on additional HAC candidates in the FY 2010 IPPS proposed rule.

4. Collaborative Process

CMS experts worked closely with public health and infectious disease professionals from the CDC to identify the candidate preventable HACs, review comments, and select 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 and on the payment implications of the various POA reporting options.

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 CMS Web site at:

http://www.cms.hhs.gov/HospitalAcqCond/07_EducationalResources.asp. CMS and CDC also received verbal comments during the listening session and subsequently received numerous written comments.

Comment: Several commenters recommended that CMS develop an advisory panel of clinicians and scientists to provide the agency with guidance on which conditions are appropriate for inclusion under this policy.

Response: We are committed to working with stakeholders as we refine and make additions to the HAC list each year. We intend to engage the public through rulemaking as discussed in section II.F.3. of this preamble and other mechanisms similar to those discussed above.

5. Selection Criteria for HACs

In selecting proposed candidate conditions and finalizing conditions as HACs, CMS and CDC staff evaluated each condition against the criteria established by section 1886(d)(4)(D)(iv) of the Act.

- Cost or Volume – Medicare data⁸ must support that the selected conditions are high cost, high volume, or both. We have not yet analyzed 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.

- 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 considered 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.

⁸ For the HAC section of this FY 2009 IPPS final 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.

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

6. HACs Selected During FY 2008 IPPS Rulemaking and Changes to Certain Codes

The conditions that were selected for the HAC payment provision through the FY 2008 IPPS final rule with comment period are listed below. The HAC payment provision implications 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.

Selected HAC	Medicare Data (FY 2007)	CC/MCC (ICD-9-CM Codes)	Selected Evidence-Based Guidelines
Foreign Object Retained After Surgery	<ul style="list-style-type: none"> • 750 cases* • \$63,631/hospital stay** 	998.4 (CC) or 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	<ul style="list-style-type: none"> • 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

Selected HAC	Medicare Data (FY 2007)	CC/MCC (ICD-9-CM Codes)	Selected Evidence-Based Guidelines
Blood Incompatibility	<ul style="list-style-type: none"> ● 24 cases ● \$50,455/hospital stay 	999.6 (CC)	<p>NQF Serious Reportable Adverse Event</p> <p>NQF’s Safe Practices for Better Healthcare available at the Web site: http://www.ahrq.gov/qual/nqfpract.htm</p>
Pressure Ulcer Stages III & IV	<ul style="list-style-type: none"> ● 257,412 cases*** ● \$43,180/hospital stay 	707.23 (MCC or 707.24 (MCC)	<p>NQF Serious Reportable Adverse Event</p> <p>Available at the Web site: http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hsat2.chapter.4409</p>
<p>Falls and Trauma:</p> <ul style="list-style-type: none"> - Fracture - Dislocation - Intracranial Injury - Crushing Injury - Burn - Electric Shock 	<ul style="list-style-type: none"> ● 193,566 cases ● \$33,894/hospital stay 	<p>Codes within these ranges on the CC/MCC list:</p> <p>800-829 830-839 850-854 925-929 940-949 991-994</p>	<p>NQF Serious Reportable Adverse Events address falls, electric shock, and burns.</p> <p>NQF’s Safe Practices for Better Healthcare available at the Web site: http://www.ahrq.gov/qual/nqfpract.htm</p>

Selected HAC	Medicare Data (FY 2007)	CC/MCC (ICD-9-CM Codes)	Selected Evidence-Based Guidelines
Catheter-Associated Urinary Tract Infection (UTI)	<ul style="list-style-type: none"> ● 12,185 cases ● \$44,043/hospital stay 	<p>996.64 (CC)</p> <p>Also excludes the following from acting as a CC/MCC:</p> <p>112.2 (CC)</p> <p>590.10 (CC)</p> <p>590.11 (MCC)</p> <p>590.2 (MCC)</p> <p>590.3 (CC)</p> <p>590.80 (CC)</p> <p>590.81 (CC)</p> <p>595.0 (CC)</p> <p>597.0 (CC)</p> <p>599.0 (CC)</p>	<p>Available at the Web site:</p> <p>http://www.cdc.gov/ncidod/dhqp/gl_catheter_assoc.html</p>
Vascular Catheter-Associated Infection	<ul style="list-style-type: none"> ● 29,536 cases ● \$103,027/hospital stay 	<p>999.31 (CC)</p>	<p>Available at the Web site:</p> <p>http://www.cdc.gov/ncidod/dhqp/gl_intravascular.html</p>
Surgical Site Infection-Mediastinitis After Coronary Artery Bypass Graft (CABG)	<ul style="list-style-type: none"> ● 69 cases ● \$299,237/hospital stay 	<p>519.2 (MCC)</p> <p>And one of the following procedure codes:</p> <p>36.10–36.19</p>	<p>Available at the Web site:</p> <p>http://www.cdc.gov/ncidod/dhqp/gl_surgicalsites.html</p>

*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 MCC codes 707.23 and 707.24 will be implemented on October 1, 2008.

In the FY 2009 IPPS proposed rule (73 FR 23552), we sought public comments on the following refinements to two of the previously selected HACs:

a. Foreign Object Retained After Surgery

In the FY 2009 IPPS proposed rule (73 FR 23552), we solicited public comments regarding the inclusion of ICD-9-CM diagnosis code 998.7 (Acute reaction to foreign substance accidentally left during a procedure) to more accurately and completely identify foreign object retained after surgery as an HAC.

Comment: Commenters universally supported the addition of ICD-9-CM code 998.7 to identify foreign object retained after surgery as an HAC. The commenters also reiterated their support for recognizing foreign object retained after surgery as an HAC.

Response: We appreciate the commenters’ support. We refer readers to a more detailed discussion of HAC coding for foreign object retained after surgery in section II.F.10.a. of this preamble.

After consideration of the public comments received, we are finalizing our proposal to include diagnosis code 998.7 as an additional code to code 998.4 selected in FY 2008 to identify foreign object retained after surgery as an HAC under the HAC payment provision.

Foreign Object Retained After Surgery	
ICD-9-CM Codes	Code Descriptor
998.4	Foreign body accidentally left during a procedure
998.7	Acute reaction to foreign substance accidentally left during a procedure

b. Pressure Ulcers

In the FY 2009 IPPS proposed rule (73 FR 23552), we proposed that, beginning October 1, 2008, the codes used to make MS-DRG adjustments for pressure ulcers under the HAC provision would include proposed MCC codes 707.23 and 707.24 (pressure ulcer stages III and IV).

Comment: Commenters supported the creation of the new ICD-9-CM codes 707.23 and 707.24 to capture the stage of the pressure ulcer and supported the use of these codes to identify pressure ulcer stages III and IV as HACs. However, some commenters expressed concern about the proposal to classify ICD-9-CM codes 707.23 and 707.24 as MCCs and to remove the CC/MCC classifications from the existing pressure site codes.

Response: We appreciate the commenters support for using codes 707.23 and 707.24 to identify pressure ulcer stages III and IV as HACs.

In response to the commenters’ concerns regarding the CC/MCC classification for these codes, we refer readers to section II.G.12. of this preamble where we address specific concerns about the creation of new codes for identifying pressure ulcers.

After consideration of public comments received, we are adopting as final our proposal that, beginning October 1, 2008, the codes used to identify pressure ulcer stages III and IV as HACs include the following MCC codes:

Pressure Ulcers	
ICD-9-CM Codes	Code Descriptor
707.23	Pressure ulcer, stage III
707.24	Pressure ulcer, stage IV

7. Candidate HACs

CMS and CDC have diligently worked together and with other stakeholders to identify and select candidates for the HAC payment provision. The additional candidate HACs selected in this FY 2009 IPPS final rule will have payment implications beginning October 1, 2008.

As in the FY 2009 IPPS proposed rule, we present in this final rule the statutory criteria for each HAC candidate in tabular format. Each table contains the following:

- HAC Candidate – We sought public comment on all HAC candidates.
- Medicare Data – We sought public comment on the statutory criterion of high cost, high volume, or both as it applies to each HAC candidate.
- CC/MCC – We sought public comment on the statutory criterion that an ICD-9-CM diagnosis code(s) clearly identifies the HAC candidate.
- Selected Evidence-Based Guidelines – We sought public comment on whether guidelines are available that hospitals should follow to prevent the condition from occurring in the hospital.
- Reasonably Preventable – We sought public comment on whether each condition could be considered reasonably preventable through the application of evidence-based guidelines.

Comment: Many commenters recommended various general standards for determining which conditions could reasonably have been prevented through the application of evidence-based guidelines. The majority of commenters favored a zero, or

near zero, standard for those conditions to be considered reasonably preventable when evidence-based guidelines are followed.

Response: We did not propose and did not specifically seek public comments on a general standard for reasonably preventable through the application of evidence-based guidelines in the FY 2009 IPPS proposed rule, and we are not setting a general standard in this final rule. We further note that the statute does not require that a condition be “always preventable” in order to qualify as an HAC, but rather that it be “reasonably preventable,” which necessarily implies something less than 100 percent.

After consideration of the public comments received and in light of the three statutory criteria, we are finalizing several additional conditions for the HAC payment provision. The additional conditions are defined by specific codes within the broad categories of manifestations of poor glycemic control, surgical site infections, and deep vein thrombosis/pulmonary embolism, as discussed below.

a. Manifestations of Poor Glycemic Control

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 manifestations of poor glycemic control are reasonably preventable through the application of evidence-based guidelines and sound medical practice while in the hospital setting; specifically, we believe that they are preventable through the use of routine serum glucose measurement and control which are basic elements of good hospital care.

