



Healthcare Law Alert, December 2010

California Department of Public Health Set to Launch Rulemaking on Administrative Penalties for Medical Information Breaches and Immediate Jeopardy and Adverse Events

By Kathryn Doi, Partner
Healthcare Law Team
Murphy Austin Adams Schoenfeld LLP

In recent years, the California legislature has passed laws that allow discretionary administrative penalties against health facilities of up to \$100,000 per violation for medical information breaches, "immediate jeopardy" situations, and adverse (the so-called "never") events. The State has assessed such penalties against many providers despite not yet having promulgated regulations to implement these new laws. The California Department of Public Health ("CDPH") is now preparing to promulgate regulations. It is holding public meetings and inviting written comments on December 14 (medical information breaches) and January 10 (immediate jeopardy and adverse events) to give interested persons the opportunity to shape how these laws will be applied in the future. Formal rulemaking will follow, which will provide another opportunity for public comment.

Background

The In 2008, the California legislature adopted SB 541 (Alquist), which increased the administrative penalties the CDPH may assess against hospitals for deficiencies that present "immediate jeopardy" to the health or safety of patients. The bill also authorized the CDPH to levy administrative penalties against facilities for failure to prevent unlawful or unauthorized access, use, or disclosure of patient medical information, and for failure to report instances of unlawful or unauthorized access, use, or disclosure of information.

SB 541 followed 2006 legislation, SB 1301(Alquist), which required hospitals to report 27 enumerated adverse events, the so-called "never" events, as well as a 28th general event defined as "an adverse event or series of events that cause the death or serious disability of a patient, personnel, or visitor," to the CDPH no later than 5 days after the detection of the adverse event (or 24 hours in the case of an urgent or emergent threat).

Administrative Penalties for Medical Information Breaches

The statute governing medical information breaches, Health & Safety Code section 1280.15, authorizes the CDPH to assess, after investigation, an administrative penalty for unlawful or unauthorized access or use of medical information of up to \$25,000 per patient, and up to \$17,500 per subsequent occurrence involving the same patient's medical information. Section 1280.15 provides that the CDPH shall consider the provider's history of compliance with section 1280.15 and other related state and federal statutes and regulations, the extent to which the facility detected violations and took preventative action to immediately correct and prevent past violations from recurring, and factors outside the facility's control that restricted the facility's ability to comply with section 1280.15. The statute also states, "The department shall have full discretion to consider all factors when determining the amount of an administrative penalty pursuant to this section."

Although the CDPH has yet to promulgate regulations to implement this section, according to its website, it assessed penalties against 14 hospitals for violations of this section in 2010, raising questions as to how it is exercising its "full discretion" in the absence of regulations or whether it is indeed exercising the discretion given to it by statute.

The pre-notice meeting regarding regulations governing medical information breaches will be held on Tuesday, December 14, 2010, at the East End Complex Auditorium, 1500 Capitol Avenue, Sacramento, California 95814 at 8:30 a.m. Any interested person may present oral or written comments at the meeting, or can submit written comments to the Contact Person identified in the CDPH Notice not later than 5:00 p.m. on Monday, December 13, 2010. A copy of the Notice is attached.

Administrative Penalties for Immediate Jeopardy and Adverse Events

Under Health & Safety Code sections 1280.1 and 1280.3, a facility can be assessed an administrative penalty in an amount not to exceed \$100,000 per violation if it receives a notice of deficiency constituting an immediate jeopardy to the health or safety of a patient. "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. The statute gives the CDPH "full discretion" to consider all factors when determining the amount of an administrative penalty pursuant to these sections.

The CDPH is also directed to promulgate regulations establishing criteria to assess an administrative penalty, which shall include, but is not necessarily limited to, (1) the patient's physical and mental condition, (2) the probability and severity of the risk that the violation presents to the patient, (3) the actual financial harm to the patients, if any, (4) the nature, scope, and severity of the violation, (5) the facility's history of compliance with related state and federal statutes and regulations, (6) factors beyond the facility's control that restrict the facility's ability to comply with the statute, (7) the demonstrated willfulness of the violation, and (8) the extent to which the facility detected the violation and took



Kathryn Doi, Attorney at Law
916-446-2300 X3115
kdoi@murphyaustin.com

Kathryn Doi is a partner in the **Healthcare Law Practice Team**. With more than twenty years of experience as an attorney in the private and public sector, Kathryn advises clients with respect to complex statutory and regulatory schemes and problem-solving involving government agencies and departments. She also represents clients in the California and federal trial and appellate courts, administrative and regulatory proceedings, and arbitration and mediation. **Murphy Austin Adams Schoenfeld LLP**, a premier law firm in the Sacramento region, is committed to client service and professional excellence. We value our long-standing relationships with our many exceptional clients as the highest form of professional compliment.

steps to immediately correct the violation and prevent the violation from recurring.

