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Major New Legislation Changes the Dynamic with the State of California

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Across the nation, increasing attention is being paid to the quality of healthcare, particularly in hospital settings. Recently the California Legislature passed, and Governor Schwarzenegger signed, four bills that together will have a significant impact on hospitals and will likely require changes in operational policies and procedures to ensure compliance. SB158 (Florez), SB1058 (Alquist), SB541 (Alquist), and AB211 (Jones) provide the State with additional authority to assess substantial fines against licensed facilities as well as unlicensed individuals and entities for violations of law. We see these new laws as indicative of systemic change in how the State of California interacts with hospitals, and as establishing increasingly higher expectations of quality and patient safety.

The combination of the provisions of SB158, SB1058, SB541 and AB211 will require significant due diligence on the part of licensed entities to ensure that their policies and procedures, operational environments, and disciplinary procedures are adequate to reasonably ensure the safety of patients and protect patient medical information. The requirements and expectations outlined in the new legislation will require renewed focus for many providers and in some instances the implementation of altogether new information and personnel management strategies.

Healthcare-Associated Infections

SB158 is focused on the reduction of healthcare-associated infections and contains the following primary elements:

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- It requires general acute care hospitals, acute psychiatric hospitals, skilled nursing facilities, and special hospitals to develop and implement a patient safety plan that includes the establishment of a patient safety committee, training for staff, and a reporting and improvement mechanism for "patient safety events." The plan must also address ongoing process improvement and patient safety training.

- It establishes training program requirements for all permanent and temporary hospital employees and contractual staff, including students, in infection prevention and control policies, including hand hygiene, facility-specific isolation procedures, patient hygiene, and environmental sanitation procedures.

- It establishes an infection surveillance, prevention, and control program within the California Department of Public Health (CDPH). This program has specific duties, including improving regulatory oversight and disseminating evidence-based standards related to infection surveillance, prevention and control practices. CDPH is also required to implement an Internet-based public reporting system and provide current infection prevention and control information to the public.

- It imposes new education and training requirements for CDPH health facility evaluator nurses and consultants to effectively survey hospitals for compliance with infection surveillance, prevention, and control recommendations, as well as state and federal statutes and regulations.

SB1058 establishes the Medical Facility Infection Control and Prevention Act, or "Nile's Law," which requires health facilities to test certain patients for methicillin-resistant Staphylococcus aureus ("MRSA"), develop and follow more comprehensive infection-control policies and procedures, and report certain healthcare-associated infections to CDPH. Specifically, the bill requires:

- Generally, patients who have recently been discharged from a general acute care hospital, are transferring to the hospital from a skilled nursing facility, are being admitted to a burn unit or intensive care unit, are receiving inpatient dialysis, or are susceptible to infection must be tested for MRSA within 24 hours of admission. If a patient tests positive for MRSA, the patient's attending physician is to inform the patient or the patient's representative immediately or as soon as practically possible, and prior to discharge the patient is to receive oral and written instruction regarding aftercare and precautions to prevent the spread of the infection to others.

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- Infection control policies must include procedures to reduce healthcare-associated infections. The bill delineates some specific facility areas, equipment, and furniture that must be included in the policies. In addition, each facility is to designate an infection control officer responsible for compliance with the provisions of the statute.

- Each health facility is to report, on a quarterly basis, all cases of specified infections, including MRSA bloodstream infections, central line-associated bloodstream infections, certain surgical site infections, and others. Commencing January 1, 2011, CDPH is to post on its website risk-adjusted data with respect to reported infections.

Immediate Jeopardy and Other Violations

In January 2007 CDPH was granted the authority to assess administrative penalties against general acute care hospitals, acute psychiatric hospitals, and special hospitals for deficiencies in licensing and regulatory compliance that constitute immediate jeopardy to the health and safety of a patient. In addition, CDPH was required to develop regulations around the assessment of administrative penalties for other violations that do not constitute immediate jeopardy.