We originally proposed the diagnosis codes representing four extreme manifestations of poor glycemic control as HACs, but we are not finalizing the following codes representing diabetic coma because the codes are nonspecific and more precise, specific codes are available to describe the condition: (1) diabetes with coma, type II or unspecified type, not stated as controlled (250.30); (2) diabetes with coma, type I, not stated as controlled (250.31); (3) diabetes with coma, type II or unspecified type, uncontrolled (250.32); and (4) diabetes with coma, type I, uncontrolled (250.33).

Comment: Commenters generally considered all of the manifestations of poor glycemic control together. The majority of commenters agreed that these extreme manifestations of poor glycemic control are reasonably preventable through the application of evidence-based guidelines. In support of selecting this condition, one commenter provided additional evidence-based guidelines addressing glycemic control.

Response: We agree with commenters that extreme manifestations of poor glycemic control are reasonably preventable through the application of evidence-based guidelines. We are including the additional evidence-based guidelines submitted by a commenter in the chart for manifestations of poor glycemic control below.

Comment: Of the proposed codes representing the manifestations of poor glycemic control, hypoglycemic coma received the most attention from commenters. Many commenters considered hypoglycemic coma to be a strong candidate because it is included in the NQF's list of Serious Reportable Adverse Events.

Response: We agree with commenters that hypoglycemic coma is reasonably preventable through the application of evidence-based guidelines.

Comment: Although the majority of commenters supported the selection of diabetic ketoacidosis, nonketotic hyperosmolar coma, and hypoglycemic coma as HACs, CMS received a small number of comments opposing the selection of codes from the manifestations of poor glycemic control category. Some commenters expressed that recent studies demonstrate that tight glycemic control in septic patients leads to poorer outcomes. One commenter identified the diabetic patient population as high risk, citing an estimate that any person with insulin-treated diabetes will experience 0.5 to 1.0 severe hypoglycemic events annually, which appears to not necessarily be within the control of caregivers.⁹

Response: We have addressed the commenters' concerns about tight glycemic control and hypoglycemic events by selecting specific, narrow codes representing extreme manifestations as HACs. For example, the commenter's concern about the preventability of all hypoglycemic events is addressed by selecting as an HAC only the code representing hypoglycemic coma (251.0), an extreme manifestation. We further note that the statute does not require that a condition be "always preventable" in order to qualify as an HAC, but rather that it be "reasonably preventable," which necessarily implies something less than 100 percent.

Comment: Commenters supported adding the following four secondary diabetes diagnosis codes: (1) ICD-9-CM code 249.10 (Secondary diabetes mellitus with ketoacidosis, not stated as uncontrolled, or unspecified); (2) ICD-9-CM code 249.11 (Secondary diabetes mellitus with ketoacidosis, uncontrolled); (3) ICD-9-CM code

⁹ The Diabetes Control and Complications Trial. *New England Journal of Medicine*, 1993, Vol. 329, pp. 977-986.

249.20 (Secondary diabetes mellitus with hyperosmolarity, not stated as uncontrolled, or unspecified); and (4) ICD-9-CM code 249.21 (Secondary diabetes mellitus with hyperosmolarity, uncontrolled). These new secondary diabetes codes will be effective on October 1, 2008.

Response: We agree with commenters that the secondary diabetes codes should be included to capture the full range of extreme manifestations of poor glycemic control as HACs. The secondary diabetes codes are clinically similar to the proposed codes and including these codes more accurately captures the range of manifestations of poor glycemic control.

We are finalizing manifestations of poor glycemic control as an HAC because we have determined after considering the comments received that these conditions meet the statutory criteria. The following chart includes the codes that describe manifestations of the poor glycemic control as an HAC:

Selected HAC	Medicare Data (FY 2007)	CC/MCC (ICD-9-CM Code)	Selected Evidence-Based Guidelines
<p><i>Manifestations of Poor Glycemic Control:</i></p> <ul style="list-style-type: none"> - Diabetic Ketoacidosis - Nonketotic Hyperosmolar Coma 	<p>Diabetic Ketoacidosis</p> <ul style="list-style-type: none"> ● 11,469 cases ● \$42,974/hospital stay <p>Nonketotic Hyperosmolar</p>	<p>A code from the following range:</p> <p style="text-align: center;">Diabetic Ketoacidosis: 250.10 – 250.13 (MCC)</p> <p style="text-align: center;">Nonketotic Hyperosmolar Coma: 250.20 – 250.23</p>	<p>NQF Serious Reportable Adverse Events addresses hypoglycemia.</p> <p>Available at the Web site:</p> <p>http://www.diabetes.org/uedocuments/InpatientDMGlycemicControlPositionStmnt02.01.06.REV.pdf</p>

Selected HAC	Medicare Data (FY 2007)	CC/MCC (ICD-9-CM Code)	Selected Evidence-Based Guidelines
<p>- Hypoglycemic Coma</p> <p>- Secondary Diabetes with Ketoacidosis*</p> <p>- Secondary Diabetes with Hyperosmolarity*</p>	<p>Coma</p> <ul style="list-style-type: none"> ● 3,248 cases ● \$35,215/hospital stay <p>Hypoglycemic Coma</p> <ul style="list-style-type: none"> ● 212 cases ● \$36,581/hospital stay 	<p>(MCC)</p> <p>Hypoglycemic Coma: 251.0 (CC)</p> <p>Secondary Diabetes with Ketoacidosis: 249.10 (MCC) or 249.11 (MCC)</p> <p>Secondary Diabetes with Hyperosmolarity: 249.20 (MCC) or 249.21 (MCC)</p>	<p>Available at the Web site: http://www.hospitalmedicine.org/Resource/RoomRedesign/GlycemicControl.cfm</p>

*Note: Medicare data are not available for FY 2007 because ICD-9-CM codes are not effective until October 1, 2008.

Manifestations of Poor Glycemic Control	
ICD-9-CM Code	Code Descriptor
249.10	Secondary diabetes mellitus with ketoacidosis, not stated as uncontrolled, or unspecified
249.11	Secondary diabetes mellitus with ketoacidosis, uncontrolled
249.20	Secondary diabetes mellitus with hyperosmolarity, not stated as uncontrolled, or unspecified
249.21	Secondary diabetes mellitus with hyperosmolarity, uncontrolled
250.10	Diabetes with ketoacidosis, type II or unspecified type, not stated as uncontrolled
250.11	Diabetes with ketoacidosis, type I [juvenile type], not stated as

Manifestations of Poor Glycemic Control	
ICD-9-CM Code	Code Descriptor
	uncontrolled
250.12	Diabetes with ketoacidosis, type II or unspecified type, uncontrolled
250.13	Diabetes with ketoacidosis, type I [juvenile type], uncontrolled
250.20	Diabetes with hyperosmolarity, type II or unspecified type, not stated as uncontrolled
250.21	Diabetes with hyperosmolarity, type I [juvenile type], not stated as uncontrolled
250.22	Diabetes with hyperosmolarity, type II or unspecified type, uncontrolled
250.23	Diabetes with hyperosmolarity, type I [juvenile type], uncontrolled
251.0	Hypoglycemic coma

b. Surgical Site Infections

In the FY 2009 IPPS proposed rule (73 FR 23553), we requested public comments on the applicability of each of the statutory criteria to surgical site infections following certain procedures. We were particularly interested in receiving comments on the degree of preventability of these infections. We also requested, and received, public comment on additional surgical procedures that would qualify for the HAC provision by meeting all of the statutory criteria.

Comment: Numerous commenters raised issues regarding the applicability of each statutory criterion to surgical site infections generally, especially with regard to degree of preventability. Commenters raised concerns that patient characteristics and other factors can put patients at risk for surgical site infections regardless of the application of evidence-based guidelines. Commenters asserted that elective procedures have a tendency to be short-stay admissions or outpatient procedures, and if a surgical site infection presents after discharge, this HAC would not be captured under the inpatient provision.

Response: We agree that the risk of a typical patient undergoing a procedure is a factor in determining whether these conditions are reasonably preventable (see discussion of risk adjustment in section II.F.9. of this preamble), but we do not agree that the average length of stay following the procedure or the ability to perform the procedure at an alternative site are determinative factors for selecting HACs.

Comment: Some commenters emphasized that certain procedures typically thought of as elective by clinicians are not necessarily elective by patients. Two commenters noted that even if total knee replacement is considered nonemergent and therefore elective from a clinician's perspective, a patient may consider the surgery critical and urgent to avoid pain and immobility.

Response: We agree with the commenters that procedures typically thought of as elective based on urgency are not necessarily viewed as elective from the perspective of the patient's quality of life. Given lack of consensus regarding the classification of procedures as elective, we have discontinued referring to this broad category of surgical site infections as "following elective procedures."

Comment: Many commenters asserted that surgical site infections following total knee replacement could be considered reasonably preventable, however those commenters questioned why CMS proposed this HAC because the candidate codes are CCs, and total knee replacement procedures typically map to MS-DRGs that only split to MCCs.

Response: We are unable to select this condition as an HAC because, as commenters noted, surgical site infection is a CC that does not trigger the higher paying

MCC MS-DRG payment for total knee replacement procedures; thus, it does not meet the second statutory criterion. If a change to the MS-DRGs results in total knee replacement procedures mapping to MS-DRGs that split to CCs in the future, we could reconsider adding surgical site infections following total knee replacement as an HAC. In addition, we will be reviewing other ICD-9-CM MCC codes relevant to total knee replacement, and we will consider proposing those codes as future HAC candidates.

