

[Health Lawyers Weekly](#)

December 19, 2008 Vol. VI Issue 48

Hospitals and Health Systems "To Err Is Human"—And Costly: Addressing The Potential Effects On Litigation Of So-Called "Never Events"

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"To err is human, to forgive, infrequent."

— Franklin P. Adams

A. Background

The Institute of Medicine (IOM) released a report in 1999 titled, *To Err is Human: Building a Safer Health System*. In its report, IOM stated that hospital-acquired conditions caused by medical errors are a leading cause of morbidity and mortality in the United States, and estimated that as many as 98,000 people die per year as a result of hospital medical errors. The costs associated with medical errors due to additional healthcare costs, lost productivity, and disability were estimated at anywhere from \$17 billion to \$29 billion.^[1]

The National Quality Forum (NQF), a national patient advocacy group that focuses on healthcare quality measures, followed up by issuing a report of its own in 2002 called *Serious Reportable Events in Healthcare*. The NQF identified "27 adverse events that are serious, largely preventable, and of concern to both the public and healthcare providers."^[2] The NQF report appears to be the first attempt to classify medical conditions as so-called "never events."

Various studies conducted in 2006 and 2007 found that:

- 87% of hospitals do not follow recommendations designed to prevent common hospital-acquired infections.[\[3\]](#)
- Medicare covers a greater percentage of patients with hospital-acquired infections than any other payor. For example, one study showed that 57% of patients with hospital-acquired infections were Medicare patients, compared to 17% commercial insurance, 15% "other," and 11% Medicaid.[\[4\]](#)

Congress responded to these reports and studies by authorizing the Centers for Medicare and Medicaid Services (CMS) to adjust Medicare payments to hospitals to encourage the prevention of hospital-acquired conditions. CMS was further encouraged to act by the President's Fiscal Year 2009 Budget, which proposed that: (1) hospitals be prohibited from billing the Medicare program for "serious, preventable adverse events," informally called "never events"; (2) the Medicare program be prohibited from paying for "never events"; and (3) hospitals be required to report *any* occurrence of a "never event," or receive a reduced annual payment update.

B. CMS' Response

Under the final version of the law, Section 1886(d)(4)(D) of the Social Security Act, the Secretary of the U.S. Department of Health and Human Services was required to publish a list of at least two hospital-acquired conditions for which Medicare payment would not be made as of October 1, 2008. CMS initially identified eight "hospital acquired conditions" (HACs), for which no reimbursement will be provided. They are:

- object inadvertently left in after surgery;
- air embolism;
- blood incompatibility;
- catheter associated urinary tract infection;
- pressure ulcer (decubitus ulcer);
- vascular catheter associated infection;
- surgical site infection-mediastinitis (infection in the chest) after coronary artery bypass graft surgery; and
- certain types of falls and trauma.

According to CMS, these conditions greatly complicate the treatment of the illness or injury that caused the hospitalization—and therefore increase the cost of treatment—and are reasonably preventable through proper care. CMS has published the following information, based on Fiscal Year 2007 data, showing the impact of HACs and the ICD-9-CM codes associated with them.[\[5\]](#)

HAC	Medicare Data	CC/MCC (ICD-9-CM codes)
Foreign Object Retained After Surgery	750 cases \$63,631/hospital stay	998.4 (CC) or 998.7 (CC)
Air Embolism	57 cases	999.1 (MCC)

	\$71/636/hospital stay	
Blood Incompatibility	24 cases	999.6 (CC)
	\$50,455/hospital stay	
Pressure Ulcer Stages III & IV	257,412 cases	717.23 (MCC) or 707.24 (MCC)
	\$43,180/hospital stay	
Falls and Trauma:	193,566 cases	Ranges: 800-829, 830-839, 850-854, 925-929, 940-949, 991-994 (CC/MCC)
Fracture	\$33,894/hospital stay	
Dislocation		
Intracranial Injury		
Crushing Injury		
Burn		
Electric Shock		
Catheter-Associated Urinary Tract Infection (UTI)	12,185 cases	996.64 (CC)
	\$44,043/hospital stay	
Vascular Catheter-Associated Infection	29,536 cases	999.31 (CC)
	\$103,027/hospital stay	
Surgical Site Infection-Mediastinitis After Coronary Artery Bypass Graft (CABG)	69 cases	519.2 (MCC)
	\$299,237/hospital stay	

