

Key California Health Laws: AB 211, SB 541

Shirley P. Morrigan, Esq.
Foley & Lardner LLP
555 South Flower, #3500
Los Angeles, CA 90071
tel: (213) 972-4668
fax: (213) 486-0065
cell: (310) 488-8788
email: smorrigan@foley.com

M. Leeann Habte, Esq.
Foley & Lardner LLP
555 South Flower, #3500
Los Angeles, CA 90071
tel: (213) 972-4679
fax: (213) 486-0065
email: lhabe@foley.com

Foley & Lardner LLP
Web Conference
Los Angeles, CA
October 15, 2008



©2008 Foley & Lardner LLP-Attorney Advertising-Prior results do not guarantee a similar outcome-Models used are not actual clients but are representative of clients-321 N. Clark Street, Suite 2800, Chicago, IL 60610-312.632.4500

Overview

- Background on New Legislation
- AB 211
- SB 541
- Recent Board of Pharmacy Enforcement Initiatives
- Recent Fines Imposed by Department of Public Health for Immediate Jeopardy

Background

- AB 211 and SB 541 were prompted by the disclosure of “snooping” into celebrity medical records at UCLA, use of patient data for fund-raising at UCSF, and other inappropriate uses
 - “Snooping” did not constitute illegal disclosure under CMIA or HIPAA
 - Enforcement is currently a prerogative of the state Attorney General or District Attorneys

2

Background

“Repeated violations of patient confidentiality are potentially harmful to Californians, which is why financial penalties are needed to ensure employees and facilities do not breach confidential medical information. Californians seeking care at a hospital or health facility should never have to worry that their private medical information will be shared.”

Governor Arnold Schwarzenegger
September 30, 2008

3

Background

- Goals of new laws
 - Improve privacy protections
 - Increase enforcement actions for medical errors
 - Give the state the tools to assess and enforce fines against health facilities and individuals who inappropriately obtain, access, use, or disclose medical information

4

AB 211 Increases Privacy Protections

- Requires health care providers to prevent unlawful access, use, or disclosure of patients' medical information
- Holds health care providers and individuals accountable for ensuring the privacy of patients' medical information
 - Adds Cal. Health & Safety Code §§ 130200-130205, revises Cal. Civil Code § 56.36
 - Effective January 1, 2009

5

AB 211 Increases Privacy Protections

“Your medical information should not be flapping in the breeze like an open hospital gown.”

Assemblyman Dave Jones (D)

6

Confidentiality of Medical Information Act (CMIA)

- CMIA currently prohibits
 - Disclosure of medical information
 - Regarding a patient of the provider of health care or an enrollee or subscriber of a health care service plan
 - By a provider of health care, health care service plan, or contractor
 - Without prior written authorization
 - Unless specific exceptions for required and permissive disclosures exist (Cal. Civ. Code § 56.10)

7

Applicability of CMIA

- “Provider” of health care is defined as
 - Any person licensed or certified under the Business and Professions Code such as dentists, physicians, physical therapists, and others
 - Chiropractors and osteopaths
 - Any clinic, health dispensary, or health facility (such as nursing facilities, home health agencies, etc.) licensed under the Health & Safety Code (Cal. Civ. Code § 56.05)

8

Applicability of CMIA

- “Provider” of health care also includes
 - Any business organized for the purpose of maintaining medical information in order to make the information available to providers or individuals to either allow the individual to manage his or her information or for the diagnosis and treatment of the individual (Cal. Civ. Code § 56.06)
 - Section 56.06 was revised in 2008 to apply to all businesses that maintain medical information – whether or not maintaining medical information is the primary purpose of the business

9

Punishment of CMIA Violations

- Violation of CMIA that results in economic loss or damage
 - Punishable as misdemeanor
 - An individual may bring a civil action for nominal or actual damages against any person or entity who has negligently released confidential information or records concerning him/her in violation of CMIA