Comment: Commenters addressed the discrepancy between the proposed CC code (Other postoperative infection) and the MS-DRG split only to MCC for total knee replacement and suggested that CMS review and consider adding other procedures that map to MS-DRGs that split by CC. One commenter referenced a 2002 meta-analysis finding that antibiotic prophylaxis is successful in significantly reducing the rates of postoperative spinal infections.¹⁰

Response: We agree with the commenters' recommendations and considered additional orthopedic procedures. We identified the following MS-DRGs that split by CC:

- MS-DRGs 453, 454, and 455 (Combined Anterior/Posterior Spinal Fusion with MCC, CC and without CC/MCC);
- MS-DRGs 471, 472, and 473 (Cervical Spinal Fusion, with MCC, CC and without CC/MCC);
- MS-DRGs 507 and 508 (Major Shoulder or Elbow Joint Procedures, with CC/MCC and without CC/MCC).

¹⁰ Baker, F.G.: Efficacy of prophylactic antibiotic therapy in spinal surgery: A meta-analysis. *Neurosurgery*. 51(2): 391-400 (2002).

In response to commenters' suggestions, we are selecting certain orthopedic procedures that fall within the MS-DRGs listed above in the HAC surgical site infection category. The category of surgical site infection following certain orthopedic surgeries includes selected procedures that are often elective and that involve the repair, replacement, or fusion of various joints including the shoulder, elbow, and spine. In future rulemaking, we will work with stakeholders to identify additional procedures, orthopedic and other types, for which surgical site infections can be considered reasonably preventable through the application of evidence-based guidelines.

The following chart includes the codes that describe surgical site infection following certain orthopedic procedures as an HAC:

Surgical Site Infection Following Certain Orthopedic Procedures	
ICD-9-CM Code	Code Descriptor
996.67	Infection and inflammatory reaction due to other orthopedic device and implant graft
-OR-	
998.59	Other postoperative infection
- AND -	
81.01	Atlas-axis fusion
81.02	Other cervical fusion anterior
81.03	Other cervical fusion posterior
81.04	Dorsal/dorsolum fusion anterior
81.05	Dorsal/dorsolum fusion posterior
81.06	Lumbar/lumbosac fusion anterior
81.07	Lumbar/lumbosac fusion lateral
81.08	Lumbar/lumbosac fusion posterior
81.23	Arthrodesis of shoulder
81.24	Arthrodesis of elbow
81.31	Refusion of atlas-axis
81.32	Refusion of other cervical spine anterior
81.33	Refusion of other cervical spine posterior
81.34	Refusion of dorsal spine anterior
81.35	Refusion of dorsal spine posterior
81.36	Refusion of lumbar spine anterior
81.37	Refusion of lumbar spine lateral

Surgical Site Infection Following Certain Orthopedic Procedures	
ICD-9-CM Code	Code Descriptor
81.38	Refusion of lumbar spine posterior
81.83	Shoulder arthroplast NEC
81.85	Elbow arthroplast NEC

We proposed surgical site infections following ligation and stripping of varicose veins as an HAC, but we are not finalizing this procedure because these MS-DRGs do not currently split into severity levels based on the presence of a CC, and the surgical site infection code is a CC. Thus, surgical site infection following ligation and stripping of varicose veins does not currently meet the second statutory HAC selection criterion of triggering the higher-paying MS-DRG.

We solicited comments on each of the statutory criteria as they apply to surgical site infections following laparoscopic bypass and gastroenterostomy. Laparoscopic gastroenterostomy (44.38) includes several different types of gastric bypass procedures, all of which are done using a laparoscope to avoid surgically opening the abdomen (laparotomy). Gastroenterostomy (44.39) is a general term that describes surgically connecting the stomach to another area of the intestine.

Comment: Some commenters pointed out that the 208 cases cited in the FY 2009 IPPS proposed rule (73 FR 23553) is a relatively small number of cases, which may not meet the statutory criterion of high cost, high volume, or both.

Response: As noted in the FY 2009 IPPS proposed rule, the average cost of a case with a surgical site infection following laparoscopic gastric bypass and gastroenterostomy is \$180,142 per hospital stay, which we consider high cost. Thus, this condition meets the high cost statutory criterion.

Comment: Many stakeholders from provider organizations, including medical specialty societies, cited that the population undergoing bariatric surgery for obesity is a high risk population per se; thus, the condition may not be considered reasonably preventable through the application of evidence-based guidelines. Commenters noted that these patients commonly have conditions, such as diabetes and hypertension, in addition to obesity, which are well-known risk factors for infections and other post-operative complications.

Response: We recognize that patients undergoing this procedure may typically be high risk; however, (1) selecting this procedure as an HAC will have the positive effect of encouraging attention to risk assessment prior to surgery and (2) conditions such as complicated forms of diabetes, hypertensive heart and kidney disease, and a body mass index of 40 or higher are CCs or MCCs under the IPPS payment system that, when present on the claim, will continue to trigger the higher-paying MS-DRG. Thus, the usual presence of additional CC/MCCs on claims for these procedures serves as an “inherent risk adjuster” to payment for typical bariatric surgery cases for obese patients. We further note that the statute does not require that a condition be “always preventable” in order to qualify as an HAC, but rather that it be “reasonably preventable,” which necessarily implies something less than 100 percent.

Comment: One commenter noted that gastroenterostomy is routinely used to bypass a damaged or obstructed duodenum in high risk populations such as cancer patients.

Response: In 2007, CMS issued Change Request (CR) 5477 regarding the proper use of ICD-9-CM codes for bariatric surgery for morbid obesity, available on the Web site at: <http://www.cms.hhs.gov/Transmittals/downloads/R1233CP.pdf>. This CR addresses the comment above by focusing on only those procedures with a primary diagnosis of obesity (278.01). Further, as referenced in CR 5477, bariatric surgery for obesity contains the following procedures: (1) laparoscopic gastric bypass (44.38), (2) gastroenterostomy (44.39), and (3) laparoscopic gastric restrictive procedure (44.95). Laparoscopic gastric restrictive procedure (44.95) refers to the laparoscopic placement of a restrictive band around the stomach to reduce the effective size. By adopting the coding scheme laid out in CR 5477, we are finalizing not only 44.38 and 44.39, but also 44.95, as procedures within the HAC category of surgical site infections following bariatric surgery for obesity. The addition of Laparoscopic gastric restrictive procedure (44.95) more completely and accurately captures the range of surgical site infection following bariatric surgery for obesity as an HAC.

The following chart includes the codes that describe surgical site infection following bariatric surgery for obesity as an HAC:

Surgical Site Infection Following Bariatric Surgery for Obesity	
ICD-9-CM Code	Code Descriptor
278.01*	Morbid obesity
-AND-	
998.59	Other postoperative infection
- AND -	
44.38	Laparoscopic gastroenterostomy
-OR-	
44.39	Other gastroenterostomy
-OR-	
44.95	Laparoscopic gastric restrictive procedure

*As principal diagnosis.

In the FY 2009 IPPS proposed rule, we requested, and received, public comment on additional surgical procedures that would meet the statutory criteria for a surgical site infection HAC.

Comment: A commenter recommended that CMS add surgical site infection following implantation of cardiac devices as an HAC. The commenter noted a recent estimate of approximately 300,000 pacemaker implants performed in 2007.¹¹ In addition, the commenter referenced that the estimated rate of infection following cardiac device implantation is 4 percent and that the cost to treat each pacemaker infection is approximately \$25,000.¹² Further, the commenter cited evidence-based guidelines for preventing these infections.^{13,14,15}

Response: We agree with the commenter that surgical site infection following certain cardiac device procedures is a strong candidate HAC. The condition is high cost and high volume, triggers a higher-paying MS-DRG, and may be considered reasonably preventable through the application of evidence-based guidelines. We did not propose this specific condition in the FY 2009 IPPS proposed rule; however, we expect to propose surgical site infection following certain cardiac device procedures, as well as surgical site infections following other types of device procedures, as future candidate HACs.

¹¹ Morgan, J.P.: Cardiac Rhythm Management, Market Model, August 31, 2007

¹² Darouiche, R.O.: Treatment of Infections Associated with Surgical Implants, New England Journal of Medicine, 350:1422-9 (2004).

¹³ Bratzler, D. et al.: Antimicrobial Prophylaxis for Surgery: An Advisory Statement from the National Surgical Infection Prevention Project, American Journal of Surgery, 189:395-404 (2005).

¹⁴ Da Costa, A et al.: Antibiotic Prophylaxis for Permanent Pacemaker Implantation: A Meta-Analysis, Circulation; 97:1796-1801 (1998).

¹⁵ Klug, D. et al.: Risk Factors Related to Infection of Implanted Pacemakers and Cardioverter-Defibrillators: Results of a Large Prospective Study, Circulation, 116:1349-55 (2007).

We are selecting surgical site infections following certain orthopedic procedures, and bariatric surgery for obesity. These procedures will join mediastinitis following coronary artery bypass graft (CABG), which was selected in the FY 2008 IPPS final rule with comment period, as surgical site infection HACs. We look forward to working with stakeholders to identify additional procedures, such as device procedures, in which surgical site infections can be considered reasonably preventable through the application of evidence-based guidelines.

