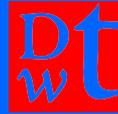


Federal Preemption and State Law and Regulation: California



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Preemption:

How It Works
and
The Fun We'll Have

State Privacy Laws

- State laws on medical confidentiality:
 - California
 - Confidentiality of Medical Information Act — requires patient authorization for release of information unless release otherwise permitted or required by law
 - Lanterman-Petris-Short Act — protects mental health information
 - HIV test confidentiality law — strict protection for information concerning HIV tests, including identity of persons tested
 - Miscellaneous other provisions

How Preemption Will Work

- Preemption will focus on specific elements and aspects of State laws
 - HIPAA will be the baseline
 - State law will be given effect only to the extent that (a) there is no HIPAA law on the issue; (b) State law is more stringent; or (c) there is an exception
 - Exemptions will apply to specific State laws, not entire State schemes

How Preemption Will Work

- No California equivalents for —
 - Business associates
 - CEs must contract with entities that receive PHI in order to perform service for/on behalf of CE
 - Minimum necessary
 - CEs should not ask for or release more than the minimum necessary PHI required for the purposes for which release is sought

How Preemption Will Work

- No California equivalents (cont'd) —
 - Notice to patient of CE practices with respect to its handling of PHI
 - No notice requirement in CA law
 - Requirement of patient consent for use of PHI for treatment, payment and operations
 - California permits disclosure for such purposes without patient authorization or notice

How Preemption Will Work

- Key California provision for preemption analysis purposes
 - Civil Code section 56.10(c)(14):
 - Information may be disclosed when the disclosure is otherwise specifically authorized by law
- This provision will permit the disclosure of health information that is permitted by HIPAA but not otherwise allowed under California law
- State response?

How Preemption Will Work

Subpoenas or Other Discovery Request

- California law is more stringent than HIPAA in some respects
 - HIPAA: Requesting party must make reasonable efforts to notify individual who is subject of PHI
 - Cal law: Requesting party must serve individual whose records are being sought with Consumer Notice
- Therefore, a Covered Entity must not release PHI unless requesting party has complied with more stringent Cal requirements

How Preemption Will Work

Other Disclosures to Law Enforcement

- HIPAA permits an array of disclosures to law enforcement, not all of which may be authorized under Cal law.
- But, CMIA says information may be disclosed when the disclosure is otherwise specifically authorized by law (Civil Code section 56.10(c)(14))
- Therefore, a Covered Entity can release PHI in response to law enforcement as specifically authorized by HIPAA

How Preemption Will Work

Disclosures for Health Care Oversight

- HIPAA permits disclosure of PHI to “health oversight agencies” for “authorized oversight activities.”
- CMIA permits disclosure to licensing agencies and a variety of specified public and private entities, but may not be as broad as HIPAA.
- But, since CMIA also permits disclosure when otherwise specifically authorized by law, a Covered Entity can release PHI to health oversight agencies for oversight activities as specifically authorized by HIPAA

How Preemption Will Work

Disclosures for Peer Review Purposes

- CMIA expressly permits Providers and Plans to disclose Medical Information to hospital medical staffs and other entities for peer review purposes
- HIPAA permits Covered Entities to use PHI for their own health care operations, which includes credentialing and peer review, but does not clearly authorize release to other hospitals or entities for *their* peer review purposes.
- Therefore, not clear how such release will be accomplished under HIPAA without authorization.

How Preemption Will Work

Disclosures for Research Purposes

- CMIA expressly permits Providers and Plans to disclose Medical Information to a variety of research related entities for bona fide research purposes without authorization.
- HIPAA permits disclosure/use of PHI for research purposes without authorization - provided that such disclosure has been approved by an IRB through a specified review process.
- HIPAA is clearly more restrictive than Cal law on this point (which is currently the subject of intense lobbying).

