

## **NEW LAWS ON CALIFORNIA HOSPITAL ADVERSE EVENT REPORTING AND FACILITY INSPECTIONS**

### Reporting Adverse Events

Effective July 1, 2007, Health & Safety Code §1279.1-1279.3 and 1280.4 will require California hospitals to report any adverse event to the California Department of Health Services ("DHS"). The reporting law creates a new set of disclosure requirements for all general acute care hospitals, acute psychiatric hospitals, and "special hospitals". The new law sets forth an extensive set of reportable events and requires DHS to publish the results of its investigation of those events to the public. Failure to report an adverse event may result in a fine of up to \$100 for each day the event is not reported to DHS. This new law is expected to have a substantial impact on hospital operations and risk management.

Adverse events include a wide array of medical, pharmaceutical, and nursing care errors, as well as criminal acts. In summary, these events are classified into categories and described as: (1) surgical events, such as surgery performed on a wrong body part that is inconsistent with the documented informed consent for that patient; (2) product or device events, such as patient death or serious disability associated with use of a contaminated product or device; (3) patient protection events, such as an infant discharged to the wrong person; (4) care management events, such as a patient death or serious disability associated with a medication error; (5) environmental events, such as a patient death or serious disability associated with an electric shock while being cared for in a health facility; or (6) criminal events, such as any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider. A seventh general category requires reporting of any adverse event or series of events that is the cause of death or serious disability of a patient, a member of the facility's personnel, or visitor.

A hospital must report a non-urgent or non-emergent adverse event within five (5) days of discovery. When the event is an "ongoing urgent or emergent threat" to a patient, personnel, or visitor, the hospital must report the event to DHS within 24 hours of detection (rather than five days). If an adverse event report indicates an ongoing threat of imminent danger or serious bodily harm, DHS must make an onsite inspection or investigation within the later of 48 hours or two business days, and complete its investigation within 45 days. Until DHS has determined that the adverse event has been resolved, it must conduct an unannounced inspection at least once per year. If the adverse event report does not indicate an ongoing threat of imminent danger or serious bodily harm DHS must complete the investigation within 45 days.

Beginning, January 1, 2009, DHS will make information regarding reports of substantiated adverse events and outcomes of inspections and investigations readily accessible to consumers in written form. Beginning in January 1, 2014, DHS will post information regarding reports of substantiated adverse events and the outcomes of inspections and investigations on the DHS website.

### Inspection Requirements

Effective July 1, 2007, pursuant to Health & Safety Code §1279-1280.6 and 1422, accredited health facilities enrolled in the Medicare or Medicaid programs will no longer be exempt from periodic inspections by DHS for compliance with state licensure regulations. The new law requires that DHS conduct unannounced inspections applying both state and federal regulations to every licensed health care facility, regardless of how the facility was certified to participate in the Medicare or Medicaid Programs. DHS is also required to commence unannounced inspections of health care facilities to ensure that California's licensure standards are upheld. The frequency of the inspections is dependent upon the type of facility and any intervening complaints or changes in administrator or director of nursing.

All general acute care hospitals, acute psychiatric hospitals, and special hospitals are subject to inspection no less than once every three years or "as often as necessary to ensure the quality of care being

provided." All other health facilities licensed by DHS (e.g., rehabilitation centers, nursing facilities, intermediate care facilities) are subject to inspection no less than once every two years or as DHS determines necessary to protect the well-being of a facility's patients. Long-term health care facilities cited for class "AA," "A," or "B" violations or active patient complaints are subject to more frequent inspections. Long-term health care facilities are also subject to an abbreviated inspection within 90 days of receipt of notice of a change in administrator or director of nursing services.

DHS is required to adopt regulations that specify the circumstances under which an administrative penalty is assessed and the amount of that penalty. In drafting the regulations, DHS must consider at least the following mitigating or aggravating conditions: (a) patient's physical and mental condition; (b) probability and severity of the risk the violation presented to the patient; (c) actual financial harm to patient; (d) nature, scope and severity of the violation; (e) facility's history of compliance; (f) contributing factors that were beyond the facility's control; (h) willfulness of the violation; and (i) whether the facility took steps to immediately correct the violation and prevent reoccurrence.

Deficiencies occurring after the July 1, 2007 effective date of the DHS regulations are subject to an administrative penalty not to exceed \$50,000 per immediate jeopardy violation. Violations of the statute or regulations governing licensed health facilities not constituting immediate jeopardy are subject to an administrative penalty not to exceed \$17,500 per violation. Notwithstanding the above, beginning January 1, 2007, if a facility receives a notice of deficiency and is required to submit a plan of correction for a violation that constitutes an immediate jeopardy to the health or safety of a patient, DHS may assess an administrative penalty of up to \$25,000 per violation. Every health facility licensed by DHS receiving a notice of deficiency constituting immediate jeopardy to the health or safety of a patient must present DHS with a plan of correction. A deficiency causing "immediate jeopardy" is defined as a "situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient."

Any health care facility cited for a deficiency or assessed an administrative penalty may appeal the decision regarding the reasonableness of the proposed deadline for corrective action or the amount of the penalty by requesting a hearing within 10 working days of the DHS finding or assessment of a fee. Any administrative penalty will be set aside until the facility's appeals have been exhausted and the DHS position upheld.

### Conclusion

It is important for all hospitals to carefully review the new laws and work with their health care law attorneys to ensure that they are compliant with the requirements. Although not required by the new laws, the development of written policies and procedures are important to address hospital risk management issues and patient protections. For example, hospitals should ensure that their policies and procedures adequately detail the proper steps for reporting an adverse event consistent with Health & Safety Code §1279.1 et. seq. In addition hospitals should prepare for unannounced state inspections and review their facility's compliance with state licensing regulations. We can provide practical advice as you develop and implement the requisite policies and procedures. If you have any questions about adverse event reporting or health care licensing issues generally, please contact Michael Dowell at [mdowell@sortm.com](mailto:mdowell@sortm.com) or the lawyer in the firm who generally handles your health care law legal matters.