

LAW WATCH

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UNPRECEDENTED REPORTING OBLIGATIONS IMPOSED ON CALIFORNIA HOSPITALS

Introduction

On September 29, 2006, California Governor Arnold Schwarzenegger signed into law Senate Bill 1301, which affects hospitals' licensure and creates unprecedented reporting obligations for hospitals and potential liability for substantial fines. Four new Health and Safety Code sections, which become effective on July 1, 2007, mandate that hospitals report "adverse events"; that the Department of Health Services (the "Department") investigate those reports within a set timeframe; and that the Department make the substantiated reports and the results of the investigations publicly available. The new law is intended to serve two basic purposes: (1) to improve hospital quality of care through more state oversight, and (2) to help health care consumers make more informed decisions when choosing a hospital. In practice, the new requirements will have a substantial effect on hospitals' operations and risk management, and ultimately may reduce practitioners' willingness to participate in hospitals' quality improvement efforts.

Reporting Requirement

Section 1279.1 requires general acute care hospitals, acute psychiat-

Executive Summary

Action: *On September 29, 2006, California's governor signed into law Senate Bill 1301, creating four new statutes imposing on hospitals unprecedented reporting obligations and exposure to monetary fines.*

Impact: *The new statutory scheme will require hospitals to report "adverse events to the Department of Health Services, and will require it to investigate those reports. If substantiated, the reports and outcomes of the investigations and inspections will become public information. The statutory scheme will affect hospitals' operations, risk management, and peer review.*

Effective Date: *July 1, 2007.*

ric hospitals, and special hospitals ("hospitals") to report "adverse events" to the Department five days after a hospital detects the adverse event, or, "if the event is an ongoing urgent or emergent threat to the welfare, health or safety of patients, personnel, or visitors, not later than

24 hours" after detection ("1279.1 Report"). Moreover, the hospital is required to inform the patient or the party responsible for the patient of the adverse event when it makes a 1279.1 Report.

The law defines an "adverse event" as one of 28 enumerated occurrences that could negatively impact patient care and safety. The list reflects the "Never 27" events – the 27 occurrences the National Quality Forum identified in 2002 as those that should never occur at a health care facility.* The events are organized under six headings: surgical events, product or device events, patient protection events, care management events, environmental events, and criminal events. The law also includes a new catch-all, "Never 28" event: "an adverse event or series of adverse events that cause the death or serious disability of a patient, personnel, or visitor."

* The text of Section 1279.1, which includes a complete list of reportable adverse events, is reproduced at the end of this *Law Watch*.

Mandatory Investigations and Inspections

Section 1279.2 details the Department's investigatory responsibilities when it receives a 1279.1 Report. If a 1279.1 Report or a complaint about a hospital indicates "an ongoing threat of imminent danger of death or serious bodily harm," then the Department must perform an onsite inspection or investigation within 48 hours or two business days, whichever is greater (the law does not address the difference between an "inspection" or an "investigation"). The Department must complete the investigation within 45 days after receiving the 1279.1 Report. Further, until the Department determines by onsite inspection that the adverse event has been resolved, it must conduct unannounced inspections of the hospital at least once a year. If the Department determines that the 1279.1 Report does not indicate a threat of imminent danger of death or serious bodily harm to any patient, the Department still must complete an investigation of the report in 45 days, but the law does not specify when, or even if, an onsite inspection is required.

At the conclusion of the investigation, the Department must issue a report and must notify the hospital and, if applicable, the complainant, in writing, of the Department's determination.

Public Information

Section 1279.3 sets deadlines for the Department to make public 1279.1 Reports and the Department's investigatory conclusions. By January 1, 2009, the Department must make information about 1279.1 Reports and the outcomes of

the resulting inspections and investigations accessible by California healthcare consumers. By January 1, 2015, the Department must provide this information on its website. Also by January 1, 2009, the Department must compile and make available to "entities deemed appropriate by the Department" data regarding substantiated 1279.1 Reports and the outcomes of the inspections and investigations so that those "entities" can post the data on their websites.

Penalties

Section 1279.4 provides penalties for failing to file a 1279.1 Report. The Department can assess up to a \$100.00 civil penalty for every day that the adverse event is not timely reported. However, the hospital can request a hearing in order to challenge the penalty. Although not stated in the new statute, if the Department determines after an inspection or investigation that an adverse event constitutes, or resulted from, noncompliance with the licensing regulations, hospitals will be subject to existing laws that impose penalties for noncompliance, including fines and, in extreme cases, license revocation.

Impact on Hospitals

This new statutory scheme is expected to impact hospitals' operations, risk management, and quality improvement. Although it does not become effective until July 1, 2007, hospitals should take immediate steps to ensure that effective processes are in place to ensure compliance, patient safety, and effective risk management.

Policies and Procedures

Although not required by the new law, the development of well-written policies and procedures is imperative to ensure compliance, sufficient patient protection, and appropriate risk management. These policies should address many issues, including the individual(s) who is authorized to make 1279.1 Reports on behalf of the hospitals; the internal reporting mechanism when an adverse event is detected; and the type of information that will be reported.