A Minnesota-based insurer, HealthPartners, was the first payor to refuse payment for iatrogenic injuries, enacting a nonpayment policy in 2005. Cigna, Blue Cross, Aetna, and Well Point have followed suit, in many cases issuing insurance contracts that stipulate they will not pay for some or all of CMS' HACs or the NQF's "never events." Additionally, while several states had already adopted Medicaid policies prohibiting hospitals from billing for HACs, CMS issued a letter to State Medicaid Directors on July 31, 2008, urging state Medicaid programs to fall into line with CMS' HACs rules for Medicare reimbursement.

C. The August 2008 Final Rule

In April 2008, CMS proposed to expand its original list of HACs from eight to seventeen total conditions. The proposed additional HACs were:

- surgical site infections following certain elective procedures;

- Legionnaires' disease (a type of pneumonia caused by a specific bacterium);
- extreme blood sugar derangement;
- iatrogenic pneumothorax (collapse of the lung);
- delirium;
- ventilator-associated pneumonia;
- deep vein thrombosis/pulmonary embolism (formation/movement of a blood clot);
- *Staphylococcus aureus* septicemia (bloodstream infection); and
- *Clostridium difficile* associated disease (a bacterium that causes severe diarrhea and more serious intestinal conditions such as colitis).

CMS accepted comments from the public up until June 13, 2008. Patient safety advocates on the whole commended CMS' efforts, but encouraged the agency to limit HACs to conditions that are significant, measurable, and truly preventable.^[6] This is in keeping with the law's requirements that these events be high cost or high volume; be designated as a complicating condition or a major complicating condition; and be considered reasonably preventable through the application of evidence-based guidelines.

On August 19, 2008, CMS published its Final Rule.^[7] In it, CMS clarified its original list of HACs as follows:

- *Foreign object retained after surgery*. CMS added ICD-9-CM code 998.7 (acute reaction to foreign substance accidentally left during a procedure) in addition to code 998.4 (foreign body accidentally left during a procedure) to identify an HAC.
- *Pressure ulcers*. CMS added proposed ICD-9-CM codes 707.23 (pressure ulcer, stage III) and 707.24 (pressure ulcer, stage IV) to identify an HAC.

In the Final Rule, CMS also added only three of the proposed nine additional HACs, and revised the events from the original April 2008 proposal. The new HACs are: (1) surgical site infections following bariatric surgery and certain orthopedic procedures; (2) manifestations of poor glycemic control; and (3) deep-vein thrombosis/pulmonary embolism.

- *Surgical site infection*. CMS expanded this condition to include infections following bariatric surgery and certain orthopedic surgeries. While there have been relatively few cases of surgical-site infection following bariatric surgery, the average cost of such a case is high, which prompted CMS' decision. CMS has stated that it is working to identify additional procedures, orthopedic and otherwise, for which surgical site infections can be considered reasonably preventable. One likely candidate is surgical site infection following cardiac device procedures.
- *Manifestations of poor glycemic control*. CMS asserts that extreme manifestations are reasonably preventable through the application of evidence-based guidelines and routine blood glucose measurement and control.
- *Deep-vein thrombosis/pulmonary embolism*. CMS bases the need for this HAC on publicly available data showing that the national rate for venous thromboembolism (VTE) prophylaxis within 24 hours after surgery was 82% in the third quarter of 2007. CMS concluded that "a significant number of patients are not receiving the recommended evidence-based prophylaxis."

The following chart shows the impact of the additional never events and the ICD-9-CM codes associated with them.

