

What ASMBS Members Need to Know About: New Medicare Payment Policy Governing Bariatric Surgery and Hospital Acquired Conditions (HACs)

Robin Blackstone, MD, FACS, FASMBS

Beginning October 1, 2008, Medicare will no longer pay hospitals for the additional costs of treating a patient that acquire certain conditions (including infections) while in the hospital. Included in this list of specific Hospital Acquired Conditions (HACs) is surgical site infection following bariatric surgery for the treatment of morbid obesity. The following article outlines both the genesis of this new Medicare policy and its likely impact on patient access to care and hospital reimbursement for bariatric surgery.

Why has the Medicare program adopted this policy?

In 2005, Congress enacted and President Bush signed into law the Deficit Reduction Act of 2005 (DRA). Among other things, the DRA directs the Centers for Medicare and Medicaid Services (CMS) to refuse to reimburse hospitals for the additional costs of treating a patient that acquires a condition (including an infection) while in the hospital.

The HAC-Present on Admission (POA) law was enacted in response to concerns from the public and some policymakers about the occurrence of so-called “never-events”-- conditions that were acquired or occurred in the hospital that reasonably could have been prevented. In 1999, the Institute of Medicine (IOM) in its report “To Err is Human” recommended that errors and adverse events that occur during the delivery of health care services be reported in a systematic way in order to prevent such errors from occurring in the future.

Following the IOM report, the National Quality Forum (NQF) developed and adopted a list of “serious reportable events” to facilitate reporting and public accountability. Neither the NQF nor IOM recommendations advocated linking payment policy to efforts to report information and perform systematic analysis for serious reportable events. However, coinciding with these efforts, some policymakers on Capitol Hill and in the Administration and private purchasers began to pursue policies known as “pay for performance” as a means to

incentivize performance improvement activities. Enactment of the HAC-POA law was a first step by Congress and the Administration in this direction.

Does the HAC-POA policy apply to all Medicare payment systems?

Currently, the HAC-POA law only applies to payments made to hospitals under the Medicare Hospital Inpatient Prospective Payment System (IPPS) and its corresponding Diagnosis Related Groups (DRG) payment scheme. The provision does not apply to Rehabilitation Hospitals, Psychiatric Hospitals or any other facility not paid under the Medicare Hospital IPPS. However, physicians that admit and care for patients in hospitals are directly impacted, given their responsibility to treat their patients in the inpatient setting, as well as by the present-on-admission coding requirements of the law.

What are the specific requirements outlined in the DRA regarding Medicare's HAC-POA policy?

The DRA requires hospitals to begin reporting secondary diagnoses that are present on the admission of patients, beginning with discharges on or after October 1, 2007. The DRA also requires the Secretary of the U.S. Department of Health and Human Services to, by October 1, 2007, identify at least two conditions that: (a) are high cost or high volume or both; (b) result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis; and (c) could reasonably have been prevented through the application of evidenced-based guidelines.

How does CMS define "present on admission?"

Present on admission is defined by CMS as "present at the time the order for inpatient admission occurs – conditions that develop during an outpatient encounter, including emergency department, observation, or outpatient surgery, are considered as present on admission." Beginning October 1, 2008, CMS cannot assign a case to a higher DRG based on the occurrence of one of the CMS-selected conditions if that condition was acquired during the hospitalization.

How did CMS determine the specific list of Hospital Acquired Conditions?

In devising its recommended list of conditions, CMS and the Centers for Disease Control and Prevention reviewed the scientific evidence for a particular intervention and consulted with scientists, clinicians, and policymakers. In addition to being deemed a condition that could “reasonably have been prevented through the application of evidenced-based guidelines” as required by the law, the condition has to be one for which there exists an ICD-9 code.

In October 2007, after considering comments on the proposed list of six HACs published in the 2008 Hospital IPPS Proposed Rule, CMS issued the final rule that included the final list of eight conditions that would trigger, beginning October 1, 2008, a higher DRG for nonpayment as either a complicating condition (CC) or major complicating condition (MCC): 1) Object Left in Surgery; 2) Air Embolism; 3) Blood Incompatibility; 4) Catheter-Associated Urinary Tract Infection; 5) Pressure Ulcers; 6) Vascular Catheter-Associated Infection; 7) Surgical Site Infection – Mediastinitis after Coronary Artery Bypass Graft; and 8) Falls and Trauma – Fractures, Dislocations, Intracranial Injuries, Crushing Injuries, Burns

Were there other conditions that CMS listed in the 2008 Hospital IPPS final rule that could be added to the HAC list for 2009?

