ENCISION®
AEM® LAPAROSCOPIC INSTRUMENTS

AEM® Technology as a Means of Eliminating Never Events

Overview

In August 2007, the U.S. Department of Health and Human Services – Centers for Medicare and Medicaid Services (CMS) announced that for discharges of Medicare patients beginning on October 1, 2008, hospitals will no longer be reimbursed for the costs associated with several medical errors acquired during an inpatient stay. Hospitals will not receive additional payments for cases in which the secondary diagnosis or one of the selected "Never Events" was not present on admission and should not have occurred to a patient during hospitalization. Serious Reportable Adverse Events, also commonly referred to as "Never Events", are serious and costly medical errors that occur in a healthcare setting and can cause serious injury or death to patients, can increase costs to Medicare to treat the consequences of the error, and should have never occurred because they could have been reasonably prevented.

On August 2008, CMS released its acute care Inpatient Prospective Payment System (IPPS) payment final rule updating Medicare payments to hospitals for FY2009, adding three more conditions to the original eight conditions that were announced in August 2007. These payment policy changes are part of a federal initiative to improve patient safety and to promote higher quality and more efficient healthcare purchased by Medicare and Medicaid.

Many of the nation's largest insurance providers such as Cigna, Aetna, and Blue Cross Blue Shield have followed suit and announced that they will no longer pay for many of these reasonably preventable medical errors.

Impact on US Healthcare System

According the National Quality Forum, a non-profit, voluntary consensus standard-setting organization, adverse healthcare events are the leading cause of death and injury in the United States. The federal Agency for Healthcare Research and Quality estimates that preventable errors that can occur during or after surgery cost employers $1.5 billion annually. An article in the New York Times estimates that these medical mistakes purchased through Medicare cost taxpayers $400 billion per year. In 1999, the Institute of Medicine (IOM) attributed an estimated 98,000 death per year to medical errors. Another IOM study estimates that Never Events can add a range of charges to Medicare payments from $700/case for decubitus ulcers to $9,000 per case for post-operative sepsis. Another study estimates that medical errors may account for 2.4 million extra hospital days, $9.3 billion in excess charges for all payers, and 32,600 deaths.

Background

Definition of Never Events

The National Quality Forum compiled a list of 28 Serious Reportable Adverse Events or Never Events that are:

1. unambiguous -- clearly identifiable and measurable for reporting purposes;
2. usually preventable (some events may not be avoidable);
3. serious--resulting in death or loss of a body part, disability, or more than a transient loss of a body function;
4. indicative of a problem in a healthcare facility's safety system; and
5. important for public accountability or for public credibility.

Medicare and Medicaid Program

Medicare is the largest purchaser of healthcare services in the United States. Originally the Medicare program was designed as a "fee-for-service" payment system without quality controls, measurable patient outcomes, or cost controls. The Deficit Reduction Act of 2005 authorizes the Secretary of the Department of Health and Human Services to select Hospital-Acquired Conditions (HACs) that are:

1. high cost, high volume or both,
2. identified through ICD-9-CM diagnosis coding as Complicating Conditions or Major Complicating Conditions that result in a case being assigned to a higher paying Medicare Severity Diagnosis-Related Group when present as a secondary diagnosis, and
3. reasonably preventable through the application of evidence-based guidelines.

These new initiatives tie pay to performance with value-based purchasing and quality; therefore, paying for Never Events would be inconsistent with these initiatives. The Deficit Reduction Act allows the CMS to adjust payment for HACs as outlined in the IPPS FY2009 payment final rules. CMS has incorporated some of the National Quality Forum's list of Never Events into Medicare's list of HACs. The eleven (11) HACs that Medicare will not reimburse are as follows:

- Foreign object retained after surgery
- Air Embolism

- Blood Incompatibility
- Pressure Ulcers (Stages III & IV)
- Falls and Trauma (includes Fracture, Dislocation, Intracranial injury, Crushing Injury, BURN, and Electric Shock)
- Catheter-associated Urinary Tract Infection
- Vascular Catheter-associated Infection
- Manifestations of Poor Glycemic Control
- Surgical Site Infection (mediastinitis) following Coronary Artery Bypass Graft
- Surgical Site Infection following certain orthopedic procedures
- Surgical Site Infection following bariatric surgery for obesity
- Deep Vein Thrombosis and Pulmonary Embolism following certain orthopedic procedures

CMS initiatives addressing Never Events include six (6) event categories—Surgical, Product or Device, Patient Protection, Care Management, Criminal, and Environmental. The Never Event relevant to Encision's technology is as follows:

CMS Initiatives Addressing Never Events

Serious Reportable Adverse Event	CMS Initiative	Relevant ICD-9-CM Codes
Environmental Events		
Patient death or disability associated with a burn incurred from any source while being cared for in a healthcare facility*	HAC**	Generic category of injury codes: 940 through 949

* Note: Burns were included in the initial IPPS FY2008 final rule.
**Note: Falls, burns, and electric shock are grouped into one HAC.

AEM® Technology as a Solution

In September 2008, the American Society for Quality (ASQ) conducted an email survey to healthcare quality practitioners regarding procedures and technologies that hospitals could implement to reduce medical errors and steps that patients can also take. James M. Levett, M.D., who chairs the ASQ Healthcare Division, states, "The technologies have great potential for hospitals [in reducing never events]. Technology is the part we're missing."

Encision Inc. manufactures innovative medical devices that can prevent the Never Event or HAC associated with electrosurgical burns that can occur during laparoscopy. Many post-laparoscopic burn victims can suffer from perforated colons or other internal burn injuries. When left untreated, these complications can lead to peritonitis and even death.

Encision's patented active electrode monitoring is the only technology on the market that continuously shields and monitors its AEM laparoscopic instrument during surgery to prevent stray energy burns that can cause unintended injury to patients. Encision's flagship offering is patient safety.

Important Links and References for More Information

www.cms.hhs.gov/apps/media/fact_sheets.asp for more information on additional quality measures
www.whitehouse.gov/news/releases/2006/08/20060822-2.html President's Executive Order: Promoting Quality and Efficient Health Care in Federal Government
www.hhs.gov/valuedriven Four Cornerstones of Secretary of the Department of Health and Human Services' Value-driven Health Care Initiative
www.cms.hhs.gov/HospitalAcqCond for more information on CMS' HAC and POA initiative
www.cms.hhs.gov/AcuteInpatientPPS for more information on the FY2009 IPPS final rule
http://www.qualityforum.org/publications/reports/sre_2006.asp for National Quality Forum's Serious Reportable Events in Healthcare 2006 Update
www.msnbc.msn.com/id/26081421 Article by JoNel Aleccia, 8/12/08, "More states shred bills for awful medical errors"
www.asq.org/quality-report/reports/200810.html American Society for Quality, ASQ Quarterly Quality Report, October 2008
http://www.iom.edu/Object.File/Master/4/117/ToErr-8pager.pdf Institute of Medicine, "To Err Is Human: Building a Safer Health System", November 1999 Report
Pear, R., "Medicare Says It Won't Cover 'Preventable' Hospital Errors", *New York Times*, Sunday, August 19, 2007