For example, a hospital would be well advised to authorize specific individual(s) (by title, not name) to submit 1279.1 Reports on behalf of the hospital when a reportable event is detected. The hospital should also ensure that its policies make clear the chain of reporting so that all vital information about the adverse event will quickly make its way to the authorized individual(s). For most hospitals, existing incident reporting procedures should be integrated into this process; however, all hospitals should assess whether in practice their current processes would inform the authorized individual(s) in sufficient time to permit the filing of a timely 1279.1 Report.

Hospitals should also provide guidance to the authorized individual(s) concerning the information that must be provided in the report. In most cases, hospitals should limit the information to a simple description of the adverse event; however, there may be instances where including mitigating information will be of benefit. Hospitals also may wish to consult their legal counsel on a case-by-case basis to determine what information should be included in a

report, especially during the early stages of compliance.

Education

Hospitals should educate their employees and medical staff members on compliance with the new law. All personnel will need to be informed of the definition of adverse event and the need for, and how to make, timely internal reports of these events. The authorized individual(s) will need instruction on how to file a timely 1279.1 Report that complies with the law without unnecessarily creating additional risk management issues. In particular, authorized individual(s) will need to learn to differentiate between an adverse event as defined in the new law and an unsuccessful patient outcome that does not need to be reported. Hospitals should avoid over reporting, as this will create additional risk management and public relations consequences – especially because of the requirement to inform the patient (or the patient’s representative) of the report and because the information itself may ultimately become public.

Patient Safety and Risk Management

For patient safety and risk management purposes, a hospital should take all reasonable measures to minimize the possibility that a reported adverse event will occur again. This could include an internal, root-cause analysis and appropriate corrective action, done in a manner that protects the process and conclusions from discovery.

Department Investigations and Inspections

In the past, the Department often was unable to perform immediate investigations of complaints or finalize reports quickly because of insufficient staffing. Now, pursuant to Section 1279.2, the Department has mandatory deadlines to complete investigations or inspections. Because the new law does not require that the Department increase its current staffing, its ability to comply with the new law remains in question. This issue was not lost on the legislature, which included a provision mandating the Department to report on the number and timeliness of its investigations of adverse events when it prepares its annual staffing and systems analysis.

Inevitably, under these new requirements, hospitals will be subject to more inspections and investigations than they have previously experienced. Moreover, these investigations and inspections will take place within what could be a very short timeframe. Therefore, as soon as a hospital detects an adverse event, and even before it files a 1279.1 Report, the hospital should immediately prepare for the inevitable investigation.

Litigation

It is impossible to estimate how significantly 1279.1 Reports will affect the incidence of malpractice claims, or whether the reports themselves will be deemed admissions of liability. With the public availability of the required information, as well as the requirement that hospitals inform patients about the reports, it seems inevitable that the volume of malpractice claims against hospitals, practitioners, and equip-

ment suppliers will increase. A hospital’s report may even be deemed an admission that the event occurred. More worrisome, however, is the possibility that because a reportable event is one of the “Never 27” events (those which a portion of the healthcare community have pronounced should never happen at a hospital), a plaintiff may attempt to assert a *res ipsa loquitur* theory of liability (“the facts speak for themselves”) – in other words, that the event could not have occurred without negligence on the hospital’s or physician’s part.

Hospitals should discuss with their legal counsel strategies for ensuring that these reports are limited to only reportable adverse events, and contain only factual information describing the event itself, rather than details or supposition about the cause of the event. Hospitals also should discuss with legal counsel means to ensure that any subsequent internal investigations and corrective measures are performed with sufficient discovery protections. Finally, to avoid charges from insurance companies that the hospital violated coverage agreements by making alleged admissions, hospitals should notify their malpractice insurance carrier(s) that they are now legally required to inform their patients of adverse events if they fall within the purview of the new law.

Peer Review

Another unknown is the effect this new law may have on peer review. The laws that protect certain medical staff documents and proceedings from discovery do not preempt the obligation to file a 1279.1 Report. 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 (though not the details of the peer review process that led to the event's discovery). Whether this will have a chilling effect on a physician's willingness to participate in peer review is difficult to predict. Although the vast majority of physicians appreciate the role of peer review in improving patient care, some may be concerned about the potential discovery of reportable events during peer review, and therefore may attempt to downplay peer review findings or may even refuse to participate in the process. To minimize those possibilities, hospitals should educate their medical staffs on the new law and clearly explain the unchanged scope peer review's discovery protections.

Conclusion

The new law will require hospitals to make operational changes and almost certainly will have some effect on risk management, litigation defense, and peer review. Although the law does not go into effect until July 1, 2007, hospitals should not delay in discussing strategies for compliance with their management teams, medical staff leaders, and legal counsel. The development of effective policies and sufficient education for employees and medical staff should help hospitals achieve adherence to this new legislation with minimal disruption in operations.