10

Punishment of CMIA Violations

- In addition, administrative fines and civil penalties may be assessed against any person or entity, whether licensed or unlicensed by the licensing agency or certifying board or court
 - In amounts of
 - \$2,500 for negligent disclosure
 - Up to \$25,000 for knowingly and willfully obtaining, disclosing and using medical information in violation of CMIA
 - Up to \$250,000 if information is also used for financial gain (Cal. Civil Code § 56.36)

11

Health Insurance Portability and Accountability Act (HIPAA)

- Pursuant to the Privacy Rule, a covered entity
 - May not use or disclose
 - Protected health information
 - Except as permitted or required by HIPAA (45 CFR § 164.502)

12

Applicability of HIPAA

- Covered entity is defined as a
 - Health plan
 - Health care clearinghouse or
 - Health care provider who transmits any health information in electronic form in connection with a transaction covered by HIPAA (45 CFR § 164.104)

13

HIPAA Privacy and Security Rules

- Security Rule requires Covered Entities to implement physical safeguards and policies and procedures to
 - Ensure confidentiality of protected health information and
 - Protect against reasonably anticipated threats or unauthorized uses or disclosures of protected health information (45 CFR § 164.306)

14

AB 211 Requires Providers to Prevent Unauthorized Access

- Requires every provider of health care to
 - Implement appropriate administrative, technical, and physical safeguards to protect the privacy of a patient's medical information
 - Safeguard patient medical information from unauthorized or unlawful access, use, or disclosure

15

AB 211 Defines Unauthorized Access

- Unauthorized access is defined as “the inappropriate review or viewing of patient medical information without a direct need for diagnosis, treatment, or other lawful use as permitted by the Confidentiality of Medical Information Act (CMIA) . . . or by other statutes or regulations governing the lawful access, use, or disclosure of medical information”

16

AB 211 Definition of Providers

- “Provider of health care” means the term as defined on pp. 8-9 of this outline
 - Definition does not include health care service plans or contractors

17

AB 211 Definition of Medical Information

- “Medical information” means
“any individually identifiable information, in electronic or physical form, in possession of or derived from a provider of health care, health care service plan, pharmaceutical company, or contractor regarding a patient's medical history, mental or physical condition, or treatment. ‘Individually identifiable’ means that the medical information includes or contains any element of personal identifying information sufficient to allow identification of the individual, such as the patient's name, address, electronic mail address, telephone number, or social security number, or other information that, alone or in combination with other publicly available information, reveals the individual's identity.” Cal. Civ. Code § 56.05(g)

18

AB 211 Creates New State Office to Enforce CMIA

- Creates the Office of Health Information Integrity (“OHII”) within the California Health and Human Services Agency
- Purpose
 - To ensure enforcement of CMIA
 - To impose administrative penalties for unauthorized use of medical information

19

AB 211 Definition of Providers

- Will the new law apply to businesses organized to maintain medical information?
 - OHII is chaptered under Cal. Health & Safety Code §§ 130200-130205
 - Section 56.06 states that “nothing in this section shall be construed to make a business specified in this subdivision a provider of health care for the purposes of any law other than this part, including laws that specifically incorporate by reference the definitions of this part.”

20

AB 211 Allows OHII to Assess Penalties

- Penalties may be assessed
 - Against any person or provider of health care, whether licensed or unlicensed
 - Up to \$250,000 as set forth in CMIA
 - Requires referral from DPH for assessment of fines

21

AB 211 Allows OHII to Assess Penalties

- OHII shall consider
 - History of compliance
 - Extent to which the facility detected violations and took preventive action to correct and prevent reoccurrence
 - Factors outside its control that restricted the facility's ability to comply

AB 211 Allows OHII to Refer for Further Action

- Gives OHII the authority
 - To refer individuals, if licensed, to appropriate licensing boards for discipline
 - Documentation and accompanying evidence is deemed an investigative communication and protected from public disclosure
 - To recommend that civil actions be brought by the Attorney General, District Attorney, county counsel, city attorney, city prosecutor