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

In the FY 2009 IPPS proposed rule, we proposed DVT/PE as a candidate HAC. We solicited comments on each of the statutory criteria, with particular focus on the degree to which DVT can be diagnosed on hospital admission and can be considered reasonably preventable. DVT occurs when a blood clot forms in the deep veins of an extremity, usually the leg, and causes pain, swelling, and inflammation. PE occurs when a clot or piece of a clot migrates from its original site to the lungs, causing the death of lung tissue, which can be fatal.

Comment: The majority of commenters emphasized the inability to determine whether DVT was present on admission. The commenters were concerned about the lack of a standard clinical definition and diagnostic criteria, as well as difficulty in identifying at-risk patients. One commenter suggested that nearly half of all DVT/PEs are asymptomatic on admission. One commenter explained that obtaining the most accurate results would require expensive diagnostic testing of all patients, implying that this strategy would not be cost-effective and would, therefore, be unreasonable.

Response: The commenters' concerns about the ability to diagnose DVT do not preclude DVT/PE from being selected as an HAC, as the attending physician determines whether the condition was present on admission ("Y" POA reporting option) or whether presence on admission cannot be determined based on clinical judgment ("W" POA reporting option). Hospitals will continue to be paid the higher MS-DRG amount for HACs coded as "Y" or "W" (we refer readers to section II.F.8. of this preamble).

Comment: Regarding the preventability of DVT/PE, one commenter cited reduction of DVT/PE occurrence through mentoring and onsite consultation as a particularly effective intervention strategy.

Response: We agree that the occurrence of DVT/PE can be significantly reduced through the use of intervention strategies, including mentoring and onsite consultation.

Comment: A large proportion of commenters underscored the importance of considering risk factors in weighing the degree of preventability. Commenters noted that common risk factors, some of which cannot be modified, include clotting disorders, obesity, hypercoagulable state, cancer, HIV, or rheumatoid arthritis.

Response: We agree with commenters that the risk factors of a typical patient are important to consider when weighing the degree of preventability as it applies to DVT/PE (discussion of risk adjustment in section II.F.9. of this preamble). Selecting DVT/PE for these procedures as an HAC will have the positive effect of encouraging attention to risk assessment prior to surgery. Further, conditions such as clotting disorders, obesity, hypercoagulable state, cancer, HIV, and rheumatoid arthritis are CCs or MCCs under the IPPS payment system that, when present on the claim, will continue to trigger the higher-paying MS-DRG. Thus, the usual presence of additional CC/MCCs on claims for these procedures serves as an “inherent risk adjuster” to payment for total knee replacement and hip replacement cases.

Comment: Although no commenters submitted quantitative data to establish a rate of preventability, many commenters noted that adherence to evidence-based pharmacologic and nonpharmacologic interventions will not prevent all DVTs. One

commenter suggested that DVT/PE should only be considered for the HAC payment provision when a patient did not receive proper prophylaxis.

Response: The fact that prophylaxis will not prevent every occurrence of DVT/PE does not preclude its selection as a reasonably preventable HAC. Further, as discussed in section IV.B. of this preamble, the Reporting Hospital Quality Data for the Annual Payment Update program includes a process of care measure regarding venous thromboembolism (VTE) prophylaxis within 24 hours prior to or after surgery. An analysis of publicly available data on Hospital Compare indicates that the national rate for the VTE prophylaxis measure for the third quarter of 2007 is approximately 82 percent.¹⁶ We have concluded from these data that a significant number of patients are not receiving the recommended evidence-based prophylaxis. We further note that the statute does not require that a condition be “always preventable” in order to qualify as an HAC, but rather that it be “reasonably preventable,” which necessarily implies something less than 100 percent.

Comment: Commenters also noted that, in some cases, anticoagulation prophylaxis may be contraindicated based on individual patient factors, including an increased risk of bleeding in postoperative patients.

Response: We agree with commenters that, in some cases, anticoagulation prophylaxis may be contraindicated. However, we do not view this as precluding the selection of DVT/PE as an HAC, as evidence-based interventions beyond pharmacologic prophylaxis, such as mechanical prophylaxis and early movement, should also be applied.

¹⁶ Hospital Compare available at the Web site: <http://www.hospitalcompare.hhs.gov>. Reviewed July 8, 2008.

Comment: Some commenters supported DVT/PE as reasonably preventable through the application of evidence-based guidelines for certain subpopulations, specifically following certain orthopedic procedures.

Response: We agree with commenters that DVT/PE is reasonably preventable in specific subpopulations, and we are therefore selecting DVT/PE following certain orthopedic surgeries, specifically certain hip and knee replacement surgeries, as HACs. Total knee replacement is a surgery performed to replace the entire knee joint with an artificial internal prosthesis because the native knee joint is no longer able to function, because it is very painful, or both, usually due to advanced osteoarthritis, and total hip replacement is the analogous operation involving the hip joint. Our decision may be construed as only applying to the MCC PE, rather than DVT/PE, following certain hip and knee replacement surgeries as HACs because of coding considerations. The MS-DRGs that these procedures typically map to do not currently split based on CCs, and DVT is a CC.

The following chart includes the codes that describe DVT/PE following certain orthopedic surgeries as an HAC:

Selected HAC	Medicare Data (FY 2007)	CC/MCC (ICD-9-CM Codes)	Selected Evidence-Based Guidelines
<p><i>Deep Vein Thrombosis (DVT)/Pulmonary Embolism (PE)</i></p> <p>- Total Knee Replacement</p> <p>- Hip Replacement</p>	<ul style="list-style-type: none"> ● 4250 cases ● \$58,625/hospital stay 	<p><i>DVT</i> 453.40 – 453.42 (CC) OR <i>PE</i> 415.11 (MCC) or 415.19 (MCC) AND <i>Total Knee Replacement</i> (81.54) OR <i>Hip Replacement</i> (00.85-00.87, 81.51-81.52)</p>	<p>Available on the Web site: http://www.chestjournal.org/cgi/reprint/126/3_suppl/172S</p> <p>Available on the Web site: http://orthoinfo.aaos.org/topic.cfm?topic=A00219</p>

Deep Vein Thrombosis (DVT)/Pulmonary Embolism (PE)	
ICD-9-CM Codes	Code Descriptors
00.85	Resurfacing hip, total, acetabulum and femoral head
00.86	Resurfacing hip, partial, femoral head
00.87	Resurfacing hip, partial, acetabulum
81.51	Total hip replacement
81.52	Partial hip replacement
81.54	Total knee replacement
415.11	Iatrogenic pulmonary embolism and infarction
415.19	Other pulmonary embolism and infarction – other
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

Deep Vein Thrombosis (DVT)/Pulmonary Embolism (PE)	
ICD-9-CM Codes	Code Descriptors
453.42	Venous embolism and thrombosis of deep vessels of distal lower extremity

d. Delirium

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. The clinician must establish that the onset has been abrupt and that the deficits affect the ability to maintain attention, maintain orderly thinking, and learn from new information. Delirium is substantially under-recognized and is regularly conflated with dementia. Because of the high rate of mortality and incidence noted above, we proposed delirium as a candidate HAC, and provided the following information for consideration:

HAC Candidate	Medicare Data (FY 2007)	CC/MCC (ICD-9-CM Code)	Selected Evidence-Based Guidelines
Delirium	<ul style="list-style-type: none"> ● 480 cases ● \$23,290/hospital stay 	293.1 (CC)	Available on the Web site: http://www.ahrq.gov/clinic/psafety/chap28.htm

We solicited comments on each of the statutory criteria, with particular focus on the degree to which delirium can be considered reasonably preventable through the application of evidence-based guidelines.

Comment: Most commenters strongly opposed placing delirium on the HAC list. Citing a study mentioned in the FY 2009 IPPS proposed rule (73 FR 23555), commenters emphasized that the ability to prevent only 30 to 40 percent of all delirium cases through the application of evidence-based guidelines does not, in their opinion, meet that statutory criterion. Many commenters stated that evidence-based guidelines, such as reducing certain medications, reorienting patients, assuring sleep and sensory input, and improving patient nutrition and hydration, were more appropriately used as process rather than outcome measures.

A number of commenters stated that it is difficult to define and diagnose a condition that varies in degree, such as delirium. They stated that symptoms of delirium may be intermittent. In addition, the commenters indicated that it may be difficult to differentiate between delirium and intensive care unit psychosis resulting from pre-admission hypoxia. Many commenters noted that delirium may be caused by many factors unrelated to clinical treatment. For example, commenters stated that delirium is a

common symptom in Alzheimer’s patients, who are likely to become disoriented in unfamiliar hospital surroundings. One commenter also noted that the diagnosis is difficult to make if a patient is intoxicated.

In addition to those commenters who expressed blanket support for selecting all candidate HACs, a few commenters explicitly supported inclusion of delirium as an HAC. One commenter suggested that delirium resulting from medication error could be reasonably prevented by implementation of computerized physician order entry systems. Another commenter suggested that prevention based on the six factors in the Confusion Assessment Model would improve intake assessment and health care quality.

Response: After consideration of the public comments received, we have decided not to select delirium as an HAC in this final rule. We will continue to monitor the evidence-based guidelines surrounding prevention of delirium. If evidence warrants, we may consider proposing delirium as an HAC in the future. Although we are not selecting delirium as an HAC, we would like to recognize two additional ICD-9-CM codes 292.81 (CC) and 293.0 (CC) that the commenters suggested to identify delirium and note that their input will be taken into account in any future reconsideration.

