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Life Sciences Health Industry Alert

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California Health Care Update: Review of New Laws Adopted in 2009 and Effective in 2010

During 2009, the California legislature passed several bills impacting health care providers. In this memorandum, we provide our annual end-of-year summary of major legislation impacting California physicians, hospitals, nursing facilities, and other licensed health care facilities. Unless otherwise noted, each new law described below will become effective January 1, 2010.

Although California legislators devoted a significant amount of time and resources to addressing the state's budget shortfall and the economic recession, the 2009 legislature debated and passed a surprising number of bills related to health care. A select number of these bills were signed into law by Gov. Schwarzenegger at the end of the fall legislative session. Topics addressed by the new laws include amendments to the 2008 law requiring certain health care providers to disclose unlawful and unauthorized uses or disclosure of medical information.[1] In addition, the legislature put more pressure on the Department of Public Health (the "Department") by requiring the agency to more timely process and approve applications for new or modified hospital outpatient services.

A number of provisions impacting the delivery of radiologic and diagnostic imaging services were also passed and signed by Gov. Schwarzenegger, including a provision permitting physician assistants to provide fluoroscopy services under the supervision of a physician. Further, in passing Assembly Bill 215, California becomes one of the first states to recognize and incorporate the controversial Five-Star Quality Rating for nursing facilities as created by the Centers for Medicare & Medicaid Services ("CMS"). Moreover, long-term care providers will be subject to new ownership disclosure requirements as a result of Assembly Bill 1457. Finally, we have summarized amendments to California's False Claim Act that expand the types of claims subject to the law, extend the state's prosecutorial authority, and increase the penalties for violating the statute.

For ease of reading, we have grouped the following summary according to the type of health care provider impacted by each new law.

I. Clinics, Hospitals, Home Health Agencies and Hospices

In the 2008 legislative session, the California legislature enacted a new law protecting the privacy of patients' confidential medical information from unauthorized use or disclosure by licensed health care professionals and third parties. *See* Cal. Health & Safety § 1280.15. The 2008 law requires that clinics, hospitals, home health agencies, and hospices report any unlawful or unauthorized access, use, or disclosure of a patient's medical information to the Department and the affected patient or the patient's representative no later than five days after such access, use, or disclosure has been detected. See id.

In the 2009 legislative session, the California legislature revisited the 2008 law in order to clarify that the five-day period is five business days (not calendar days). Additionally, the legislature created an exception to the reporting period when law enforcement is investigating the breach of a patient's medical information. Specifically, a clinic, hospital, home health agency, or hospice may delay reporting unlawful or unauthorized access, use, or disclosure of a patient's medical information to the affected patient or the patient's representative later than five business days if a law enforcement agency or official provides a written or oral statement that the reporting requirement would impede the law enforcement agency's activities related to the breach. The delay in reporting the breach to the patient may not exceed 60 days after a written request is made, or 30 days after an oral request is made. If the original request for a reporting delay was made orally by a law enforcement official, then the health care provider must document the oral statement by recording the identity of the official and the date of the request.

A delay in reporting the breach may be extended further if a law enforcement agency or official provides a written declaration that (1) there exists a *bona fide*, ongoing, significant criminal investigation of serious wrongdoing relating to the breach, (2) notification of patients will undermine the law

enforcement agency's activities, and (3) a date upon which the delay will end, which may not exceed 60 days after the original delay period, is specified. Regardless of whether a report of the breach is delayed by a written request, an oral request, or a further written declaration, the clinic, hospital, home health agency, or hospice must submit a report to the affected patient or the patient's representative no later than five business days after the date designated as the end of the delay. The law does not permit a clinic, hospital, home health agency, or hospice to delay making a report to the Department.

