

# HIPAA PREEMPTION:

## Compliance Implications

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## What's the problem?

- Most states have extensive laws relating to patient privacy and medical records
- No uniformity
- Inconsistent requirements
- Compliance challenges for multi-state operations

## **The Preemption Rule: 45 CFR 160.203**

- A standard, requirement, or implementation specification adopted under this subchapter that is contrary to a provision of State law preempts the provision of State law, except if one or more of the following conditions is met:

# Exceptions

## 45 CFR 160.203(a):

1. A determination is made by the Secretary of Health and Human Services (HHS) under 160.204 that the provision of State law:
  - a. Is necessary:
    - To prevent fraud and abuse related to the provision or payment of health care;
    - To ensure appropriate State regulation of insurance and health plans to the extent expressly authorized by statute or regulation;
    - For state reporting on health care delivery or costs; or
    - For purposes of serving a compelling need related to public health, safety, or welfare, and, if a standard, requirement, or implementation specifications under part 164 of this subchapter is at issue, if the Secretary determines that the intrusion into privacy is warranted when balanced against the need to be served;

## Exceptions (continued)

- b. Has as its principal purpose the regulation of the manufacture, registration, distribution, dispensing, or other control of any controlled substance (under federal law) or that is deemed a controlled substance by State law.

## Exceptions (continued)

2. The provision of State law relates to the privacy of individually identifiable health information and is more stringent than a standard, requirement, or implementation specification adopted under subpart E ( Part 164-Privacy of Individually Identifiable Health Information) of this subchapter.

## Exceptions (continued)

3. The provision of State law, including State procedures established under such law, as applicable, provides for the reporting of disease or injury, child abuse, birth, or death, or for the conduct of public health surveillance, investigation, or intervention.

## Exceptions (continued)

4. The provision of State law requires a health plan to report, or to provide access to, information for the purpose of management audits, financial audits, program monitoring and evaluation, or the licensure or certification of facilities or individuals.



## Key Definitions

### 45 CFR 160.202

- **“Contrary”** when compared to a provision of State law to a standard, requirement, or implementation specification adopted under this subchapter means:
  - The covered entity would find it impossible to comply with both the State and federal requirements; or
  - The provision of State law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of HIPAA.

## Definitions (continued)

- **“More Stringent”** means, in the context of a comparison of a provision of State law and a standard, requirement, or implementation specification adopted under subpart E of part 164 of this subchapter, a State law that meets one or more of the following criteria:
  - With respect to a use or disclosure, the law prohibits or restricts a use or disclosure in circumstances under which such use or disclosure otherwise would be permitted under this subchapter, except if the disclosure is:
    - ☐ Required by the Secretary in connection with determining whether a covered entity is in compliance with this subchapter; or
    - ☐ To the individual who is the subject of the individually identifiable information.

## Definitions (continued)

- With respect to the rights of an individual, who is the subject of the individually identifiable health information regarding access to or amendment of individually identifiable health information, permits the greater rights of access or amendment, as applicable.
- With respect to information to be provided to an individual who is the subject of the individually identifiable health information about a use, a disclosure, rights and remedies, provides the greater amount of information.

## Definitions (continued)

- With respect to the form, substance, or the need for express legal permission from an individual, who is the subject of the individually identifiable health information, for use or disclosure of individually identifiable health information, provides requirements that narrow the scope or duration, increase the privacy protections afforded (such as by expanding the criteria for), or reduce the coercive effect of the circumstances surrounding the express legal permission, as applicable.

## Definitions (continued)

- With respect to recordkeeping or requirements relating to accounting of disclosures, provides for the retention or reporting of more detailed information or for a longer duration.
- With respect to any other matter, provides greater privacy protection for the individual who is the subject of the individually identifiable health information.

## Definitions (continued)

- **“Relates to the privacy of individually identifiable health information”** means, with respect to a State law, that the State law has the specific purpose of protecting the privacy of health information or affects the privacy of health information in a direct, clear, and substantial way.

## Definitions (continued)

- **“State law”** means a constitution, statute, regulation, rule, common law, or other State action having the force and effect of law.

## Performing a Preemption Analysis

- Step 1: Identify applicable state laws and regulations.
  - Develop scope parameters based on the entity
  - Create research protocol:
    - 📁 Confidentiality laws regarding medical records
    - 📁 Access to medical records
    - 📁 Patient Bill of Rights (including mental health, long term care facilities, etc.)
    - 📁 Insurance Fair Information Act (NAIC Model)
    - 📁 Age of Consent-parental rights, rights of minors to consent to medical treatment



# Performing a Preemption Analysis Step 1 (continued)

- ☐ Categorical Exceptions under HIPAA
  - Health Plan information
  - Birth reporting
  - Death reporting
  - Disease reporting (Cancer surveillance, communicable diseases, etc.)
  - Injury reporting
  - Public health intervention
  - Public health investigation
  - Public health surveillance

## Performing a Preemption Analysis Step 1 (continued)

- ❖ Physician-patient relationships and privilege
- ❖ Disclosures by psychologists, social workers, and professional counselors
- ❖ Vulnerable adult reporting
- ❖ Rights of personal representatives
- ❖ Medical research
- ❖ Psychotherapy notes
- ❖ Peer review records
- ❖ Anatomical gifts
- ❖ Chemical dependency and substance abuse
- ❖ Duty to warn
- ❖ Patient authorization/consent requirements
- ❖ Health Plan reporting requirements

## Performing a Preemption Analysis

- Step 2: Identify the relevant portion of the Privacy Rule implicated in the analysis.
- Step 3: Determine whether the State law is consistent with, contrary to, or more stringent than the parallel Privacy Rule requirement.
- Step 4: Determine whether a preemption exception applies.

## Examples

- Minn. Stat. Sec. 144.335, subd. 3a: Patient consent to release of records; liability. (a) A provider, or a person who receives health records from a provider, may not release a patient's health records to a person without a signed and dated consent from the patient or the patient's legally authorized representative authorizing the release, unless the release is specifically authorized by law. Except as provided in paragraph ( c ) or (d), a consent is valid for one year or for a lesser period specified in the consent or for a different period provided by law. (b) This subdivision does not prohibit the release of health records: (1) for a medical emergency when the provider is unable to obtain the patient's consent due to the patient's condition or the nature of the medical emergency; or (2) to other providers within related health care entities when necessary for the current treatment of the patient.

## Examples

- Privacy Rule: Providers and health plans may release PHI without patient consent for treatment, payment or health care operations.
- Conclusion: Minnesota law is more stringent than the Privacy Rule, therefore a consent must be obtained prior to disclosing PHI to third parties.

## Examples

- Minn. Stat. 144.335, subd. 2 (b): Upon a patient's written request, a provider, at a reasonable cost to the patient, shall promptly furnish to the patient copies of the patient's health record. . .If a provider, reasonably determines that the information is detrimental to the physical or mental health of the patient, or is likely to cause the patient to inflict self harm, or to harm another, the provider may withhold the information from the patient.

## Examples

- Privacy Rule: 45 CFR 164.524: An individual has a right of access to inspect and obtain a copy of protected health information about the individual in a designated record set, for as long as the protected health information is maintained in the designated record set, except for psychotherapy notes.
- Analysis: Minnesota law provides greater individual access to psychotherapy notes. Therefore, access to such notes cannot be denied unless the provider makes a determination regarding potential harm in releasing the notes.

## Final Thoughts

- Compare definitions carefully.
- Analysis may result in a patchwork set of requirements that blends State law and the Privacy Rule.
- Make adjustments to policies, procedures and training to reflect state law considerations.





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