AB 211 Prevents Double Administrative Penalties

- Enforcement authority is limited to persons or providers not governed by provisions enacted in SB 541
 - OHII may not assess administrative penalties against clinics, health facilities (hospitals, nursing facilities and other health facilities), home health agencies, or hospices licensed under Health & Safety Code §§ 1204, 1250, 1725, or 1745

24

AB 211 Budget Considerations

- OHII shall be funded through non-General Fund sources
- Fines assessed by OHII pursuant to Cal. Civil Code 56.06 must be deposited in the Health Information Integrity Quality Improvement Account
 - Money can be used for supporting OHII's quality improvement activities, on appropriation from the legislature
- Authorizes OHII to adopt rules to carry out statutory responsibilities
 - No timeframe for promulgating rules

25

SB 541 Increases Amounts of Fines for Adverse Events

- Increases the fines for “immediate jeopardy”
- Extends the law to apply beyond hospitals to nursing homes and other health facilities, clinics, home health agencies, and hospices
- Sets health facility fines for privacy breaches
 - Amends Sections 1280.1 and 1280.3 and adds Section 1280.15 to the Health and Safety Code
 - Effective January 1, 2009

26

Definition of Immediate Jeopardy

- Current law
 - “Immediate jeopardy” is a situation in which the hospital's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient
 - Regulations not yet promulgated to the criteria to assess an administrative penalty against a health facility
 - Under new law, regulations are not required to implement increased administrative penalty

27

Current Law Applies to Hospitals

- Under Cal. Civil Code 1279.1, DPH may assess penalties for deficiencies against
 - General acute care hospitals, acute psychiatric hospitals and special hospitals
 - For deficiencies
 - After an investigation of a facilities' non-compliance with licensure standards
 - By the DPH, Licensing and Certification Program

28

SB 541 Extends Administrative Penalties to Other Health Facilities and Providers

- Under SB 541, penalties are assessed against
 - Clinics
 - Health facilities (hospitals, intermediate care facilities, congregate living facilities, correctional treatment centers, and nursing facilities)
 - Home health agencies
 - Hospices
 - Licensed under the Health & Safety Code §§ 1204, 1250, 1725, or 1745

29

Current Law Requires Reporting of Adverse Events

- California Health & Safety Code § 1279.1
 - Requires hospitals to report “adverse events to DPH within 5 days of detection or if event is an ongoing urgent, emergent, threat to the welfare, health or safety of patients, personnel or visitors not later than 24 hours”
 - Hospitals must inform patient of the adverse event before reporting

30

Current Law Requires Reporting of Unusual Occurrences

- 22 Cal. Code Regs. § 75053
 - Requires hospitals to report “unusual occurrences”
 - Occurrences such as epidemic outbreaks, poisonings, fires, major accidents, deaths from unnatural causes or other catastrophes and unusual occurrences which threaten the welfare, safety or health of patients, personnel or visitors

31

Current Law Requires Reporting of Unusual Occurrences

- What does that mean?
 - The State has tried to define unusual occurrences broadly
 - Triggers reporting requirements
 - Not privacy breaches

32

Reportable Adverse Events

- Never 28
 - Surgical events
 - Surgery performed on a wrong body part
 - Surgery performed on the wrong patient
 - The wrong surgical procedure performed on a patient
 - Retention of a foreign object in a patient after surgery or other procedure
 - Death during or up to 24 hours after induction of anesthesia after surgery of a normal, healthy patient

33

Reportable Adverse Events

- Product or device events
 - Patient death or serious disability associated with the use of a contaminated drug, device, or biologic
 - 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
 - Patient death or serious disability associated with intravascular air embolism

34

Reportable Adverse Events

- Patient protection events
 - An infant discharged to the wrong person
 - Patient death or serious disability associated with patient disappearance for more than four hours
 - A patient suicide or attempted suicide resulting in serious disability

35

Reportable Adverse Events

- Care management events
 - A patient death or serious disability associated with a medication error
 - A patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products
 - Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy

