Illinois Association of Defense Trial Counsel
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IDC Quarterly | Volume 18, Number 2 (18.2.21)

Health Law

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What Every Litigator Needs to Know About "Never Events"

History of Never Events

The National Quality Forum (NQF), an advocacy group focused on developing a national strategy for healthcare quality measurement, identified 28 adverse events now commonly referred to as "never events." This list of events was meant to bring order to adverse event reporting, which Illinois requires. 410 ILCS 522/10-1 *et seq*. Such events are deemed preventable and are events that should *never* occur in the healthcare setting.

The Leapfrog Group, a healthcare purchasing coalition, endorsed this list by providing public recognition to healthcare facilities that take responsibility when such an event occurs. In order to receive such recognition, the facility must apologize to those affected by the event, report the event to a reporting agency, perform a root cause analysis, and waive all costs directly related to the event.

In an effort to decrease Medicare and Medicaid spending, the Centers for Medicare and Medicaid Services (CMS) have since adopted a modified list of never events, including: (1) object left in patient after surgery; (2) air embolism; (3) blood incompatibility; (4) catheter-associated urinary tract infection; (5) pressure ulcers; (6) vascular catheter-associated infection; (7) surgical site infection; and (8) hospital-acquired injuries, including those associated with falls. If just one of these conditions is present and did not exist upon admission of the patient, no subsequent Medicare or Medicaid payments will be paid to the hospital for any resulting bills.

NQF, Leapfrog, and CMS are seeking to improve healthcare quality and patient safety while decreasing Medicare and Medicaid spending. However, in doing so, they have provided plaintiffs' attorneys with a new weapon against healthcare facilities. Plaintiffs will likely use never events as a new standard of care, a method of attacking defense experts, and a means of attaining admissions of liability by fact witnesses. Ultimately, never events might even provide an argument similar to the doctrine of *res ipsa loquitur*.

Res Ipsa?

Under traditional standards, defendants can respond to allegations of negligence via expert testimony regarding the standard of care. However, consider a situation where a patient falls and injuries result. Here, the healthcare facility might have directed the patient to stay in bed, provided a call button within the patient's reach, set the bed to the lowest position, and activated a bed alarm. No matter the level of prudence, if the patient decides to get out of bed, thereby falling and suffering injuries, the facility will not receive payment for any resulting bills. Furthermore, the jury will hear that CMS, upon examination of falls in healthcare facilities, determined they are always preventable. If the fall was preventable, yet occurred, this answers the question of

liability for the jury. Consequently, never events will significantly impact the standard of care, essentially imposing the doctrine of *res ipsa loquitur*.

Impact on Expert Testimony

At some point during trial, the jury is likely to hear testimony regarding never events and CMS standard of care with regard to such events. Presumably, a plaintiff's expert could be allowed to opine that CMS sets the standard of care, at least with regard to its listed never events. However, even if the defendant prevents the jury from hearing such testimony, the defendant's own experts will be subject to questions regarding CMS standards of care on cross-examination. As an expert on the standard of care, the expert will be forced to address the conflicting standards. Thus, not only will the jury hear testimony regarding such standards, but it might impact the credibility of the defense expert in the eyes of the jury.

Admissions of Liability

Presumably, healthcare facility administration will be made aware of never events and CMS standards regarding such events. As such, during the deposition of an administrator, a plaintiff might simply ask whether the witness agrees with the government's determination that such acts are preventable, or should never happen. If the witness responds affirmatively, such testimony could potentially result in an admission of liability. Regardless, the defense will find great difficulty convincing a jury otherwise.

Solutions

Evidence of state hospital regulations, national hospital accreditation standards, and hospital bylaws, although relevant, do not conclusively determine the standard of care. *Darling v. Charleston Community Memorial Hospital*, 33 Ill. 2d 326, 332, 211 N.E.2d 253 (1965). Consequently, CMS policies are not the standard of care. Furthermore, although it might be argued CMS standards will confuse the jury on the applicable standard of care and should thus be excluded entirely, CMS standards are likely to be deemed relevant. Counsel should also consider obtaining an instruction from the court or utilizing IPI 60.01.

Additionally, defendants must prepare witnesses for examination regarding CMS standards. Witnesses should acknowledge never events and CMS standards in order to appear knowledgeable and maintain credibility. However, it must be asserted that CMS does not set the standard of care, nor is there any law establishing such. Emphasis should be placed on the fact that never events simply deal with reimbursement, *i.e.*, payment issues, not the standard of care.

Also, as mentioned, a healthcare facility must apologize to those impacted by a never event in order to attain recognition from Leapfrog. While seemingly simple, an apology could potentially impact a case in two very distinct ways.

On one hand, the apology may serve to prevent lawsuits. Patients and their families might view such actions as an appropriate response to the incident, rather than a healthcare facility that closes off all communications upon its occurrence. Furthermore, it may afford the opportunity to explain what happened so as to clear up any questions and minimize the desire to bring suit only to exact revenge upon or get answers from the facility.

On the other hand, an apology may be viewed as an admission of guilt. The patient and family, or even the jury, might view an apology as an indication that the facility or its staff did something wrong thereby necessitating an apology. Illinois, however, is working to prevent an apology from being viewed as an admission of guilt by implementing the Sorry Works! Pilot Program Act. 710 ILCS 45/401.

Finally, in cases involving never events, a greater emphasis will be placed on admission records. Such records must not be overlooked by defense counsel and witnesses must be prepared to address them and respond appropriately.

Conclusion

We might continue to see quality of care as a method of regulating Medicare and Medicaid expenses. Consequently, the CMS list of never events might continue to grow and adopt more events listed by NQF. Such cases will become increasingly difficult to defend. In preparation, significant emphasis must be placed on witness preparation regarding CMS standards associated with never events and the distinction between the standard of care and payment issues must be emphasized.

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