If you have questions about the new adverse event reporting requirements, or health facility licensing issues generally, please contact **Sarah Benator, Lowell Brown, Jon Cohn, or Shirley Morrigan** in our

Los Angeles office, **Jody Root** in our San Diego office, **Michael Scarano** in our San Diego/Del Mar office, **Inge Penner** or **Jon Lindeke** in our San Francisco office, or the member of the firm who normally handles your legal matters.

This *Law Watch* was co-authored by **Sarah G. Benator, Jonathon E. Cohn, and Lowell C. Brown** of our Los Angeles office. *Law Watch* is a review of recent legal developments prepared by **Foley & Lardner LLP**. The information reported should not be construed as legal advice, nor utilized to resolve legal problems. Recent issues of *Law Watch* are also available on our web site at:

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Health and Safety Code Section 1279.1.

(a) A health facility licensed pursuant to subdivision (a), (b), or (f) of Section 1250 shall report an adverse event to the department no later than five days after the adverse event has been detected, or, if that event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, not later than 24 hours after the adverse event has been detected. Disclosure of individually identifiable patient information shall be consistent with applicable law.

(b) For purposes of this section, "adverse event" includes any of the following:

(1) Surgical events, including the following:

(A) Surgery performed on a wrong body part that is inconsistent with the documented informed consent for that patient. A reportable event under this subparagraph does not include a situation requiring prompt action that occurs in the course of surgery or a situation that is so urgent as to preclude obtaining informed consent.

(B) Surgery performed on the wrong patient.

(C) The wrong surgical procedure performed on a patient, which is a surgical procedure performed on a patient that is inconsistent with the documented informed consent for that patient. A reportable event under this subparagraph does not include a situation requiring prompt action that occurs in the course of surgery, or a situation that is so urgent as to preclude the obtaining of informed consent.

(D) Retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained.

(E) Death during or up to 24 hours after induction of anesthesia after surgery of a normal, healthy patient who has no organic, physiologic, biochemical, or psychiatric disturbance and for whom the pathologic processes for which the operation is to be performed are localized and do not entail a systemic disturbance.

(2) Product or device events, including the following:

(A) Patient death or serious disability associated with the use of a contaminated drug, device, or biologic provided by the health facility when the contamination is the result of generally detectable contaminants in the drug, device, or biologic, regardless of the source of the contamination or the product.

(B) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. For purposes of this subparagraph, “device” includes, but is not limited to, a catheter, drain, or other specialized tube, infusion pump, or ventilator.

(C) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a facility, excluding deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

(3) Patient protection events, including the following:

(A) An infant discharged to the wrong person.

(B) Patient death or serious disability associated with patient disappearance for more than four hours, excluding events involving adults who have competency or decision making capacity.

(C) A patient suicide or attempted suicide resulting in serious disability while being cared for in a health facility due to patient actions after admission to the health facility, excluding deaths resulting from self-inflicted injuries that were the reason for admission to the health facility.

(4) Care management events, including the following:

(A) A patient death or serious disability associated with a medication error, including, but not limited to, an error involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration, excluding reasonable differences in clinical judgment on drug selection and dose.

(B) A patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.

(C) Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a facility, including events that occur within 42 days post delivery and excluding deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy.

(D) Patient death or serious disability directly related to hypoglycemia, the onset of which occurs while the patient is being cared for in a health facility.

(E) Death or serious disability, including kernicterus, associated with failure to identify and treat hyperbilirubinemia in neonates during the first 28 days of life. For purposes of this subparagraph, “hyperbilirubinemia” means bilirubin levels greater than 30 milligrams per deciliter.

(F) A Stage 3 or 4 ulcer, acquired after admission to a health facility, excluding progression from Stage 2

to Stage 3 if Stage 2 was recognized upon admission.

(G) A patient death or serious disability due to spinal manipulative therapy performed at the health facility.

(5) Environmental events, including the following:

(A) A patient death or serious disability associated with an electric shock while being cared for in a health facility, excluding events involving planned treatments, such as electric countershock.

(B) Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by a toxic substance.

(C) A patient death or serious disability associated with a burn incurred from any source while being cared for in a health facility.

(D) A patient death associated with a fall while being cared for in a health facility.

(E) A patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health facility.

(6) Criminal events, including the following:

(A) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider.

(B) The abduction of a patient of any age.

(C) The sexual assault on a patient within or on the grounds of a health facility.

(D) The death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of a facility.

(7) An adverse event or series of adverse events that cause the death or serious disability of a patient, personnel, or visitor.

(c) The facility shall inform the patient or the party responsible for the patient of the adverse event by the time the report is made.

(d) "Serious disability" means a physical or mental impairment that substantially limits one or more of the major life activities of an individual, or the loss of bodily function, if the impairment or loss lasts more than 7 days or is still present at the time of discharge from an inpatient health care facility, or the loss of a body part.

(e) Nothing in this section shall be interpreted to change or otherwise affect hospital reporting requirements regarding reportable diseases or unusual occurrences, as provided in Section 70737 of Title 22 of the California Code of Regulations. The department shall review Section 70737 of Title 22 of the California Code of Regulations requiring hospitals to report "unusual circumstances" and consider amending the section to enhance the clarity and specificity of this hospital reporting requirement.

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