Delirium	
ICD-9-CM Codes	Code Descriptors
292.81	Drug-induced delirium
293.0	Delirium due to conditions classified elsewhere
293.1	Subacute delirium

e. Ventilator-Associated Pneumonia (VAP)

VAP is a serious hospital-acquired infection associated with high mortality, significantly increased length of stay, and high cost. It is typically caused by the

aspiration of contaminated gastric or oropharyngeal secretions. The presence of an endotracheal tube facilitates both the contamination of secretions and aspiration. We presented the following information in the FY 2009 IPPS proposed rule for consideration:

HAC Candidate	Medicare Data (FY 2007)	CC/MCC (ICD-9-CM Code)	Selected Evidence-Based Guidelines
Ventilator-Associated Pneumonia (VAP)	<ul style="list-style-type: none"> ● 30,867 cases ● \$135,795/hospital stay 	997.31 (CC)	Available on the Web site: http://www.rcjournal.com/cpgs/09.03.0869.html

Ventilator-Associated Pneumonia	
ICD-9-CM Code	Code Descriptor
997.31	Ventilator-associated pneumonia

The CDC recently updated the ICD-9-CM coding guidelines for proper use of code 997.31, which goes into effect on October 1, 2008. The ICD-9-CM Official Coding Guidelines are available at:

<http://www.cdc.gov/nchs/datawh/ftp/ftpICD9/ftpICD9.htm>

We solicited comments on each of the statutory criteria, with particular focus on the degree to which evidence-based guidelines can reasonably prevent VAP.

Comment: The majority of commenters addressed whether or not VAP could be considered reasonably preventable through the application of evidence-based guidelines. Citing literature mentioned in the IPPS FY 2009 proposed rule, commenters noted that VAP is only preventable 40 percent of the time, which, in their opinion, does not meet the statutory requirement for reasonably preventable through the application of

evidence-based guidelines. (The proposed rule referenced the American Association of Respiratory Care (AARC) Evidence-Based Clinical Practice Guidelines as one example of an existing evidence-based standard designed to prevent VAP.) A few commenters questioned the narrow focus of the AARC's guidelines.

In addition to problems related to its preventability, many commenters also argued that VAP may be difficult to diagnose based on shortfalls associated with clinical definitions and diagnostic tests. The commenters stated that clinical cultures are not predictive for pneumonia, radiographic evidence of pneumonia is difficult to standardize, and vaccines do not protect against infection during the current hospital stay. The commenters pointed out that no standard definition of VAP exists—the definition is constructed of nonspecific clinical signs common to many complications; thus, because of its imprecise definition, selection of VAP as an HAC could be especially susceptible to unintended consequences. One commenter stated that the flexibility inherent to VAP's imprecise definitions coupled with threat of nonpayment created a “perverse incentive” to diagnose VAP as another condition. Commenters noted that patient risk factors may also impact the risk of developing VAP. For example, burn patients are especially susceptible to infections.

While some commenters indicated that VAP is a serious condition and could be a good candidate HAC in the future, the many commenters argued that current evidence and technology are not well-enough developed at this time to meet the statutory requirement of reasonably preventable through the application of evidence-based guidelines. One commenter pointed out that the Institute for Healthcare Improvement

and the Joint Commission are currently evaluating alternative standards for VAP prevention.

Response: In light of the public comments that we received, we are not selecting VAP as an HAC. We will work in partnership with the CDC and closely monitor the evolving literature addressing the prevention of VAP through the application of evidence-based guidelines. If evidence warrants, we may consider proposing VAP as an HAC in the future.

f. *Staphylococcus aureus* Septicemia

Staphylococcus aureus is a bacterium that lives on multiple anatomic sites in most people. It usually does not cause physical illness, but it can cause a variety of infections ranging from superficial boils to cellulitis to pneumonia to life-threatening bloodstream infections (septicemia). It typically becomes pathogenic by infecting normally sterile tissue through traumatized tissue, such as cuts or abrasions, or at the time of invasive procedures and can be both an early and/or late complication of trauma or surgery. *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 history of an invasive medical procedure.

In the IPPS FY 2009 proposed rule, we presented the following information for consideration:

HAC Candidate	Medicare Data (FY 2007)	CC/MCC (ICD-9-CM Codes)	Selected Evidence-Based Guidelines
<i>Staphylococcus aureus</i> Septicemia	<ul style="list-style-type: none"> • 27,737 cases • \$84,976/hospital stay 	038.11(MCC) or 038.12 (MCC) Also excludes the following from acting as CC/MCC: 995.91 (MCC) 995.92 (MCC) 998.59 (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 <i>Staphylococcus aureus</i> Septicemia only)

<i>Staphylococcus aureus</i> Septicemia	
ICD-9-CM Codes	Code Descriptors
038.11	<i>Staphylococcus aureus</i> septicemia
038.12	Methicillin-resistant <i>Staphylococcus aureus</i> septicemia
995.91	Sepsis
995.92	Severe sepsis
998.59	Other postoperative infection

We solicited comments on each of the statutory criteria, with particular focus on the degree to which this condition can be considered reasonably preventable through the application of evidence-based guidelines.

Comment: Many commenters described difficulty in determining whether an infection was present upon admission, as the development of infection while in a hospital may not necessarily indicate that the infection was hospital-acquired. The commenters suggested that *Staphylococcus aureus* septicemia may also result from permanent tunneled and nontunneled catheters used in cancer patients or through dialysis shunts.

The commenters asserted that the risk of infection may be higher for different subpopulations of patients.

A large number of commenters suggested that the CDC's guidelines specific to vascular catheter-associated infections do not extend to *Staphylococcus aureus* septicemia generally. However, because the majority of *Staphylococcus aureus* septicemia events are related to catheters and skin lesions, commenters also argued that the previously-selected HAC, vascular catheter-associated infections, will already capture the vast majority of preventable *Staphylococcus aureus* septicemia events. According to the commenters, adopting *Staphylococcus aureus* septicemia as an additional condition would yield little quality improvement but could cause expensive and unnecessary treatments for both hospitals and patients.

Response: In light of these public comments, we are not selecting *Staphylococcus aureus* septicemia as an HAC in this final rule. If evidence warrants, we may consider proposing *Staphylococcus aureus* septicemia as an HAC in the future. We note that several commenters recognized that *Staphylococcus aureus* septicemia cases are being addressed through the vascular catheter-associated infection HAC that was selected in the FY 2008 IPPS final rule with comment period.

g. *Clostridium difficile*-Associated Disease (CDAD)

Clostridium difficile is a bacterium that colonizes the gastrointestinal (GI) tract of a certain number of healthy people as well as being present on numerous environmental surfaces. 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 the 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.

In the IPPS FY 2009 proposed rule, we presented the following information for consideration:

HAC Candidate	Medicare Data (FY 2007)	CC/MCC (ICD-9-CM Code)	Selected Evidence-Based Guidelines
<i>Clostridium difficile</i> -Associated Disease (CDAD)	<ul style="list-style-type: none"> ● 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

<i>Clostridium difficile</i>-Associated Disease	
ICD-9-CM Code	Code Descriptor
008.45	<i>Clostridium difficile</i>

We solicited comments on each of the statutory criteria, with particular focus on the degree to which CDAD can be reasonably prevented through the application of evidence-based guidelines.

Comment: The majority of commenters addressed preventability and the inability to distinguish between community-acquired and hospital-acquired infections without culturing each patient to determine strain or type of infection. The commenters emphasized that CDAD is a known adverse side effect of appropriate broad spectrum antibiotic use. One commenter suggested establishing a unique ICD-9-CM code to identify cases of CDAD that occur other than as a side effect of broad spectrum treatment to distinguish situations of patient-to-patient transmission of *Clostridium difficile* that are more likely to be considered reasonably preventable. Commenters further asserted that the appropriate use of proton pump inhibitors and H2 blockers is also associated with CDAD infections and outbreaks. Many commenters stated that no specific evidence-based prevention guidelines are currently available, rather the CDC guidelines apply to patient-to-patient transmissions generally and do not apply to CDAD specifically. Many commenters addressed the difficulty of distinguishing between community-acquired and hospital-acquired infection as a barrier to adopting CDAD as an HAC.

Response: In light of these public comments, we are not selecting CDAD as an HAC in this final rule. However, we continue to receive strong support from consumers and purchasers to include CDAD as an HAC, and we will continue to consult with the CDC regarding the evidence-based prevention guidelines and coding for CDAD. If evidence warrants, we may consider proposing CDAD as an HAC in the future.

h. Legionnaires’ Disease

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. 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.

In the FY 2009 IPPS proposed rule, we presented the following information for consideration:

HAC Candidate	Medicare Data (FY 2007)	CC/MCC (ICD-9-CM Code)	Selected Evidence-Based Guidelines
Legionnaires’ Disease	<ul style="list-style-type: none"> ● 351 cases ● \$86,014/hospital stay 	482.84 (MCC)	Available at the Web site: http://www.cdc.gov/ncidod/dbmd/diseaseinfo/legionellosis_g.htm Available at the Web site: http://www.legionella.org/

Legionnaires’ Disease	
ICD-9-CM Code	Code Descriptor
482.84	Legionnaires’ disease

We requested public comment regarding the applicability of each of the statutory criteria to Legionnaires’ Disease, particularly addressing the degree of preventability of this condition through the application of evidence-based guidelines and the degree to

which hospital-acquired Legionnaires' Disease can be distinguished from community-acquired cases. We also sought comments on additional water-borne pathogens that would qualify for the HAC provision by meeting the statutory criteria.

