

A New Tool for Medical Malpractice Cases in California

By Bruce G. Fagel, MD, JD

Starting on July 1, 2007, Health & Safety Code Sec. 1279 went into effect with little public notice outside of the healthcare industry. But in less than two years, this new law has shown that it may have a widespread effect on both the conditions in California hospitals and medical malpractice cases against these same hospitals.

As enacted by the Legislature and signed by the Governor in 2006, the law required all California hospitals to report the occurrence of any of 28 so-called “never events” to the California Department of Public Health. These include 27 specific events such as wrong-site surgery, wrong-patient surgery, wrong surgery on a patient, retention of a foreign body, medication errors, and other very specific events. But it also includes a category for reporting “an adverse event or series of adverse events that cause the death or serious disability of a patient.” The law requires hospitals to report any such “never event” within 5 days after the hospital detects the adverse event, and the Department of Public Health then must perform an on-site inspection within 48 hours of the report. The Department must complete its investigation within 45 days after receiving the report.

Section 1279.4 provides penalties for failing to file a report, up to \$100 per day for every day that the adverse event is not timely reported. Since the reporting is basically voluntary, however, it is not clear how the Department would find out that a report has not been timely made. More importantly, under Health & Safety Code section 1280.1, the Department can issue fines up to \$25,000 for cases that pose immediate jeopardy to a patient’s health or safety. By Nov. 7, 2007, the Department had imposed such maximum

fines against nine hospitals. This number grew to 11 hospitals by March 2008, but by June 2008, 27 hospitals had been cited. By Aug. 19, 2008, the list of hospitals fined grew to 42 hospitals, with 61 separate penalties, since several hospitals received more than one fine for separate events. On March 3, 2009, an additional 10 hospitals were fined under Health and Safety Code section 1280.1 for incidents that occurred in 2007 and 2008. At \$25,000 each, the Department of Public Health has assessed more than \$1.75 million in fines in less than two years. This amount of money provides both a mechanism for the Department of Public Health to carry out its regulatory inspection obligations, and a certain incentive to continue the process as a way of obtaining money, especially when the state faces severe budgetary cutbacks. At the same time, it is difficult for hospitals to object to these fines since they serve an important public interest, although several hospitals have attempted to appeal some of the fines. Effective January 1, 2009, a new law will increase these fines to \$50,000 for the first violation, \$75,000 for the second violation, and \$100,000 for the third violation. Once new regulations are written, the amount of these fines will increase to \$75,000, \$100,000 and \$125,000.

At the end of June 2008, the Department of Public Health issued its first report, providing a statistical analysis of the errors that were reported over the first year that the statute was in effect. As reported by the *Los Angeles Times*, 1,002 cases of serious medical harm were disclosed by California hospitals between July 2007 and May 2008, or about 91 cases per month. While this statistic pales in comparison to other reports of medical errors causing serious injury or death in



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hospitals in the U.S. it is important to note that these reports are both voluntary by hospitals and they actually represent specific cases. The other published data about the number of deaths, including the Institute of Medicine report about an estimated 98,000 deaths annually in U.S. hospitals, is based on an extrapolation of data from studies involving chart reviews in a few states. It will be interesting to see if the number of reported cases goes up over the next few years. Since the cases involving actual fines only represent less than 10% of the cases of adverse events reported by hospitals, more time and data will be needed to determine if the impact of these fines will increase or decrease the number of reported adverse events over the next few years.

Under the law, starting Jan. 1, 2009, the Department of Public Health must make information about these section 1279.1 reports and the outcomes of the resulting inspections and investigations accessible to the public, and by Jan. 1, 2015, the Department must provide this information on its website. It is not clear what form such information will take or how the public will access this information between Jan. 1, 2009, and Jan. 1, 2015. But since the Department must issue a report at the conclusion of its investigation and notify the Hospital in writing about their determination about the adverse event even if there is no monetary fine, there is a potential for obtaining this

information as part of a medical malpractice claim.

Therefore, whenever a medical malpractice complaint is filed involving an allegation of negligent care in a hospital, the defendant hospital should be asked in a formal interrogatory if a report was filed pursuant to Health & Safety Code section 1279.1, when it was filed, and who filed the report. A separate request should also be made in a notice to produce for a copy of the report. In several cases we have had to file a motion with the court to compel production before the defense would agree to produce the report. Despite the clear intent and purpose of this new statute, it seems that many hospitals never established any policies or procedures for who or how such a report is to be made to the Department of Public Health, and rarely are these reports filed within five days of the actual adverse event. Hospital defendants will often claim that their interpretation of the law is that a report is only made if there is a clear relationship between an adverse event and an actual injury. Even in obvious cases of medication errors, the defense may admit the error to the family but claim that there is no direct evidence that the medication error caused any injury or harm. Since there are penalties for not reporting an event in a timely manner, and the Department of Public Health seems quite willing to levy the maximum fine more frequently, even the filing of a complaint may be sufficient to cause the

hospital to report an event to the Department of Public Health, even if it is significantly after the event.

Such a report by a hospital, even without the levy of a fine, can be a substantial help in proving both negligence and causation, since the investigation report often correlates the specific adverse event with an adverse outcome. This is especially important in the case of medication errors, where it may be more difficult to show the relationship between the error and the injury or death. These reports can also open a window into the black box of peer review. The law requires that even if an adverse event is detected solely through a peer review process that is otherwise protected from discovery, the hospital may still be required to report the adverse event to the Department, although the details of the peer review process that led to the event's discovery are still protected. Since hospitals have traditionally used peer review as a shield against discovery of any information about an adverse event that is not specifically described in the medical chart, physicians and nurses have become accustomed to putting little information in the medical record and then at deposition claiming that everything they know about an event or discussed with anyone else was part of a protected peer review process. It may take some time before it can

be determined if such 1279.1 reports will provide some chink in the armor of peer review. Since the investigation by the Department of Public Health often involves interviews with personnel involved in the adverse event, within 48 hours of the report to the Department, a written

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report of that investigation may be invaluable in being able to prove a claim.

Detailed information about the 71 cases where the Department of Public Health has issued a \$25,000 fine is currently available on the website of the Department at www.cdph.ca.gov. This information is listed by county, and a click on the name of the hospital will link to the actual report which gives details of the event, the investigation, and the conclusions by the Department. The names of those interviewed at the hospital are not given, but their titles are listed. Thus, it is possible to identify through formal discovery the names of those interviewed by the Department and, at deposition, any information given in these interviews cannot be blocked by the defense. ■

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