36

Reportable Adverse Events

- Care management events, cont'd
 - Patient death or serious disability directly related to hypoglycemia
 - Death or serious disability, including kernicterus, associated with failure to identify and treat hyperbilirubinemia in neonates during the first 28 days of life
 - A Stage 3 or 4 ulcer, acquired after admission to a health facility
 - A patient death or serious disability due to spinal manipulative therapy

37

Reportable Adverse Events

- Environmental events
 - A patient death or serious disability associated with an electric shock
 - 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
 - A patient death or serious disability associated with a burn incurred from any source
 - A patient death associated with a fall
 - A patient death or serious disability associated with the use of restraints or bedrails

38

Reportable Adverse Events

- Criminal events
 - Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider
 - The abduction of a patient of any age
 - The sexual assault on a patient within or on the grounds of a health facility
 - 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

39

Reportable Adverse Events

- Catch-All # 28
 - An adverse event or series of adverse events that cause the death or serious disability of a patient, personnel, or visitor
 - What does this mean?

40

SB 541 Also Requires Reporting of Privacy Breaches

- Licensed health facilities (e.g. hospitals, nursing facilities, and others) must report all privacy breaches to the patient and DPH or face fines for non-reporting
 - \$100/day beginning 5 days after detection
- The total combined penalty may not exceed \$250,000

41

SB 541 Definition of Privacy Breach

- The law requires
 - A licensed clinic, health facility (hospital, nursing facility or other), home health agency, or hospice
 - To prevent unlawful or unauthorized access to, use, or disclosure of a patient's medical information as defined in CMIA

42

SB 541 Increases Facility Fines for Immediate Jeopardy

- Current Law
 - \$25,000 for initial breach
 - Fines will rise to \$50,000 when regulations are written
- SB 541
 - 50,000 - 1st violation
 - \$75,000 - 2nd violation
 - \$100,000 - 3rd violation
 - Fines will rise by \$25,000 increments (to \$75,000, \$100,000, and \$125,000) when regulations are written
 - Must consider special conditions of small, rural hospitals

43

SB 541 Increases Administrative Fines for Reportable Adverse Events

- Deficiencies that are not immediate jeopardy
- Current Law
 - \$17,500
- SB 541
 - Fines will rise to \$25,000

44

SB 541 Administrative Penalties

- Administrative penalty issued 3 years after date of last issued immediate jeopardy violation shall be considered a first administrative penalty
 - As long as the facility has not received additional immediate jeopardy violations and
 - That facility is found by DPH to be in substantial compliance with all state and federal licensing laws and regulations

45

SB 541 Penalties for Privacy Breach

- DPH may assess an administrative penalty of up to \$25,000 per patient whose medical information was unlawfully or without authorization accessed, used, or disclosed
 - Up to \$17,500 for each subsequent occurrence
 - Unauthorized access is defined as on p. 16 of this outline

46

SB 541 Penalties for Privacy Breach

- Total combined penalties may not exceed \$250,000 per reported event
 - “Reported event” means all breaches included in any single report that is made pursuant to California Health & Safety Code Section 1280.15, regardless of the number of breach events contained in the report

47

SB 541 Penalties for Privacy Breach

- DPH shall consider
 - Must consider special conditions of small rural hospitals and primary care clinics
 - For long-term care facilities, penalty should be higher penalties under Health & Safety Code § 1280.15 or §§ 1423, 1424, 1424.1, or 1424.5

48

Appeals Process

- May request a hearing pursuant to Section 131071 within 10 days of penalty assessment
- Or must pay 75 percent of the total for each violation within 10 business days of receipt of administrative penalty
 - Same appeals process as for other administrative penalties imposed for reportable adverse events
- May refer violations to OHII

49

SB 541 Budget Considerations

- Administrative penalties assessed must be deposited in the Internal Departmental Quality Improvement Account
 - Money can be used for supporting the Licensing and Certification Program's quality improvement activities, on appropriation from the legislature