How Preemption Will Work

Disclosures for Marketing/Fundraising

- CMIA has no express provision permitting disclosures for marketing/fundraising.
- CMIA prohibits providers/plans from disclosure/use of Medical Information for purpose not necessary to provide health care services to patient (56.10(d))
- CMIA prohibits contractors/corporations from disclosure of Medical Information to any person not engaged in providing direct health care services to patient or provider/plan/insurer (56.10(e)).

How Preemption Will Work

Disclosures for Marketing/Fundraising (continued)

- These limitations in the CMIA on disclosure/use of Medical Information for purposes unrelated to providing health care services to the patient are both subject to the provision that Medical Information may be disclosed when the disclosure is otherwise specifically authorized by law (Civil Code section 56.10(c)(14)).
- Therefore, CMIA permits disclosure for purposes unrelated to providing health care services to the patient so long as such disclosure/use is specifically authorized by HIPAA.

How Preemption Will Work

Disclosures in Response to Media Inquiries

- CMIA: In absence of specific written request to the contrary, provider may release basic information in response to inquiry concerning a specific person.
- HIPAA is more restrictive than the CMIA on the information that may be released and permits release only if the inquiry specifically contains the patient's name (as under CMIA, patient can block release by objecting).
- HIPAA is more restrictive than Cal law here.

Information Covered

- HIPAA

“Health Information”: any information, whether oral or recorded, in any form or medium, that relates to past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present or future payment for the provision of care to an individual.
(§160.103)

- California

“Medical information”: any individually identifiable information in electronic or physical form regarding a patient’s medical history, mental or physical condition or treatment, that is in the possession of or derived from a provider of healthcare, health care service plan or contractor.
(§56.05(f))

Information Covered

- HIPAA

“Individually identifiable health information”: that health information (including demographic information) which is created or received by a provider, plan, employer or health care clearinghouse and *which identifies the individual or upon which there is a reasonable basis to believe the information may be used to identify an individual.*
(§164.501)

- California:

“Individually identifiable”: that medical information which includes or contains any element of personal identifying information *sufficient to allow identification of the individual, e.g., the patient’s name, address, e-mail address, phone number, social security number or other information that reveals identity, whether alone or in combination with other publicly available information.*
(§56.05(f))

Information Covered

- HIPAA
“Protected health information”:
individually identifiable health
information that is transmitted
or maintained in any form.
(§164.501)
- California
See definition above of “Medical
information.” (§56.05(f))

Entities Covered

- HIPAA - Covered Entities
- Health care providers – hospitals & other facilities; medical groups; doctors and other individual practitioners; laboratories, etc.
- Health plans – individual or group plans, private or governmental, that provide or pay for medical care.
- Health care clearinghouses – billing services, repricing companies and “value-added” networks and switches.
- California
- Providers of health care – hospitals, clinics and other licensed health facilities; includes licensed health care professionals.
- Licensed health care professionals – physicians, psychologists, nurses, etc.
- Contractors – Medical groups, IPAs, pharmaceutical benefits managers.
- Health care service plans – Knox-Keene health care service plans.