Comment: Many commenters noted that Legionnaires' Disease is not a high volume condition and questioned whether it should be prioritized as an HAC. In addition, the commenters emphasized that CDC's Environmental Infection Control Guidelines recognize that the mere presence of the bacterium *Legionella* in the water supply is not necessarily associated with Legionnaires' Disease, and that without evidence of a dose-response relationship, surveillance and treatment is not recommended. The commenters stated that even when decontamination efforts are pursued, there is no guarantee that treatment will ensure *Legionella* can be completely eradicated from hospital water intakes without damaging infrastructures. In addition, many commenters expressed concern regarding the unintended consequence of increasing the use of costly sterile water in hospitals.

When addressing the degree to which hospital-acquired Legionnaires' Disease can be distinguished from community-acquired cases, the commenters noted that the epidemiologic strain causing the disease is widespread in the community.

Response: In light of these public comments, we are not selecting Legionnaires' Disease as an HAC in this final rule. Although we are not selecting Legionnaires' Disease as an HAC in this final rule, we will continue to consult with the CDC about the evidence-based prevention guidelines. If evidence warrants, we may consider Legionnaires' Disease and other water-borne pathogens suggested by commenters and

noted in section II.F.9. of this preamble (Enhancement and Future Issues) as HACs in the future.

i. Iatrogenic Pneumothorax

Iatrogenic pneumothorax refers to the accidental introduction of air into the pleural space, which is the space between the lung and the chest wall, by medical treatment or procedure. 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 the pleural space, including needle biopsy of the lung, thoracentesis, central venous catheter placement, pleural biopsy, tracheostomy, and liver biopsy. Iatrogenic pneumothorax can also occur secondary to positive pressure mechanical ventilation when an air sac in the lung ruptures, allowing air into the pleural space. In the FY 2009 IPPS proposed rule, we presented the following information for consideration:

HAC Candidate	Medicare Data (FY 2007)	CC/MCC (ICD-9-CM Code)	Selected Evidence-Based Guidelines
Iatrogenic Pneumothorax	<ul style="list-style-type: none"> ● 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	
ICD-9-CM Code	Code Descriptor
512.1	Iatrogenic pneumothorax

We solicited public comment on the applicability of each of the statutory criteria to this condition. We were particularly interested in receiving comments on the degree to which iatrogenic pneumothorax could be considered reasonably preventable through the application of evidence-based guidelines.

Comment: Most commenters opposed the selection of iatrogenic pneumothorax as an HAC. They indicated that the evidence-based guidelines often acknowledge that iatrogenic pneumothorax is a known, relatively common risk for certain procedures. Further, with regard to evidence-based guidelines, many commenters opposed designation of this condition as an HAC due to a lack of consensus within the medical community regarding its preventability.¹⁷ Some commenters offered suggestions to exclude certain procedures or situations, including central line placement, thoracotomy, and use of a ventilator, if iatrogenic pneumothorax were to be selected as an HAC.

Response: In light of these public comments, we are not selecting iatrogenic pneumothorax as an HAC in this final rule. Although we are not selecting iatrogenic pneumothorax as an HAC in this final rule, we do recognize this as an adverse event that occurs frequently. We will continue to review the development of evidence-based guidelines for the prevention of iatrogenic pneumothorax. If evidence warrants, we may consider iatrogenic pneumothorax as an HAC in the future.

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

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

¹⁷ Accidental Iatrogenic Pneumothorax in Hospitalized Patients. Zhan et al. Medical Care 44(2):182-6, 2006 Feb.

“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. In the proposed FY 2009 IPPS rule, we presented the following information for consideration:

Condition	Medicare Data (FY 2007)	CC/MCC (ICD-9-CM Code)	Selected Evidence-Based Guidelines
<u>Methicillin-resistant <i>Staphylococcus aureus</i> (MRSA)</u> (Code V09.0 includes infections with microorganisms resistant to penicillins)	<ul style="list-style-type: none"> ● 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

During its March 19-20, 2008 meeting, the ICD-9-CM Coordination and Maintenance Committee discussed several new codes to more accurately capture MRSA. The following new codes will be implemented on October 1, 2008:

Methicillin-Resistant <i>Staphylococcus aureus</i>	
ICD-9-CM Codes	Code Descriptors
038.12	Methicillin-resistant <i>Staphylococcus aureus</i> septicemia
041.12	Methicillin-resistant <i>Staphylococcus aureus</i> in conditions classified elsewhere and of unspecified site
482.42	Methicillin-resistant Pneumonia due to <i>Staphylococcus aureus</i>

Methicillin-Resistant <i>Staphylococcus aureus</i>	
ICD-9-CM Codes	Code Descriptors
V02.53	Carrier or suspected carrier of Methicillin-susceptible <i>Staphylococcal aureus</i>
V02.54	Carrier or suspected carrier of Methicillin-resistant <i>Staphylococcal aureus</i>
V12.04	Personal history of Methicillin-resistant <i>Staphylococcal aureus</i>

Though we did not propose MRSA as a candidate HAC in the FY 2009 IPPS proposed rule, MRSA can trigger the HAC payment provision. For every infectious condition selected as an HAC, 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 (72 FR 47212), colonization by MRSA is not a reasonably preventable condition according to the current evidence-based guidelines. Therefore, MRSA does not meet the "reasonably preventable" statutory criterion for an HAC.

Comment: The majority of commenters strongly supported the CMS decision not to propose MRSA as an HAC candidate.

Response: We appreciate the support of the commenters and reiterate that MRSA is addressed by the HAC payment provision in situations where it triggers a condition that we have identified as an HAC. We also direct readers to a detailed discussion regarding coding of MRSA in section II.F.10.b. of this preamble. As we noted in the FY 2009 IPPS proposed rule (73 FR 23559), 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 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 its Web sites at: http://www.guideline.gov/browse/guideline_index.aspx and <http://www.ahrq.gov/clinic/ptsafety/pdf/ptsafety.pdf>.

8. Present on Admission Indicator Reporting (POA)

Collection of present on admission (POA) indicator data 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 (CR) No. 5679 (released June 20, 2007), CMS issued instructions requiring IPPS hospitals to submit POA indicator data for all diagnosis codes on Medicare claims. CMS also issued

CR No. 6086 (released June 30, 2008) regarding instructions for processing non-IPPS 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 CDC Web site:

<http://www.cdc.gov/nchs/dataawh/ftpserv/ftp/cd9/icdguide07.pdf> (POA reporting guidelines begin on page 92). Additional information regarding POA indicator reporting and application of the POA reporting options is available at the CMS Web site:

<http://www.cms.hhs.gov/HospitalAcqCond>. CMS has historically not provided coding advice, rather we collaborate with the American Hospital Association (AHA) through the *Coding Clinic* for ICD-9-CM. CMS has been collaborating with the AHA to promote the *Coding Clinic* for ICD-9-CM as the source for coding advice about the POA indicator.

There are five POA indicator reporting options, as defined by the ICD-9-CM Official Coding Guidelines:

Indicator	Descriptor
Y	Indicates that the condition was present on admission.
W	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.
N	Indicates that the condition was not present on admission.
U	Indicates that the documentation is insufficient to determine if the condition was present at the time of admission.
1	Signifies exemption from POA reporting. CMS established this code as a workaround to blank reporting on the electronic 4010A1. A list of exempt ICD-9-CM diagnosis codes is available in the <i>ICD-9-CM Official Coding Guidelines</i> .

In the FY 2009 IPPS proposed rule for the HAC payment provision (73 FR 23559), we proposed to pay the CC/MCC MS-DRGs only for those HACs coded with “Y” and “W” indicators.

Comment: Commenters overwhelmingly supported payment for both the POA “Y” and “W” options.

Response: We agree with commenters and are finalizing our proposal to pay for both the POA “Y” and “W” options. 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 proposed to not pay the CC/MCC MS-DRGs for HACs coded with the “N” indicator.

Comment: Commenters were in favor of not paying for the POA “N” indicator option.

Response: We agree with the commenters and are finalizing our proposal to not pay for the POA “N” indicator option.

Comment: The majority of commenters opposed not paying for the POA “U” indicator option. Commenters expressed that the reporting of the POA indicators is still new, and hospitals continue to learn how to apply them, as well as educate their physicians on the required documentation without which POA reporting is impossible.

Response: Although we recognize that POA indicator reporting is new for some IPPS hospitals, we are finalizing the proposed policy of not paying for the “U” option.

We believe that this approach will encourage better documentation and will result in more accurate public health data.

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 and POA indicators must be reported accurately on claims regardless of the fact that diagnoses coded with an “N” or “U” indicator may no longer trigger a higher paying MS-DRG. Medicare program integrity initiatives closely monitor for inaccurate coding and coding inconsistent with medical record documentation.

Although we proposed, and are now finalizing, the policy of not paying the CC/MCC MS-DRGs for HACs coded with the "U" indicator, we recognize that 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 sought public comments on the potential use of patient discharge status codes to identify exceptional circumstances.

Comment: The majority of commenters did not address the patient discharge status codes as an exception for payment when the “U” POA indicator is used. The commenters who did address this issue were in favor of using patient discharge status codes as an exception for payment.

Response: We will monitor the extent to which and under what circumstances the “U” POA indicator code is used. In the future, we may consider proposing use of the patient discharge status codes to recognize exceptions for payment.

9. Enhancement and Future Issues

In section II.F.9. of the FY 2009 IPPS proposed rule (73 FR 23560), we encouraged the public to provide ideas and models for combating preventable HACs through the application of VBP principles. We note that we are not proposing Medicare policy in this discussion. However, we believe that collaborating with stakeholders to improve the HAC policy is another step toward fulfilling VBP’s potential to provide better health care for Medicare beneficiaries.