50

Enforcement of Immediate Jeopardy

- First fines were assessed in October 2007
- DPH has issued 61 penalties to 42 hospitals
 - Totaling \$1,525,000
- Immediate jeopardy citations have all been fined at highest level of \$25,000

51

Recent Board of Pharmacy Enforcement Actions

- Recalls on Heparin
 - The Board of Pharmacy cited 94 hospitals and fined their head pharmacists for keeping tainted Heparin on the shelf
 - Penalties of \$5,000 were imposed on about 15 hospitals for injecting patients with the recalled drug
 - Penalties of \$2,500 were imposed on pharmacist and on hospital if Heparin was found on shelf
 - Facilities could face harsher fines if DPH determines immediate jeopardy existed
 - Board is expected to issue an advisory in a few weeks to pharmacists on how to check orders for patient condition

52

Recent Board of Pharmacy Enforcement Actions

- The FDA ordered a full recall of the drug in March
- In August, manufacturers said that California hospitals stocking Heparin had all been told about the recall
 - It is not clear whether smaller Heparin manufacturers also sent recall notices to California hospitals
 - One out of four of the hospitals violating the recall still had Heparin after being warned by pharmacy regulators to remove it
 - About 200 patients received Heparin after the recall was announced, according to the citations

53

Enforcement of Immediate Jeopardy

- Nine hospitals were fined in 2007
 - Key deficiencies
 - Medication errors
 - Lack of effective system for distribution/administration/monitoring of drugs and biologicals
 - Failure to appropriately assess, treat, refer patients presenting at ER

54

DPH Enforcement of Immediate Jeopardy

- Most recent citations were in August 2008
 - DPH cited 19 hospitals and assessed 44 penalties
 - Immediate jeopardy citations include patient deaths from
 - Medication errors
 - Lack of response to lab results
 - Failure to activate ventilator
 - Failure to use seatbelt in wheelchair

55

Other DPH Immediate Jeopardy Enforcement Actions

- Citations for having caused serious injury or death to the patient
 - Patient fell off surgical cart
 - Insufficient anesthesia
 - Sponge left in
 - Sexual assault
 - Surgery on wrong patient
 - Device safety issues
 - Lack of competent insertion of catheter
 - Failure to prove prompt emergency care, etc.
 - Failure to monitor condition or medication

56

Other DPH Immediate Jeopardy Enforcement Actions

- Citations where adverse event was “likely” to cause serious injury or death to the patient
 - Lack of on-call surgeon
 - Lack of proper refrigeration/food handling
 - Failure to develop and implement a hospital infection control program
 - Lack of sufficient nursing staff
 - Failure to appropriately screen ER patients
 - Failure to supply appropriate emergency equipment/supplies
 - Failure to sterilize surgical equipment
 - Unsafe bed rails

57

Recommendations

– AB 211

- Ensure that policies prohibit “unauthorized,” rather than merely “unlawful,” access to medical information
- Assess security measures, including administrative, technical, and physical safeguards for medical information
- Implement robust security audits of access to medical information that identify unauthorized access

58

Recommendations

- Educate employees on privacy laws and the provider’s policies on privacy of medical information
- Include access to medical information within the provider’s compliance program and encourage reporting by employees of suspected unauthorized access
- Report to OHII and take appropriate action which is documented if unauthorized access to medical information occurs

59

Recommendations

– SB 541

- Understand state reporting laws
- Report when legally required to do so
- Assess all events that involve noncompliance with licensure that causes, or is likely to cause, serious injury or death to the patient
- Look widely for opportunities for improvement and take appropriate action if reportable events occur

60

Questions?

Shirley P. Murrigan, Esq.
Foley & Lardner LLP
555 South Flower, #3500
Los Angeles, CA 90071
tel: (213) 972-4668
fax: (213) 486-0065
cell: (310) 488-8788
email: smurrigan@foley.com

M. Leeann Habte, Esq.
Foley & Lardner LLP
555 South Flower, #3500
Los Angeles, CA 90071
tel: (213) 972-4679
fax: (213) 486-0065
email: lhabe@foley.com

61