HAC	Medicare Data	CC/MCC (ICD-9-CM codes)
Surgical Site Infection Infection and inflammatory reaction following orthopedic device and implant graft Other postoperative infection following a combined anterior/posterior spinal fusion, cervical spine fusion, or major shoulder or elbow joint procedures	269 cases \$148,172/hospital stay	996.67 (CC), 998.59(CC), 81.01-81.08, 81.23, 81.24, 81.31-81.38, 81.83, 81.85
Surgical Site Infection Following bariatric surgery for obesity	37 cases \$233,614/hospital stay	278.01, 998.59, 44.38, 44.39, 44.95
Manifestations of Poor Glycemic Control Diabetic ketoacidosis	11,469 cases \$42,974/hospital stay	250.10-250.13
Manifestations of Poor Glycemic Control Nonketotic hyperosmolar coma	3,248 cases \$35,215/hospital stay	250.20-250.23
Manifestations of Poor Glycemic Control Hypoglycemic coma	212 cases \$36,581/hospital stay	251.0
Manifestations of Poor Glycemic Control Secondary diabetes with ketoacidosis Secondary diabetes with hyperosmolarity	<i>Data not available</i>	249.10, 249.11 240.20, 249.21

D. Role HACs May Play in Litigation

In addition to the effect on reimbursement, these new CMS rules may provide additional challenges to hospitals defending litigation over patient care. It is important to remember that these are ***billing and reimbursement rules***, which do not define the standard of care applicable to the care and treatment of patients. Nevertheless, plaintiffs' attorneys may seize upon the CMS rules and attempt to use them to shore up their allegations of negligence against hospitals.

Arguments that plaintiffs' attorneys may make in litigation based on these new CMS rules (and some of the possible legal responses to them) include the following:

- *Arguments that the occurrence of an HAC is negligence per se (liability based on the violation of a safety statute).* Under the "negligence *per se*" doctrine in certain states, when the defendant violated a public safety statute, the plaintiff does not have to demonstrate that the defendant did not meet the "reasonable person" standard, as is generally required in a negligence case. Plaintiffs may argue that when an HAC or "never event" occurs, that constitutes negligence *per se*.

Counsel for the hospital, however, should point out that CMS' federal rules regarding reimbursement do not constitute a state "public safety statute"[\[8\]](#) of the type to which the negligence *per se* doctrine typically applies. Counsel should look carefully at state laws regarding the applicability of negligence *per se*, rather than assuming that the CMS rules would fall within that rubric.

- *Arguments that the occurrence of an HAC constitutes res ipsa loquitur (the thing speaks for itself).* In medical malpractice cases in many jurisdictions, the standard of care is defined by medical providers in the same or a similar community. In a *res ipsa loquitur* case in those jurisdictions, however, no expert testimony may be needed because the event in question is so obviously negligent or harmful that its damaging effect can be easily recognized by a layperson.

The CMS rules do not change the legal analysis pursuant to the *res ipsa loquitur* doctrine. In North Carolina, for example, *res ipsa loquitur* rarely applies to medical malpractice litigation, because the issues in those cases can seldom be decided "'as a matter of common experience' . . . without the assistance of expert testimony."[\[9\]](#) Plaintiffs' attorneys may argue that a "never event" should never occur, and the fact that the event occurred is proof in and of itself of negligence on the part of the medical provider. As defense counsel should point out, however, the vast majority of HACs are medically complex and may be caused by a number of factors unrelated to negligence.

- *Suggestions that CMS' rules regarding HACs, or CMS' studies or descriptions of these events, are admissible in court as evidence.* Defense counsel should argue that CMS' reimbursement rules are not relevant in subsequent litigation brought by the patient. These rules do not tend to prove what standard of care applied to the provider, whether the provider met or violated that standard, whether any such violation caused harm to the patient, and if so, what the patient's damages are. Moreover, use of the phrase "never events"—terminology that can be misleading, inaccurate, and non-descriptive when applied to many of the listed clinical situations—could be highly prejudicial to a

defendant, particularly if there is medical evidence that the type of event at issue can happen even when a patient receives completely appropriate care. Indeed, CMS does not generally use the term "never events" to describe the events covered by its new rule—it calls them HACs.