SB541 increases the administrative penalties for deficiencies constituting immediate jeopardy ("IJ Violation") on a graduated scale. Current law allows the imposition of a $25,000 fine for each IJ Violation. Effective January 1, 2009, the initial fine for an IJ Violation will be $50,000. Subsequent IJ Violations will be assessed at $75,000 for the second and $100,000 for the third and each subsequent IJ Violation. A facility must be free of IJ Violations for three years, and meet other requirements, before the fine reverts to the $50,000 level. Upon promulgation of regulations, the fines increase to a maximum of $75,000, $100,000, and $125,000 for IJ Violations and a fine of up to $25,000 for other licensing/regulatory violations not constituting immediate jeopardy.

SB541 also establishes new reporting requirements and fiscal penalties on clinics, health facilities, agencies, and hospices related to the unauthorized access, use or disclosure of a patient's medical information. It is important to note that the data and entities covered under this new provision are broader than HIPAA-covered entities or HIPAA-covered data. In addition, the bill requires that the affected patient and CDPH be notified within 5 days of the entity becoming aware

of the breach and the entity is subject to financial penalties that accrue on a daily basis if reporting does not occur. A fine of up to $25,000 may be assessed by CDPH for the initial violation and $17,500 for each subsequent violation. In determining the amount of a penalty, CDPH has the latitude to consider specific aspects of the entity's prior behavior, including prior violations and actions the entity may have taken to prevent past violations from recurring.

Individual Liability for Disclosure of Medical Information

AB211 represents a significant change in the way the State of California expects medical information to be managed and protected. While SB541 focuses on specific licensed facilities and an organizational duty to protect information about individuals in their care, AB211 provides the State with new authority to assess administrative penalties or civil fines on licensed and unlicensed *individuals* and providers of health care not covered under SB541 who knowingly and willfully obtain, disclose or use medical information. The bill further provides that individuals who are not licensed health care professionals can be assessed an administrative penalty or civil fine of up to $25,000. Licensed health care professionals will be subject to fines on a graduated scale based on the number of violations. In addition, the bill establishes significant financial penalties if the individual uses medical information for financial gain, but even mere negligent disclosure of medical information in violation of the statute will subject the person or entity to a fine of $2,500. Again, the penalty provisions draw a distinction between licensed health care professionals and other individuals. The bill also establishes the Office of Health Information Integrity in the Health and Human Services

Maximum Administrative Fine or Civil Penalty Levels

Licensed Health Care Professional

Obtains, discloses, uses medical information

- $2,500 for first violation
- $10,000 for second violation
- $25,000 for third and subsequent violations

Obtains, discloses, uses medical information for financial gain

- $5,000 for first violation
- $25,000 for second violation
- $250,000 for third and subsequent violations

Others

Negligent disclosures, uses of medical information

- $2,500

Obtains, discloses, uses medical information

- $25,000

Obtains, discloses, uses medical information for financial gain

- $250,000

Agency and vests that entity with the authority to levy these newly established administrative penalties.

While SB541 contains provisions that allow CDPH to begin imposing administrative penalties at the new higher levels on January 1, 2009, full implementation of the provisions of AB211 will require that the Office of Health Information Integrity promulgate regulations.

FOR ADDITIONAL INFORMATION ON THIS ISSUE, CONTACT:

Ann Boynton Ms. Boynton's active and strong policy background complements Manatt's state and federal policy objectives. Her knowledge of the government space, in particular her experience as a member of the Governor's Senior Staff and as Undersecretary of the Health and Human Services Agency, establishes Ms. Boynton as a well-recognized, highly respected, and extremely connected figure among government leadership and their staffs. Ms. Boynton's insight into state department and agency structure and activities and policy background will strengthen Manatt's current and future engagements.

Francis J. LaPallo Mr. LaPallo's practice focuses on the representation of healthcare enterprises including transactions, fraud and abuse, licensing and certification, operational, regulatory and litigation matters. He represents both publicly traded and privately held operators of hospitals, nursing homes, dialysis clinics, mental health units, home health agencies, physician organizations and other participants in the healthcare business. Mr. LaPallo also represents clients on significant litigation matters and sensitive internal investigations.

Jeffrey J. Maurer Mr. Maurer's practice focuses on a wide range of complex litigation matters for Manatt's national healthcare clients. His experience in healthcare litigation includes complex business, unfair competition, provider/payor payment, managed care contracting, antitrust, and fraud and abuse disputes. He also advises clients on regulated transactions involving the sale of non-profit healthcare facilities, corporate governance, charitable trust laws, and healthcare licensing issues.