The Rise of Never Events, Adverse Events, and Hospital Acquired Conditions

An Uneasy Intersection Between Clinical Care and Liability Litigation

In 1999, the Institute of Medicine ("IOM") reported that hospital-acquired conditions caused by medical errors ("HACs") were a significant cause of injuries across the nation and of rising medical care costs. In order to facilitate a better understanding of HACs, enable uniform HAC reporting, and to improve overall patient safety, the National Quality Forum ("NQF") published Serious Reportable Events in 2002. This publication initially identified twenty-seven health care related events the NQF deemed to be serious, preventable, and of significant concern to the public and health care providers. Recent updates published by the NQF in 2011 brought the total number of preventable HACs (or, “never events”) to twenty-nine.

In 2006, Congress also recognized the need to reduce health care costs and raise awareness of preventable HACs by passing the Deficit Reduction Act of 2005. These provisions authorized Centers for Medicare and Medicaid Services ("CMS") to link health care facilities’ Medicare eligibility to the occurrence of the HACs. In other words, CMS was required to create its own list of HACs, which, if occurred, could impact a health care facility’s Medicare eligibility.

By 2008, CMS published a list of its own HACs. Although the original CMS list was limited to only eight types of hospital-acquired conditions, the list has since grown. As recently as August 2013, CMS revised the list of HACs by adding two new conditions, bringing the total number up to 14. Mirroring the NQF’s list of serious reportable events very closely, the current HACs include incidents of falls, trauma, stage III and IV pressure ulcers, and foreign retained objects following surgery, to name a few.

In California, the legislature has recognized a similar, but distinct set of hospital acquired conditions, referred to as “adverse events.” The list of “adverse events” includes approximately 28 occurrences, which are categorized into six event types:

1. Surgical
2. Product
3. Patient Protection
4. Care Management
5. Environmental
6. Criminal

Regardless of whether certain events are termed “hospital acquired conditions,” “never events,” or even “adverse events,” the import of the above regulations is clear. Health care facilities are not only implored to avoid the above conditions, but now have an ever-growing affirmative duty to:
1. Evaluate and respond to any such events, if they occur;
2. Take the appropriate Federal and State reporting measures; and

**DUTY TO REPORT NEVER EVENTS**

**Federal Reporting Requirements Under CMS**

Considering the CMS guidelines regulate HACs and payment for medical costs, it is no surprise that the reporting duty arises at the time the facility makes a claim for Medicare payments. Indeed, under CMS guidelines, when a health care facility submits claims for Medicare payments, that facility must report whether a patient had any of the established HACs, and whether they were present at the time of admission.

For discharges occurring after October 1, 2008, facilities will not receive any additional payment for cases if a patient had one of the HACs and that condition was not present at the time of admission. Instead, Medicare would pay for the health care costs as though that secondary, hospital-acquired condition were not present.

Under CMS, failure to appropriately report HACs causes a facility’s Medicare claim to be returned to the facility unpaid. Considering the substantial costs of health care today and the rising number of Medicare patients, that policy can have severe financial implications for a health care facility. To be sure, the least costly scenario would be if the HACs never occurred in the first place. Unfortunately, however, many of the HACs can and often do happen, even in the absence of negligence. For this reason, it is important for health care facilities to implement and maintain appropriate measures for risk management.

**California State Reporting Requirements Under Health and Safety Code § 1279.1**

California’s reporting requirements impose somewhat of a stricter reporting duty on health care facilities. Under Health and Safety Code § 1279.1, health care facilities are required to report any “adverse events” to the Department of Health Services within five days after the event has been detected, or, if that event is an ongoing or emergent threat, no later than twenty-four hours after it has been detected.

Health care facilities also have an affirmative reporting duty to their patients: the facility must also inform the patient or the party responsible for the patient about the adverse event by the time the report to the Department of Health Services is made.

