



## **Addressing the Potential Litigation Impacts of CMS's "Never Events" Rules**

Effective October 1, 2008, the Centers for Medicare and Medicaid Services (CMS) will not provide reimbursement to hospitals for certain conditions acquired after a patient's hospital admission. CMS initially identified eight conditions, termed "never events," 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 are reasonably preventable through proper care.

As of April 2008, CMS has proposed expanding its list of "never events" to include:

- 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).

Public comment on the rule proposing this expansion will end June 13, 2008, and a final rule will be issued on or before August 1, 2008. Several third-party payors, including CIGNA, have decided to follow CMS's lead regarding these reimbursement issues.

These new CMS rules may provide additional challenges to health care providers defending litigation over patient care. Arguments that plaintiffs' attorneys may make in litigation based on these new CMS rules (and some of the possible legal responses to them) might include the following:

- *Arguments that the occurrence of a "never event" is negligence per se (liability based on the violation of a safety statute) or constitutes res ipsa loquitur (the thing speaks for itself).* CMS's rules regarding reimbursement do not constitute a "public safety statute"<sup>1</sup> of the type to which the negligence *per se* doctrine applies in states like North Carolina. These rules also do not change the legal analysis pursuant to the *res ipsa loquitur* doctrine, which 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."<sup>2</sup>
- *Suggestions that CMS's rules regarding "never events," or CMS's studies or descriptions of these events, are admissible in court as evidence.* It is difficult to imagine how CMS's reimbursement rules could be 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, if not most, 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.
- *Attacks on the "same or similar community" standard of care, with respect to conditions that fall within CMS's list of "never events."* Again, CMS's reimbursement rules do not define the standard of care for health care 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 health care 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 health care provider was refused reimbursement for certain conditions, according to these CMS rules.* Whether or not CMS reimbursed a defendant health care provider for care provided to the plaintiff patient is, for reasons stated above, irrelevant to the issues to be resolved by the fact-finder in a malpractice lawsuit. Indeed, in jurisdictions (like North Carolina) where the collateral source rule applies, information about how a collateral source like CMS handled payment of a patient's medical bills should be inadmissible.
- *Attempts to hold hospitals responsible when alleged physician error results in later readmission for treatment of these "never events."* In states like North Carolina, where hospitals generally are not held legally responsible for the actions of non-employed physicians, some patients might argue that the occurrence of a "never event," pursuant to CMS's rules, changes the legal equation. Again, the response to this argument goes back to the fundamental nature of CMS's rules. A federal body's reimbursement rules should not affect our courts' legal framework for analyzing whether a hospital is legally responsible for a non-employed physician's actions.

There are several ways that health care providers can prepare for and deal with the potential litigation impacts of CMS's new rules about these events. Examples include:

1. As you revise admission forms, policies, and procedures to gather information that may be pertinent to the new CMS rules, consult with your clinical, financial, and legal resources about those changes. Make sure that your revisions are appropriate from all three of those perspectives.
2. Thoughtfully and thoroughly train your 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's new rules.
3. As we note above, the shorthand term "never events" can be misleading when applied to many of the listed clinical situations. Your clinical staff should not be trained or encouraged to use that terminology, and you should not use it in clinical documents or other materials where it is unnecessary. Instead, you should continue to use (or, if you are creating new programs, initiatives, or forms, consider creating) your facility's own language for describing these types of outcomes or events. The American Hospital Association (AHA), for example, has used the term "serious adverse events"<sup>3</sup> in some of its recent materials. Make sure your staff understands that these kinds of events, as unfortunate as they are, can occur even when the patient's care has been appropriate.
4. If there is some reason that your written materials must refer to CMS's rules or "never events" terminology – such as in billing guidelines or procedures – consider including appropriate disclaimer language, to make clear that the events at issue can happen even when the patient has received high-quality care.
5. When a patient has an outcome that might fall within CMS's "never events" rules, think carefully about how the billing should be handled. 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."<sup>4</sup> 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 are often litigation advantages to not billing patients for these types of events.

6. If you already have a policy about disclosing serious, adverse events like this to patients (which may include an apology component), evaluate whether you need to revise that policy in any way in light of these new CMS rules. If you do not have a patient disclosure/apology policy 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 health care providers’ professional associations are responding to CMS’s new rules. Both the American Medical Association and the 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 “never events” – such as statements and evidence that these events can happen even when patients have received completely appropriate care – can help you or your lawyer to respond to arguments that CMS’s 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’s reimbursement rules or language (especially to the extent that physicians or other professional organizations have objected to them).
8. Unless your existing policies already require it, train your 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 or practice is sued with respect to an event subject to these new CMS rules, talk with your counsel early on about that. Work with your attorney on a thoughtful, consistent approach to handling any assertions by plaintiffs that CMS rules are relevant to the case, which might include:
  - a. Moving to dismiss any complaint filed without expert certification based on the new CMS rules.
  - b. Moving to dismiss or strike any allegations of negligence *per se* based on the new CMS rules.
  - c. Moving for a protective order regarding any inappropriate efforts to conduct discovery based on the CMS rules or CMS’s handling of the plaintiff’s billing.
  - d. Moving to exclude references at trial to “never events” or related CMS rules or statements.
  - e. Moving to exclude evidence of CMS’s handling of the plaintiff’s billing.
  - f. Alerting fact and expert witnesses to the possibility that plaintiff’s counsel may ask them questions about these CMS rules or materials, and insuring that they understand – at least in a general sense – these rules’ context and applicability.

Only time will tell how CMS's new rules will actually impact litigation against health care providers. We hope this proves a valuable resource as health care providers navigate these uncharted waters.

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<sup>1</sup> *Hart v. Ivey*, 332 N.C. 299, 303-04, 420 S.E.2d 174, 177 (1992).

<sup>2</sup> *Diehl v. Koffer*, 140 N.C. App. 375, 378, 536 S.E.2d 359, 362 (2000) (quoting 57 Am.Jur.2d, *Negligence* § 1826 (1989) (emphasis and footnotes omitted)).

<sup>3</sup> For additional examples, go to [www.aha.org](http://www.aha.org) and type "serious adverse events" into the search engine box.

<sup>4</sup> <http://www.aha.org/aha/advisory/2008/080212-quality-adv.pdf>.



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