To stimulate reflection and creativity, we presented several enhancement options, including: (a) applying risk adjustment to make the HAC payment provision more precise; (b) collecting HAC rates to obtain a more robust longitudinal measure of a hospital’s incidence of these conditions; (c) using POA information in various ways to decrease the incidence of preventable HACs; (d) adopting ICD–10 to facilitate more precise identification of HACs; (e) applying the principle of the IPPS HAC payment provision to Medicare payments in other care settings; (f) using CMS’ authority to address events on the NQF’s list of Serious Reportable Adverse Events; and (g) additional potential candidate HACs, suggested through comment, for future consideration.

a. Risk-Adjustment of Payments Related to HACs

In the FY 2009 IPPS proposed rule, we suggested that payment adjustments made when one of the selected HACs occurs could be made more precise by reflecting various sources and degrees of individual patient or patient population risk. For example, a patient's medical history, current health status (including comorbidities), and severity of illness can affect the expected occurrence of conditions selected as HACs. Rather than not paying any additional amount when a selected HAC occurs during a hospitalization, payment reductions could be related to the expected occurrence of that condition (that is, the less likely the complication, the greater the payment reduction).

In general, most commenters supported the idea of risk-adjusted payments for HACs, noting that proportional payments could reduce the risk of unintended consequences, as compared to the current HAC payment policy, through more equitable treatment of both hospitals and patients. Specifically, a few commenters expressed concern that all-or-nothing payment for HACs may disproportionately impact urban, teaching, and academic hospitals that treat under-served populations. Commenters stated that, because these populations may be at greater risk for HACs, risk-adjusted payments could allow all hospitals to continue treating high-risk populations without being penalized for treating riskier patients.

Commenters proposed addressing patient risk factors on both the individual and population levels. The majority of commenters supported assessing risk at the individual patient level. Although this approach may offer the most precise risk adjustment, current technology and resources limit the ability to risk adjust at this level, as we discussed in

the FY 2009 IPPS proposed rule. Risk adjustment at the subpopulation level, however, could capture and correct for high patient risk related to specific medical conditions. For example, many commenters noted that burn patients in particular are at high risk for some of the selected HACs, including infections. Other high-risk patient populations mentioned by commenters included trauma, immunosuppressed, and palliative care patients.

Other commenters emphasized that for certain HACs, risk adjustment strategies would not be appropriate. Commenters stated that payments for “never events,” such as retention of a foreign object after surgery, air embolism, and blood incompatibility, should never be adjusted for risk because such occurrences can be considered absolutely preventable.

b. Rate-Based Measurement of HACs

In the FY 2009 IPPS proposed rule, we suggested that a hospital’s rates of HACs could be included as a measurement domain within each hospital’s total performance score under a pay-for-performance model like the Medicare Hospital Value-Based Purchasing Plan. (We refer readers to section IV.C. of this preamble for a discussion of the Plan.) We asserted that 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, while public reporting of the measured rates of HACs would give hospitals an additional, nonfinancial incentive to prevent occurrence of the conditions.

The majority of commenters preferred a standardized framework for rate-based measurement and VBP payment implications for HACs, as opposed to not being paid the higher MS-DRG amount. Many commenters suggested determining expected rates of HACs and using those expected rates as benchmark targets for comparison, rewarding providers who stay at or below benchmark, while decreasing payment for those who exceed the benchmark.

Though the majority of commenters supported rate-based measurement of HACs, some commenters raised issues. A number of commenters noted that the extremely low incidence of “never events” could preclude meaningful rate-based measurement of the occurrence of those events. Other commenters opposed public reporting of the rates as a nonfinancial VBP incentive.

c. Use of POA Information

In the FY 2009 IPPS proposed rule, we asserted that POA data could be used to better understand and prevent the occurrence of HACs. Medicare data could be analyzed separately or in combination with private sector or State POA data, which are currently available in certain States. Health services researchers could use these data in a variety of ways to assess the incidence of HACs and to identify best practices for HAC prevention. In addition, publicly reported POA data could also be used to support better health care decision making by Medicare beneficiaries, as well as other health care consumers, professionals, and caregivers.

Commenters addressed various uses of POA data, including informing risk adjustment, making benchmark comparisons between and within hospitals, and public

reporting. Commenters noted that POA data have important applications to risk adjustment for quality measurement. In the absence of risk adjustment mechanisms, one commenter suggested that CMS expand POA codes beyond those discussed in section II.F.8. of the preamble of the proposed rule to include a code that would preclude reduced payment if the provider attests that “the HAC is believed to be the result of a natural disease process/severe patient condition and is not believed to be indicative of the level of the quality of care provided.” Nearly all commenters addressing the use of POA data urged CMS to provide hospitals with timely feedback of POA information. Specifically, many commenters wanted CMS to provide each hospital with its POA rates and comparisons to peer hospitals.

Commenters’ responses to publicly reporting POA data were mixed. A large number of commenters opposed public reporting of POA data, arguing that only measures endorsed by the NQF and adopted by the HQA should be considered for public reporting. A few commenters voiced concern that public reporting would discourage hospitals from accurately reporting POA data. A few commenters suggested a phased-in public reporting timeline for POA data, allowing hospital data to remain confidential for a period while hospitals adjust to new coding and reporting requirements. Nearly all commenters stated that if, POA data were to be publicly reported, the data should be posted on Hospital Compare.

d. Transition to ICD-10

In the FY 2009 IPPS proposed rule, we suggested that adopting ICD-10 codes to replace the outdated, vague codes of ICD-9-CM would allow CMS to capture more

accurate and precise information about HACs.¹⁸ Noting that the current ICD-9-CM codes are over three decades old, we proposed that ICD-10 codes more precisely capture information using 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 has 125 codes to capture this information.

A number of commenters supported the adoption of ICD-10. Many of the commenters pointed out that the adoption of ICD-10 would facilitate more precise identification of HACs. Several commenters supported the adoption of ICD-10 with an appropriate 2-year transition period. Commenters stated that they have known since the 1990's that the ICD-9-CM coding structure was reaching its limits, and it was becoming increasingly difficult to identify new technologies that are commonly used in today's medical practices. The commenters stated that there is a critical need to move in a timely manner to CM and ICD-10-PCS because hospitals would have the ability to capture data more accurately, thus providing higher quality and more accurate data for reporting. Commenters urged the implementation of ICD-10 to ensure the availability of appropriate, consistent, and accurate clinical information reflective of patients' medical conditions and care provided. Commenters asserted that this would allow the nation to better measure quality, implement value-based purchasing, identify hospital-acquired conditions, and continue to refine a prospective payment system that improves recognition of variances in severity of illness.

¹⁸ In the FY 2009 IPPS proposed rule, there is a typographical error such that the rule refers to ICD-10-PCS (procedure codes) rather than ICD-10 (diagnosis codes).

One commenter expressed concern about the benefit of moving to ICD-10 and believed that its benefit in the outpatient setting had not been demonstrated. The commenter expressed concern about the cost of moving to a new coding system with the need to update software and redraft policies.

e. Healthcare-Associated Conditions in Other Payment Settings

In the FY 2009 IPPS proposed rule, we suggested that the broad principle of Medicare not paying for preventable healthcare-associated conditions could potentially be applied in Medicare payment settings beyond IPPS hospitals, including for example, hospital outpatient departments, SNFs, and physician practices. Although the implementation would be different for each setting, alignment of incentives across settings of care is an important goal for all of CMS' VBP initiatives. To stimulate public input, we have included a discussion in several Medicare payment regulations regarding application of the broad principle of Medicare not paying for preventable healthcare-associated conditions in payment settings beyond IPPS. The discussion was included in the following regulations: FY 2009 IRF proposed rule (73 FR 22688), the CY 2009 OPPTS/ASC proposed rule (73 FR 41547), the FY 2009 SNF proposed rule (73 FR 25932), and the FY 2009 LTCH final rule (73 FR 26829).

Commenters' reaction to the notion of applying the IPPS HAC payment provision to other settings was mixed. A number of commenters recognized that this use of payment incentives could promote better continuity of care (including documentation) and a reduction in avoidable readmissions. Commenters noted that aligned payment incentives would force pre- and post-acute care settings to share accountability for

preventing healthcare-associated conditions. One commenter who supported expanding the policy to nursing homes suggested that CMS consider including dehydration measures for nonpayment in that setting.

While many commenters recognized potential benefits, many other commenters raised concerns or opposed implementing the IPPS HAC payment provision in other settings. Generally, commenters who were opposed to expanding the policy's reach believed that doing so would be premature until CMS assesses the impacts of the policy in the IPPS setting. Commenters also raised concerns about applying the policy in particular settings. For example, many commenters stated that Medicare payment for the physician setting is extremely different from that of the IPPS setting and that attribution issues in particular would make the policy difficult to accurately and fairly implement.

Commenters suggested that, if CMS did implement a similar policy in the physician setting, the agency should ensure that the policy does not create disincentives for treating high-risk patients. From the long-term care perspective, one commenter noted that the risk of an adverse event occurring increases with the duration of the stay and so such a policy would be particularly concerning for LTCHs.

f. Relationship to NQF's Serious Reportable Adverse Events

In the FY 2009 IPPS proposed rule, we discussed how CMS has applied its authority to address the events on the NQF's list of Serious Reportable Adverse Events (also known as "never events"). We have adopted a number of items from the NQF's list of events as HACs. However, we also discussed that the HAC payment provision is not ideally suited to address every condition on the NQF's list.