While the Federal reporting provisions result in a withholding of funding, the California reporting requirements can actually result in a monetary fine for each adverse event that occurs. For example, if an adverse event places a patient in immediate jeopardy, then the California Department of Health can impose a fine of up to $75,000 for the first event, $100,000 for the second, and up to $125,000 for the third.

If an adverse event occurs in a hospital and that hospital fails to report it, the California Department of Health can charge that hospital up to $100.00 for every day the hospital failed to make a timely report. Once any fines have been assessed, a hospital only has only ten
LOOKING FORWARD: LEGAL REMEDIES AND RESPONSES TO “NEVER EVENTS” IN THE CONTEXT OF MEDICAL MALPRACTICE LITIGATION

Unfortunately, the impact of HACs and adverse events does not necessarily end with the duty to report or the imposition of monetary fines. Recently, such events present facilities with unique difficulties when defending a medical malpractice claim—especially as plaintiffs’ attorneys begin to argue the mere existence of “never events” is evidence of negligence.

By definition, “never events” are indeed serious conditions. While they may have even been the impetus to file a medical malpractice claim in the first place, it is important to remember the “never event” policies are designed to target billing practices, growing deficits, and improve overall patient safety. They do not define the scope of liability, and certainly do not establish a new standard of care. While it is uncertain exactly what position the courts or the legislature will take regarding the admissibility of “never events,” past judicial and legislative policy suggest it is unlikely such events (and their reporting provisions) will be admissible to prove liability.

Take, for example, the norms surrounding peer review. In general terms, “peer review” is when a committee or group of individuals informally investigates a complaint involving claims of malpractice. It is well-established in California that peer review is not discoverable and not admissible at trial. These decisions are based in no small part on the recognition that with peer review, like the reporting of “never events,” there are strong public policy considerations for maintaining its confidentiality, such as encouraging candor and achieving improved quality of care. Considering “never events” and “adverse events” are similarly geared toward improving patient safety and reducing health care costs, it follows that they should also be excluded from discovery and admissibility into evidence.

Although the courts and legislature have not yet tackled this issue or provided a specific answer regarding the discoverability and/or admissibility of never events, there are several tools at the defense’s disposal to help reduce their potential impact at the time of trial.

First, careful review of a plaintiff’s complaint can provide a very early indication if a plaintiff is going to allege either negligence per se or res ipsa loquitur based on the CMS or “adverse event” determinations. If a plaintiff does so, the defense can demur the complaint or move to strike portions pertaining to the CMS or “adverse event” provisions; neither the CMS nor the “adverse event” determination establishes what the community standard of care is or what constitutes a breach of that standard. They therefore cannot be used to establish individual liability.

Once the pleadings are established, the defense should be on guard for any discovery regarding CMS or “adverse event” reporting and related matters. Although the actual facts surrounding a never event are subject to discovery, timely objections can and should be made to the discoverability of the “never event” or “adverse event” classification and reported matters; ultimately, information of this type is not reasonably calculated to lead to the discovery of admissible evidence and, again, is not dispositive to establish the standard of care.
By the time of trial, defendants have two primary defense mechanisms. First the term “never event” or “adverse event” is highly prejudicial to any health care provider and should be excluded at the time of trial. Moreover, “never events” and the related reporting provisions govern payment mechanisms, not an evaluation of liability. To the extent the collateral source rule precludes the defense from showing evidence of payment for plaintiff’s health care services, plaintiffs should also be precluded from showing evidence of nonpayment for services.

Accordingly, there are many existing strategic decisions the defense can make to address reportable events and their potential impact on malpractice litigation. While it remains uncertain exactly how the judiciary or legislature will address these concerns, one aspect remains clear: reportable events, like never events or adverse events, are not only here to stay, but are also on the rise. As Federal and State provisions continue to broaden the scope of reportable events, it becomes increasingly more important for health care facilities to identify, evaluate, and respond to such events, take appropriate and timely reporting measures, and implement comprehensive prevention strategies. After all, the best defense is a good offense.

For more information about this topic, please contact one of our Healthcare [1] or Professional Liability [2] attorneys at 619.238.1712.