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Never Events

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THE TOPIC OF NEVER EVENTS is an important development within the healthcare industry, bringing changes to the hospital environment in which many physicians practice. Those changes are a result of many hospitals' efforts to reduce these events.

Physicians should find value in being able to identify Never Events, and in understanding the impact of recent state and federal regulations on Never Event reporting and reimbursement, and preparing for coming changes in inpatient care.

The term "Never Event" was first introduced in 2001 by Ken Kizer, MD, former CEO of the National Quality Forum (NQF). There are currently 28 Never Events. They are grouped into six categories:

1. Surgical (*e.g.*, wrong site, wrong procedure, wrong person surgery, retained objects, intraoperative or immediately post-operative death in a normal healthy patient)
2. Product or device (*e.g.*, death or disability caused by contaminated drugs or devices, the use or function of a device or air embolism)
3. Patient protection (*e.g.*, infants released to the wrong parents, patient elopement or patient suicide)
4. Care management (*e.g.*, stage 3 or 4 pressure ulcers, death or serious disability caused by medication error, hemolytic reaction, hypoglycemia, kernicterus, spinal manipulative therapy or labor and delivery in a low risk pregnancy)
5. Environmental (*e.g.*, an oxygen or gas line containing the wrong gas or contaminated with a toxic substance, patient death or serious disability caused by fires, electrical shock, falls or restraints)
6. Criminal (*e.g.*, care ordered or provided by someone impersonating a licensed health care provider, sexual assault of a patient, abduction of a patient, death or significant injury caused by a physical assault).¹

In general, Never Events are difficult to defend in medical liability litigation, mostly due to the alarm associated with their occurrence and the tendency for them to occur as a result of failed patient-safety systems or substandard medical care. That is not to say, however, that these events cannot occur when a patient's care has been appropriate.

Healthcare providers should also be aware of Never Event reporting laws. For example, in September of 2006, the California Legislature adopted legislation that directs hospitals to report Never Events (referred to in the legislation as "adverse events").²

The Joint Commission considers all of the NQF Never Events to be "Sentinel Events." Accredited organizations are expected to identify and "respond appropriately" to all sentinel events, according to the Joint Commission. An appropriate response includes "conducting a timely, thorough, and credible root cause analysis; developing an action plan designed to implement improvements to reduce risk; implementing the improvements; and monitoring the effectiveness of those improvements." Although the Joint Commission does not mandate reporting, the organization encourages it.³ More information on sentinel event policies and requirements can be accessed on the Joint Commission website, www.jointcommission.org.

In addition to professional liability concerns, Joint Commission requirements and reporting mandates, hospitals will also experience increased difficulty obtaining reimbursement for treatment rendered as a result of a Never Event.

For example, in August 2007, the Centers for Medicare and Medicaid Services (CMS) announced that beginning October 1, 2008, Medicare will no longer pay at a higher weighted MS-DRG for 11 conditions (some are on the Never Events list) when acquired during a hospital stay. These conditions are referred to as "Hospital-acquired Conditions" (HACs). As anticipated, private health insurers are following CMS's lead in refusing to reimburse for care rendered as a result of a Never Event/HAC. For example, Aetna and WellPoint have started to include reimbursement refusal provisions in some of their contracts.^{4,5}

Although Never Event rules, regulations and guidelines are currently directed towards hospitals, individual healthcare providers will feel their effects. Hospitals, if they haven't already, will begin developing new policies and procedures to deal with these changes, and providers will be expected to comply with them.

Furthermore, it is anticipated that Never Event legislation and reimbursement limitations will be used in malpractice claims against individual providers to support allegations of medical negligence. Finally, some commentators suggest that the Medicare and private health insurer reimbursement limitations will be extended to individual providers.⁶

Keeping a Never Event from occurring is an appropriate goal for any healthcare provider. Consistently adhering to policies and procedures designed to guard against the occurrence of Never Events can protect patients, reduce liability exposure, reduce reporting burdens and preserve reimbursement rates.

NORCAL has provided risk management advice via the monthly *Claims Rx* and CME courses related to many of the 28 Never Events and CMS's HACs. Providers are encouraged to review the following publications, available at www.norcalmutual.com.

- Wrong patient, wrong site, wrong surgery, surgical site infections - The July 2008 *Claims Rx* entitled: "Risk Management and Patient Safety Strategies for Surgeons"
- Medication errors, contaminated devices - The June 2008 *Claims Rx* entitled: "Strategies for Making the Medication Delivery Process Safer"
- Hypoglycemia - The November 2006 NORCAL CME course entitled: "Diabetes: Managing Comorbidities"

- Hyperbilirubinemia/Kernicterus - The May 2008 *Claims Rx* entitled: "Focus on Newborn Patients: Strategies for Reducing the Incidence of Kernicterus as a Result of Hyperbilirubinemia and Vision Deficits as a Result of Retinopathy of Prematurity"
- Surgical Fires - The December 2007 *Claims Rx* entitled: "Reducing the Risk of Surgical Fires"
- Deep Vein Thrombosis/Pulmonary Embolism - The March 2008 *Claims Rx* entitled: "Deep Vein Thrombosis Prophylaxis"

To learn more about new Medicare rules on reimbursement for hospital-acquired conditions (HACs), see "Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates," in the Federal Register/Vol. 72, No. 162, August 22, 2007/Rules and Regulations.

To learn more about proposed 2009 rule changes on HACs, see "CMS Proposes Additions to List of Hospital-Acquired Conditions for Fiscal Year 2009" at the CMS website at www.cms.hhs.gov.

To learn more about California's new rules on reporting adverse events, see the California Health and Safety Code, Sections 1279.1-1279.3 and 1280.4.

As physicians interface with hospital staff and administrators, they will hear more about Never Events. As hospitals face the lack of reimbursement for patients who experience these events, physicians will be witnessing policy and procedure changes, discussions at medical quality and peer review committees, and other measures aimed at the prevention of these events. By understanding the history and the reimbursement factors associated with Never Events, physicians will be better prepared to be involved in these activities and offer support and input.

Keeping a Never Event from happening from occurring is optimal. However, they continue to occur at a significant rate. Having appropriate policies and procedures in place to guard against the occurrence of Never Events can increase patient safety, reduce liability exposure, reduce reporting burdens and preserve reimbursement rates. When those policies and procedures do not work and a Never Event occurs, in addition to analyzing those policies and procedures to determine what has gone wrong, hospitals must follow adverse event reporting laws and be prepared for limitations in Medicare and private insurance reimbursement.

1. Patient Safety Primer: Never Events. Available on the AHRQ Patient Safety Network website.
2. California Health and Safety Code §§ 1279.1-1279.3 and 1280.4.
3. Sentinel Events. Available on the Joint Commission website.
4. CMS proposes additions to list of hospital-acquired conditions for fiscal year 2009. April 14, 2008. Available on the CMS website.
5. Report of the board of trustees. Presented by: Edward L. Langston, MD, Chair. Available on the AMA website.
6. Medicare's no-pay conditions: not always preventable. July 14, 2008. Available on the American Medical News website.