Commenters unanimously asserted that CMS should not pay for never events. However, many commenters were concerned about the widespread misperception that HACs are never events, which can be considered absolutely preventable. Commenters urged CMS to explicitly differentiate its “reasonably preventable” HACs from the “never events” on the NQF’s list of Serious Reportable Adverse Events.

Commenters suggested alternatives to Medicare’s existing authority under the HAC provision to address never events. One commenter suggested that no higher CC/MCC MS-DRG payment should be made for claims including a selected HAC if that HAC overlaps with a never event. This would preclude a higher MS-DRG payment regardless of whether any other CC/MCCs that would otherwise trigger a higher MS-DRG payment are present on the claim.

g. Additional Potential Candidate HACs, Suggested Through Comment

We received the following suggestions of potential candidates for the HAC payment provision:

- Surgical site infection following device procedures
- Failure to rescue
- Death or disability associated with drugs, devices, or biologics
- Events on the NQF’s list of Serious Reportable Adverse Events, not previously

addressed by the HAC payment provision

- Dehydration
- Malnutrition

- Water-borne pathogens, not previously addressed by the HAC payment provision.

We reiterate that we are not making policy in this subsection; rather, we are providing a summary of the comments. We would like to thank commenters for the thoughtful comments received, and we will take this input into consideration as we develop any future regulatory and/or legislative proposals to refine and enhance the HAC payment provision.

10 HAC Coding

This HAC coding section addresses additional coding issues that were raised by commenters regarding the selected and candidate HACs.

a. Foreign object retained after surgery

Comment: One commenter requested that CMS provide technical guidance on how to address certain situations related to retained foreign objects. According to the commenter, in certain circumstances, it may be in the best interest of the patient not to remove the object. For example, the commenter stated that leaving a patient under anesthesia for a prolonged period of time and displacing internal organs in search of a surgical object left in the body may be more harmful than leaving the object inside the patient and completing a surgery in an expedited fashion. The commenter suggested that CMS clearly specify that the policy applies to an *unintended* retention of a foreign object, to allow physicians to exercise clinical judgment regarding the relative risk of leaving an object versus removing it.

Response: We believe that ICD-9-CM codes 998.4 and 998.7 clearly describe the application of the HAC provision to a foreign body “inadvertently” or “accidentally” left in a patient during a procedure.

b. MRSA

Comment: Commenters raised issues regarding the MRSA coding. One commenter stated that the recent addition of unique MRSA ICD-9-CM codes will allow for improved tracking of MRSA infections and will complement the surveillance efforts underway at the CDC and the AHRQ. The commenter stated that the creation of new MRSA-specific codes will generate better data on which to base important MRSA prevention and management policy decisions, and will allow the health care community to more effectively address this growing public health problem. The commenter stated that CMS could reflect the increased utilization of resources associated with MRSA diagnoses by making CC/MCC classifications for the following three MRSA codes: code 038.12 (Methicillin-resistant *Staphylococcus aureus* septicemia – MCC); code 482.42 (Methicillin-resistant pneumonia due to *Staphylococcus aureus* – MCC); and code 041.12 (Methicillin-resistant *Staphylococcus aureus* in conditions classified elsewhere and of unspecified site – CC).

As justification for this request, the commenter pointed out that the predecessor codes for 038.12 and 482.42 are MCCs. The predecessor code for 038.12 is 038.11 (*Staphylococcus aureus* septicemia), which is an MCC. The predecessor code for 482.42 is 482.41 (Pneumonia due to *Staphylococcus aureus*), which is also an MCC.

The commenter's justification for making 041.12 a CC is not based on the predecessor code's CC/MCC assignment. The commenter acknowledged the predecessor code, 041.11 (*Staphylococcus aureus*) is a non-CC. The commenter reviewed data provided in the development of the original CC/MCC classifications for the MS-DRGs and acknowledged that the data did not clearly support making predecessor code 041.11 a CC. The commenter also recognized that clinical judgment was also used in deciding the non-CC/CC/MCC classification of each diagnosis code. Given CMS' use of both data and clinical evaluation, the commenter stated that code 041.11 "captures many minor and routine bacterial infections that are relatively simple and inexpensive to treat – in other words, diagnoses that do not lead to substantially increased use of hospital resources." Therefore, the commenter found it understandable that the predecessor code, 041.11, was classified as a non-CC.

However, the commenter believed that the new MRSA specific code, 041.12, will allow differentiation between MRSA and other infections and will likely show that these MRSA infections are significantly more difficult and expensive to treat. Therefore, the commenter requested that code 041.12 be classified as a CC.

Response: The final CC/MCC classifications for new ICD-9-CM diagnosis codes are shown in Table 6A of the Addendum to this final rule. This table shows that we have classified codes 038.12 (Methicillin-resistant *Staphylococcus aureus* septicemia) and 482.42 (Methicillin-resistant pneumonia due to *Staphylococcus aureus*) as MCCs. We agree that, based on the predecessor code and our clinical evaluation, this MCC classification is warranted.

We disagree with classifying code 041.12 (Methicillin-resistant *Staphylococcus aureus* in conditions classified elsewhere and of unspecified site) as a CC. As is shown in Table 6A, we have classified this code as a non-CC. We agree with the commenter that the predecessor code was a non-CC. However, we also point out that all codes in the 041.00 – 041.9 category of bacterial infection in conditions classified elsewhere and of unspecified site are non-CCs. All of the codes in this category are used as an additional code to identify a bacterial agent in diseases that are classified by another more precise code. For instance, if a patient has a MRSA urinary tract infection or infected toe nail, one would assign a code for the specific type and location of the infection (for example, urinary tract infection or infected toenail bed) and an additional code to fully describe the bacterial agent, such as MRSA. The CC/MCC classification would be determined by the more precise infection code (for example, urinary tract infection or infected toenail bed).

We do not believe it is appropriate to change the CC/MCC classification of one of the codes in the category of bacterial infection in conditions classified elsewhere and of unspecified site to a CC while leaving all of the others as non-CCs. Further, we believe it is more appropriate to assign a CC/MCC classification based on the more precise description of the patient's infection such as pneumonia, septicemia, or nail bed infection. Therefore, we have made code 041.12 a non-CC, as shown in Table 6A of the Addendum to this final rule.

c. POA

Comment: Commenters raised issues regarding the timing of laboratory testing (receiving results in 48-72 hours) and the effect this may have on the POA indicator

reported for the HAC candidates proposed, such as *Staphylococcus aureus* septicemia and CDAD. The commenters expressed concern that when a lab test including cultures is performed upon admission, the results may not be available until 48-72 hours later. The commenters were not clear on how the POA indicator would be applied in this scenario.

Response: We acknowledge the commenter's concerns regarding correct assignment of the POA indicator when lab tests are involved. We refer the reader to the ICD-9-CM Official Guidelines for Coding and Reporting, Appendix I, Present on Admission Reporting Guidelines. These guidelines have been updated to address the issue of timeframe for POA identification and documentation. The updated guidelines recognize that in some clinical situations it may take period of time after admission before a definitive diagnosis can be made. Determination of whether the condition was present on admission will be based on the applicable POA guidelines or on the physician's best clinical judgment. The guidelines address several scenarios, including those with infections and organisms, and how to assign the POA indicator. We also note that in this final rule we decided not to select at this time the proposed HAC cited by the commenter, *Staphylococcus aureus* septicemia, as an HAC.

11. HACs Selected for Implementation on October 1, 2008

The following table sets out a complete list of the HACs selected for implementation on October 1, 2008 in this final rule and in the FY 2008 IPPS final rule with comment period:

HAC	CC/MCC (ICD-9-CM Codes)
Foreign Object Retained After Surgery	998.4 (CC) 998.7 (CC)
Air Embolism	999.1 (MCC)
Blood Incompatibility	999.6 (CC)
Pressure Ulcer Stages III & IV	707.23 (MCC) 707.24 (MCC)
Falls and Trauma: - Fracture - Dislocation - Intracranial Injury - Crushing Injury - Burn - Electric Shock	Codes within these ranges on the the CC/MCC list: 800-829 830-839 850-854 925-929 940-949 991-994
Catheter-Associated Urinary Tract Infection (UTI)	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)

HAC	CC/MCC (ICD-9-CM Codes)
Vascular Catheter-Associated Infection	999.31 (CC)
Manifestations of Poor Glycemic Control	250.10-250.13 (MCC) 250.20-250.23 (MCC) 251.0 (CC) 249.10-249.11 (MCC) 249.20-249.21 (MCC)
Surgical Site Infection, Mediastinitis, Following Coronary Artery Bypass Graft (CABG)	519.2 (MCC) And one of the following procedure codes: 36.10–36.19
Surgical Site Infection Following Certain Orthopedic Procedures	996.67 (CC) 998.59 (CC) And one of the following procedure codes: 81.01-81.08, 81.23-81.24, 81.31-81.83, 81.83, 81.85
Surgical Site Infection Following Bariatric Surgery for Obesity	<i>Principal Diagnosis</i> – 278.01 998.59 (CC) And one of the following procedure codes: 44.38, 44.39, or 44.95
Deep Vein Thrombosis and Pulmonary Embolism Following Certain Orthopedic Procedures	415.11 (MCC) 415.19 (MCC) 453.40-453.42 (MCC) And one of the following procedure codes: 00.85-00.87, 81.51-81.52, or 81.54

G. Changes to Specific MS-DRG Classifications

1. Pre-MDCs: Artificial Heart Devices