- *Attacks on the "same or similar community" standard of care, with respect to conditions that fall within CMS' list of HACs.* Plaintiffs' attorneys may argue that the list of HACs represents a national standard of care, and that any time a patient experiences an HAC this new, national standard of care has been violated. Again, defense counsel should respond that CMS' reimbursement rules do not define the standard of care for healthcare providers; they simply define what kinds of care CMS will reimburse those providers for giving to patients. Although CMS hopes to improve the quality of patient care through these new rules—and although healthcare providers are constantly striving to improve the safety and quality of care to patients of all types, including those who suffer from conditions described in these new rules—the standard of care for any given professional is defined by the practice of others in his or her profession, not by CMS.
- *Efforts to introduce evidence that the healthcare provider was refused reimbursement for certain conditions, according to these CMS rules.* Plaintiff's counsel may assert that CMS decided the care provided was so bad/negligent that it would not reimburse the hospital for the patient's treatment. Whether or not CMS reimbursed a defendant healthcare provider for care provided to the plaintiff patient, for reasons stated above, also should be irrelevant to the issues to be resolved by the fact-finder in a malpractice lawsuit. In jurisdictions where the collateral source rule applies, defense counsel should argue that information about how a collateral source like CMS handled payment of a patient's medical bills is inadmissible.
- *Attempts to hold hospitals responsible when alleged physician error results in later readmission for treatment of these events.* In states where hospitals generally are not held legally responsible for the actions of non-employed physicians, some patients might argue that the occurrence of a HAC pursuant to CMS' rules, changes the legal equation. Again, the response to this argument goes back to the fundamental nature of CMS' rules. A federal body's reimbursement rules should not affect courts' legal framework for analyzing whether a hospital is legally responsible for a non-employed physician's actions.

E. Preparing for the Potential Effects on Litigation of HACs or "Never Events"

There are several proactive ways hospitals and their counsel can prepare for the potential effects on litigation of CMS' new rules regarding HACs. Examples include:

1. The CMS rules implemented a new coding process (mandatory as of January 1, 2008) whereby a hospital indicates whether a condition listed on the HAC list was actually present on admission (POA). So long as the condition was documented as being POA, reimbursement will be provided for treatment associated with that condition. When revising admission forms, policies, and procedures to gather information regarding conditions that are POA, consult with clinical, financial, and legal resources about those changes. Make sure that revisions are appropriate from all three of those perspectives.
2. Thoughtfully and thoroughly train staff on any new forms, policies, or procedures regarding patient admission or other aspects of care that relate to or happen to fall within CMS' new rules. Make sure staff members are aware that the CMS rules pertain to billing and reimbursement, and do not create a standard of care.
3. As we note above, the shorthand term "never events" can be misleading when applied to many of the listed clinical situations and is not even the language (HAC) that CMS uses. Clinical staff should not be trained or encouraged to use the term "never events," and it should not be used in clinical documents or other materials where it is unnecessary. Instead, facilities should continue to use (or, if creating new programs, initiatives, or forms, consider creating) its own language for describing these types of outcomes or events. The American Hospital Association (AHA), for example, has used the term "serious adverse events"[\[10\]](#) in some of its recent materials. Make sure staff understands that these kinds of events, as unfortunate as they are, can occur even when the patient's care has been appropriate.
4. To the extent that written materials must refer to CMS' rules—such as in coding/billing guidelines or procedures—use the correct term, HAC, rather than an informal shorthand term like "never events."
5. When a patient has an outcome that might fall within CMS' HAC regulations, or that falls within the NQF's list of "never events," think carefully about how the billing should be handled (beyond the obvious need to code the event properly and in a manner compliant with CMS regulations). Consider developing a policy regarding how billing decisions should be made about care relating to these events. An example of one such policy is reflected in the AHA's February 12, 2008 Quality Advisory, "Implementing a No-Charge Policy for Serious, Adverse Events," which asks hospitals to "implement a no-charge policy for patients and insurers for serious, adverse events that is appropriate for their communities and the patients they serve."[\[11\]](#) Some state hospital associations also have or are working on some helpful guidance on this issue; find out what your state's association is doing in that regard, then enact the policy that your hospital deems appropriate after your own, deliberate consideration. Be aware that even when a provider is legally entitled to bill a patient for care provided—and when the patient's new condition results from no fault on the part of the provider—there can be significant litigation advantages to not billing patients for these types of events. This is particularly true in jurisdictions where plaintiffs are allowed to show jurors all of the charges "billed," instead of showing them only the charges actually "paid."
6. If a policy already exists about disclosing serious, adverse events to patients (which may include an apology component), evaluate whether the policy needs to be revised in any way in light of the new CMS rules. If no patient disclosure/apology policy is in place, consult with appropriate colleagues and with counsel about the possibility of adopting