Entities Covered

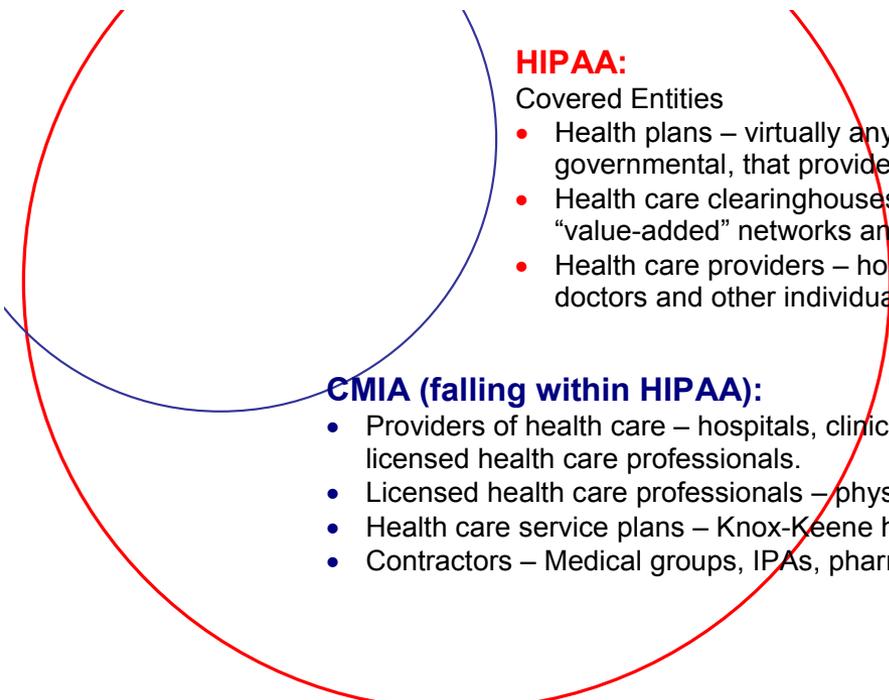
- HIPAA - Covered Entities

In order to be covered entities, plans, providers and clearinghouses must transmit health information electronically (whether directly or through others) in connection with a covered transaction

- Includes all plans and clearinghouses, but does not necessarily include all providers

- California

No equivalent requirement



HIPAA:

Covered Entities

- Health plans – virtually any individual or group plan, private or governmental, that provides or pays for medical care.
- Health care clearinghouses – billing services, repricing companies and “value-added” networks and switches.
- Health care providers – hospitals and other facilities; medical groups; doctors and other individual practitioners; laboratories, etc.

CMIA (falling within HIPAA):

- Providers of health care – hospitals, clinics and other licensed health facilities; includes licensed health care professionals.
- Licensed health care professionals – physicians, psychologists, nurses, etc.
- Health care service plans – Knox-Keene health care service plans.
- Contractors – Medical groups, IPAs, pharmaceutical benefits managers.

CMIA (not falling within HIPAA):

- Providers who do not transmit electronic health information in connection with a HIPAA standard transaction.

Release/Use for Research

Release of information for research:

- HIPAA
 - CE may use or disclose PHI for research, if:
 - An IRB or “privacy board” has approved an exception to the requirement for patient authorization
 - Additional requirements for reviews prior to research or where patient is deceased
- California
 - Provider may disclose patient information for “bona fide research purposes” to
 - Public agencies
 - Clinical investigators
 - Health care research organizations
 - Public or private nonprofit educational or health care entities

Release/Use for Research

Release of information for research:

- HIPAA
 - Documentation requirements, including
 - Description of grounds used for waiver of patient's authorization
 - Assurances against reuse or disclosure
 - Description of the patient information needed for research
- California

Penalties for Violation

Comparison of penalties for violation:

- HIPAA
 - No private right of action under HIPAA
 - Cal. B&P 17200?
- California
 - CMIA: Patients may bring actions for violations of Cal. law —
 - Compensatory damages
 - Punitive damages \leq \$3,000
 - Attorney's fees \leq \$1000

Penalties for Violation

Civil and criminal penalties:

- HIPAA
 - Knowingly disclosing, obtaining or using is criminal offense
 - Failure to comply:
 - \$100/violation, not exceeding \$25,000/yr (civil fine)
- California
 - Any violation is misdemeanor
 - Negligent disclosure:
 - Up to \$2,500/violation (civil fine)

Penalties for Violation

Civil and criminal penalties:

- HIPAA
 - Knowingly disclosing, obtaining or using
 - Up to \$50,000 and/or 1 year
 - False pretenses
 - Up to \$100,000 and/or 5 years
- California
 - Knowingly and willfully obtaining, disclosing or using
 - Up to \$25,000/violation

Penalties for Violation

Civil and criminal penalties:

- HIPAA
 - For commercial or personal gain or malicious harm
 - Up to \$250,000 and/or 10 years
- California
 - For financial gain
 - Up to \$250,000 per violation and disgorgement of proceeds received for information

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