II. Hospital Outpatient Clinics

Assembly Bill 1544 creates new standards for processing license applications for hospital outpatient services. Effective January 1, 2010, the Department is required to determine the completeness of an application for a new or modified hospital outpatient service within 30 days of receipt. A completed application must include the following:

A. The appropriate forms, fees, and documentation, as determined by the Department

B. A description of the type of outpatient clinic service to be operated; the character and scope of the service to be provided; a complete description of the building, its location and proximity to the main hospital building, facilities, equipment, apparatus, and appliances to be furnished and utilized in the operation of the outpatient clinic service; and evidence satisfactory to the Department that the hospital owns and will operate the outpatient clinic service that is the subject of the application

C. Written policies and procedures governing the operation of the outpatient clinic service and its reporting relationship to the applicant

D. Evidence of the hospital's compliance with applicable building standards and possession of a fire clearance for the outpatient clinic service space

Once a complete application has been received, the Department has 100 days to investigate the facts set forth in the application and either grant or deny the application. A denial must include a written description of the basis for the determination. If the outpatient services are approved, the Department will either add the services to the hospital's existing license or issue a new license.

III. Radiology and Diagnostic Imaging

A. Coverage and Payment of Digital Mammography

Assembly Bill 359 authorizes coverage and payment of digital mammography screening under the "Every Woman Counts" program when film or analog mammography services are not available from the provider. For diagnostic procedures conducted through January 1, 2014, payment rates are the same as film or analog rates under the California Medicaid program (Medi-Cal), which is much lower than otherwise paid for digital technology. Under existing program requirements, only mammography screening provided to individuals whose family income does not exceed 200 percent of the federal poverty level is covered.

The California Radiological Society and a number of other civic groups (e.g., Race for the Cure) have sought to expand coverage of digital mammography for several years. Until now, the program's failure to cover digital mammography meant that women who would otherwise be covered under the program were ineligible if the health care provider upgraded to new digital equipment or otherwise provided the service with digital technology. Existing law also raised a concern that providers who utilized digital technology, but billed the program for analog or film studies, could be subject to a false claim allegation. While Assembly Bill 359 arguably does not provide adequate payment for digital mammography, it does allow more women access to the service, while offering some payment and protection for health care providers with digital technology.

B. Mammography Quality Disclosures

The California legislature adopted a new law requiring facilities operating mammogram machines to post notices of serious violations in areas visible to patients. The notice must be posted within two working days after receipt of the documents from the Department and remain posted until corrective action is completed, or a minimum of five working days, whichever is later. "Serious violations" are defined as Level 1 deviations from the federal Mammography Quality Standards Act of 1992.

C. Physician Assistants and Fluoroscopy

Effective January 1, 2010, Assembly Bill 356 permits physician assistants to use fluoroscopy under the supervision of a physician. In order to receive a fluoroscopy permit, a licensed physician assistant

must meet specified training requirements. In particular, a physician assistant must complete 40 hours of coursework recognized by the Department, including fluoroscopy radiation safety and protection. Every two years, physician assistants also must earn 10 approved continuing education credits approved by the Physician Assistant Committee. The physician assistant must be supervised by a physician also having a fluoroscopy permit or who is exempt from holding a permit. The new law does not permit a physician assistant to perform any other procedures utilizing ionizing radiation.

IV. Long-Term Care Facilities

A. Ownership Notification

Assembly Bill 1457 amends section 1599.64 of the California Health and Safety Code to require nursing facilities to disclose in each resident's abbreviated or standard contract of admission (1) the name of the facility's owner and (2) the name and contact information for the entity that is responsible for resident care and operation of the facility. Therefore, beginning January 1, 2010, all standardized contracts of admission and abbreviated contracts of admission for nursing facilities in California must include the name of the owner, and the name and contact information of the facility's management company.

Assembly Bill 1457 also adds section 1599.645 to the California Health and Safety Code. This section requires any nursing facility receiving an approval of a change of ownership from the Department to send written notification of the change of ownership to all current residents, and to the primary contacts for the residents as listed in the admission agreements. The notice must be sent within 30 days of the approval of the change of ownership, and must include the name of the owner and the name of the licensee of the nursing facility, as well as the name and contact information for the entity that is accountable for resident care and operation of the facility. The skilled nursing facility must send to the Department copies of the written notice and the list of individuals and mailing addresses to whom the notice was sent.