one. Providers who implement appropriate disclosure/apology practices often have a higher patient satisfaction rate and a lower litigation rate.

7. Monitor how healthcare providers' professional associations are responding to CMS' new rules. Both the American Medical Association and AHA have already weighed in on these new rules, for example. Opinions that professional associations like this have expressed, and statements that they have made about providers' perspectives on these supposed HACs—such as statements and evidence that these events can happen even when patients have received completely appropriate care—can help respond to arguments that CMS' rules or handling of a plaintiff's bill in a particular case should be admissible or discoverable. This kind of evidence might convince a judge that guidelines that have been specifically adopted by a physician organization (which the court might view as admissible against a physician who is a member of that organization) are very different from CMS' reimbursement rules or language (especially to the extent that physicians or other professional organizations have objected to them).
8. Unless existing policies already require it, train staff to notify risk management whenever one of these events occurs. The risk manager can then determine if counsel should be consulted, in order to prepare for potential litigation and evaluate other issues from a legal perspective.
9. If your facility is sued with respect to an event subject to these new CMS rules, alert litigation counsel to that. Work with counsel on a thoughtful, consistent approach to handling any assertions by plaintiffs that the CMS rules are relevant to the case, which might include:
 - Moving to dismiss any complaint filed without the requisite expert review or certification in your state on the theory that the new CMS rules make that unnecessary.
 - Moving to dismiss or strike any allegations of negligence *per se* based on the new CMS rules.
 - Moving for a protective order regarding any inappropriate efforts to conduct discovery based on the CMS rules or CMS' handling of the plaintiff's billing.
 - Moving to exclude references at trial to "never events," HACs, NQF's list, or related CMS rules or statements.
 - Moving to exclude evidence of CMS' handling of the plaintiff's billing.
 - Alerting fact and expert witnesses to the possibility that plaintiff's counsel may ask them questions about these CMS rules or materials, and ensuring that they understand—at least in a general sense—these rules' context and applicability.

Only time will tell how CMS' new rules will actually impact litigation against healthcare providers. As hospitals implement new policies and procedures to comply with those new rules, they and their counsel should be mindful of the ways that plaintiffs may use the CMS rules as a sword in the litigation arena.

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[1] Institute of Medicine, [*To Err is Human: Building a Safer Health System*](#) (Nov. 1999).

[2] See [National Quality Forum](#).

[3] The Leapfrog Group, [*2007 Leapfrog Group Hospital Survey*](#).

[4] MedMined, Inc., *1.6 Million Admission Analysis* (Sept. 2006).

[5] 73 Fed. Reg. 48473 (Aug. 19, 2008).

[6] Pronovost, PJ, Goeschel CA, Wachter RM, *The wisdom and justice of not paying for "preventable complications,"* 299 JAMA 2197-9 (May 14, 2008).

[7] 73 Fed. Reg. 48471 (Aug. 19, 2008).

[8] *Hart v. Ivey*, 420 S.E.2d 174, 177 (N.C. 1992).

[9] *Diehl v. Koffer*, 536 S.E.2d 359, 362 (N.C. Ct. App. 2000) (quoting 57 Am.Jur.2d, *Negligence* § 1826 (1989) (emphasis and footnotes omitted)).

[10] For additional examples, visit AHA's [website](#) and type "serious adverse events" into the search engine box.

[11] See [Quality Advisory](#).

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