Yes, the agency also listed conditions being considered for inclusion in the proposed rule for the 2009 IPPS. These conditions were: 1) Ventilator-Associated Pneumonia; 2) Staphylococcus Aureus Septicemia; and 3) Deep Vein Thrombosis/Pulmonary Embolism. CMS also listed several conditions that it determined, after exhaustive consideration, needed further analysis to determine if they should be included in the future. These were: 1) Methicillin Resistant Staphylococcus Aureus; 2) Clostridium Difficile-Associated Disease; and 3) Wrong-Site Surgery.

When did CMS first mention adding surgical site infections following bariatric surgery to the HAC list?

On April 13, 2008, when CMS released the proposed IPPS rule for 2009, which included a proposal to add the following nine new conditions to the HAC list for

nonpayment beginning on October 1, 2008: 1) **Surgical site infections (SSIs) following specific elective procedures, including Laparoscopic Gastric Bypass and Gastroenterostomy**, Total Knee Replacement and Ligation and Stripping of Varicose Veins; 2) Staphylococcus Aureus Septicemia; 3) Clostridium Difficile-Associated Disease; 4) Ventilator-Associated Pneumonia; 5) Deep Vein Thrombosis/Pulmonary Embolism; 6) Legionnaires' Disease; 7) Iatrogenic Pneumothorax; 8) Delirium; and 9) Extreme Glycemic Aberrancies: Diabetic Ketoacidosis, Nonketotic Hyperosmolar Coma, Diabetic Coma, Hypoglycemic Coma.

What advocacy steps did ASMBS take to address this proposed policy?

On June 2, 2008, ASMBS submitted in-depth comments to CMS that focused on surgical site infections following laparoscopic or open Gastric Bypass and also on Deep Vein Thrombosis/Pulmonary Embolism. In addition, ASMBS leaders reached out to the American College of Surgeons and the American Medical Association and urged both groups to include strong language regarding the inclusion of gastric bypass and DVT/PE on the agency's proposed HAC list for the 2009 IPPS.

What did ASMBS specifically say about SSIs following gastric bypass procedures?

In ASMBS's June 2, 2008 comment letter, ASMBS President-Elect Dr. John Baker commented that:

"The ASMBS does not believe that surgical site infections (SSIs) following open or laparoscopic gastric bypass are appropriate for the HAC list. First, SSIs are not events that can be uniformly prevented and do not meet CMS' "could reasonably have been prevented through the application of evidence-based guidelines" criterion. SSIs can occur even when evidence-based guidelines are followed and it is not possible to always predict whether someone will get an infection.

The National Nosocomial Infections Surveillance system (NNIS) data showed that in low risk patients the mean rate of SSI's per 100 patients undergoing gastric operations was 2.63 and in high risk patients and 8.82 per 100 patients. However, the rate mentioned by Medicare for SSI's under the DRG for obesity was 208 out of 10,700 cases in 2007 for a rate of 1.9%. Thus Medicare's current data show

equivalent or better outcomes for Medicare patients treated in Bariatric Centers of Excellence.”

CMS’s response to ASMBS comments on the proposed IPPS rule for 2009

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.

Source: Final Rule for the 2009 IPPS, which CMS published in the Federal Register on August 19, 2008.

What did ASMBS say about the occurrence of DVT/PE in post-surgical bariatric patients?

In ASMBS's June 2, 2008 comment letter, ASMBS President-Elect Dr. John Baker commented that:

"The ASMBS agrees that DVT/PE incidence can be reduced, but it cannot be completely eliminated through adherence to evidence-based guidelines. For example, unrecognized patient condition, such as Factor V Leiden mutation and Protein C deficiency, play a significant role in DVT/PE. Further, some bariatric patients are immobilized due to degenerative arthritis or their size and are therefore inherently at risk for DVT/PE. They may require other surgical procedures and often have pre-existing conditions increasing their risk of bleeding. In these cases, DVT prevention mechanisms can be used when it is clinically safe to do so, yet clots can occur anyway, despite the use of appropriate prevention mechanisms. Accordingly, DVT and PE should not be added to the HAC list."

In the final rule, CMS decided to limit the HAC regarding DVT/PE to following only certain orthopedic procedures.

What are the next steps for ASMBS to address these and other issues concerning bariatric surgery outlined in the final rule for the 2009 IPPS?

ASMBS leaders will be meeting with CMS staff in the near future to discuss the Society's concerns with both the agency's HAC policy and changes in hospital inpatient payments for obesity surgery resulting from implementation of the new Medicare Severity DRGs (see related editorial on MS-DRGs from ASMBS President-Elect John Baker).