B. Five-Star Rating Notification

Assembly Bill 215 adds section 1418.21 to the California Health and Safety Code. This section requires skilled nursing facilities to post overall facility rating information determined by CMS's Five-Star Quality Rating.[2] Beginning January 1, 2011, all long-term care facilities in California must post the following information on a white or light colored sheet of paper that is at least 8.5" x 11" in size, in a clear and easily readable font: (1) the full name and full address of the facility; (2) the overall star rating given to the facility by CMS (designated with the same number of star symbols assigned by the CMS rating); (3) the text "out of five stars," directly beneath the stars; and (4) a specific text describing the Five-Star Quality Rating System that includes the address of the CMS website where a detailed explanation of the posted rating may be obtained.

This information must be posted in at least the following locations in the facility: (1) an area that is accessible and visible to members of the public; (2) an area used for employee breaks; and (3) an area used by residents for communal functions, such as dining, resident council meeting, activities or other recreation. Each facility also must make available a copy of the most recent CMS report on the facility if requested by a resident or member of the public. A violation of this section is punishable by a fine.

V. All Health Care Providers

The California False Claims Act (the "Act") prohibits persons from committing one of several acts related to submitting false or fraudulent claims for money, property, or services to the state or a political subdivision of the state. The Act imposes a civil penalty for violations, and the California attorney general (or any attorney with prosecutorial authority of a political subdivision of the state) may bring an action against a person violating the Act or may intervene in an action filed by a qui tam plaintiff.

Assembly Bill 1196 expands the definition of "claim," thereby expanding potential liability for the submission of false claims. While the bill does not change the law with respect to the definition of a "claim" as any demand for money, property, or services made to an employee, officer, or agent of the state or political subdivision, the bill does expand the definition of a "claim" when the demand is made to any contractor, guarantee, or other recipient of money, property, or services. A person may now be liable for a false request or demand for money, property, or services if the money, property, or service is to be expended on a program or interest if the state or political subdivision either provides or reimburses the contractor, guarantee, or other recipient any portion of the money, property, or service demanded or requested. The bill also amends the definition of "claim" to specifically exclude any requests or demands for money, property, or services as compensation for employment with the state or political subdivision.

The bill amends the Act to contain a mandatory civil penalty of not less than $5,000 and not more than $10,000 for each violation. Under prior law, the civil penalty was not mandatory. The bill also expands the power of the California attorney general and prosecuting authority of a political subdivision with respect to *qui tam* cases. Specifically, *qui tam* cases can no longer be dismissed without the written consent of the attorney general or prosecuting authority of a political subdivision, or both. Further, a private person may not waive a claim for a violation under the Act unless the action is part of a court-approved settlement of a false claims civil action brought by a *qui tam* plaintiff. Moreover, the bill adds a requirement that the attorney general (or any prosecuting attorney of a political subdivision) has a duty to investigate violations under the Act.

Additionally, the statute of limitations for a false claims action is amended to be three years from the date of discovery of the action by the attorney general or prosecuting authority of a political subdivision. Under prior law, the statute of limitations began to run upon the discovery of the action by an official of the state or political subdivision charged with responsibility under the Act.

Under the bill, a court's authority to award a defendant attorneys' fees is modified. Whereas prior law permitted the court to award attorneys' fees to a defendant who prevailed in a false claims action only when the claim was clearly frivolous, vexatious, or brought solely for the purposes of harassment, attorneys' fees may now be awarded when the claim was brought primarily for harassment.

Taken together, the amendments to California's False Claim Act adopted in Assembly Bill 1196 expand both the reach and consequences of the law. These changes may lead to more allegations against, and investigations of, health care providers by state officials and *qui tam* relators.

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The contents of this Memorandum are for informational purposes only and do not constitute legal advice.

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1 For a discussion of the original legislation, see our December 2008 summary of Senate Bill 541 entitled "California Update: New Laws on Patient Privacy, Billing Diagnostic Imaging Services, and Bacterial Infection Monitoring and Reporting," available at www.reedsmith.com

2 The Five-Star Quality Rating is part of the "Nursing Home Compare" program and is available on the CMS website at www.medicare.gov/NHCompare

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