Health & Safety Code sections 1279.1 and 1280.4 address a health facility's obligation to report an adverse event to the CDPH. A facility is required to report an adverse event within 5 days after the event has been detected (or 24 hours if the event is an ongoing urgent or emergent threat to the welfare, health or safety of patients, personnel, or visitors). A failure to report an adverse event may result in a civil penalty in an amount not to exceed \$100 for each that that the adverse event is not reported following the initial 5-day or 24-hour period. While these statutes do not expressly address the CDPH's discretion, it would appear the types of factors identified in the immediate jeopardy statute should also be taken into consideration in addressing civil penalties in an adverse event situation.

A pre-notice meeting regarding regulations governing these administrative penalty regulations will be held on Monday, January 10, 2011, at the East End Complex Auditorium, 1500 Capitol Avenue, Sacramento, California 95814 at 8:30 a.m. Any interested person may present oral or written comments at the meeting, or can submit written comments to the Contact Person identified in the CDPH Notice not later than 5:00 p.m. on Monday, January 10, 2010. A copy of the Notice is attached.

Please be assured that we make every effort to make certain that the information contained in this article is current at the time the article was prepared. Because laws and legislation are constantly changing, please contact us if you are unsure whether this material is still current. Nothing contained herein is meant to be legal advice. Please contact us to answer any questions you may have.



MARK B HORTON, MD, MSPH
Director

State of California—Health and Human Services Agency
California Department of Public Health



ARNOLD SCHWARZENEGGER
Governor

October 27, 2010

AFL 10-36

TO: All Health Care Facilities

SUBJECT: Pre-Notice Meeting for Regulations Governing Medical Information Breaches

NOTICE IS HEREBY GIVEN that the California Department of Public Health (CDPH), Center for Health Care Quality, Licensing & Certification Program (hereinafter referred to as the "Department"), pursuant to Government Code Section 11346.45, is inviting interested parties to participate in a public discussion and submit statements and comments regarding the substance of regulations governing Medical Information Breaches described in Health & Safety Code Section 1280.15 prior to the start of the formal rulemaking process.

Any person interested may present statements orally or in writing relevant to these issues at a pre-notice meeting to be held at the **East End Complex Auditorium, 1500 Capitol Avenue, Sacramento, CA 95814 at 8:30 a.m., Tuesday, December 14, 2010.**

Written comments, including those sent by mail, facsimile, or e-mail to the address listed under Contact Persons in this Notice, must be received by the Department at its office not later than 5:00 p.m. on Monday, December 13, 2010, or must be received at the meeting.

The meeting is accessible to the physically disabled. A person who needs a disability-related accommodation or modification in order to participate in the meeting may make a request by contacting Edwin Hoffmark at 1-800 236-9747, or email RNUnit@cdph.ca.gov, or send a written request to the Department at P.O. Box 997377; MS 3201, Sacramento, CA 95899-7337. Providing your request at least seven (7) business days before the meeting will help to ensure availability of the requested accommodation.

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Contact Persons:

Jennifer Hoke, Chief of Certification & Regulations
and/or
Edwin Hoffmark, RN Unit Chief

CDPH, Licensing & Certification
P.O. Box 997377; MS 3201
Sacramento, CA 95899-7377
Fax: (916) 324-4820
Email: RNUnit@cdph.ca.gov
Phone: 1-800-236-9747

Sincerely,

Original Signed by Kathleen Billingsley, R.N.

Kathleen Billingsley, R.N.
Deputy Director
Center for Health Care Quality

NOTICE IS HEREBY GIVEN that the California Department of Public Health, Center for Health Care Quality, Licensing & Certification Program (hereinafter referred to as the "Department"), pursuant to GC Section 11346.45, is inviting interested parties to participate in a public discussion and submit statements and comments regarding the substance of regulations governing Administrative Penalties described in Health & Safety Code Sections 1280.1, 1280.3, and 1280.4 and Adverse Events described in Health & Safety Code Section 1279.1 prior to the start of the formal rulemaking process.

Any person interested may present statements orally or in writing relevant to these issues at a pre-notice meeting to be held at the **East End Complex Auditorium, 1500 Capitol Ave., Sacramento, California 95814 at 8:30 a.m., Monday, January 10, 2011.**

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