



HIPAA Privacy Preemption: “Which Rule Rules?”

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INTRODUCTION

"Which Rule Rules?"

- ❑ Privacy Preemption Regulatory Requirement
- ❑ Analysis to determine "Which Rule Rules"

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STATUTE

General rule: 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.

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STATUTE

Privacy: "A regulation promulgated under paragraph (1) [regulating privacy of individually identifiable health information] shall not supercede a contrary provision of State law, if the provision of State law imposes requirements, standards, or implementation specifications that are more stringent than the requirements, standards, or implementation specifications imposed under the regulation."

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EXCEPTIONS/CARVEOUTS

Exception Determination

A. Where DHHS determines the law:

1. Is necessary to: a) prevent fraud and abuse in payment for healthcare; b) ensure state regulation of insurance under state law; c) allow State reporting of healthcare delivery or costs; d) serve "compelling need related to public health, safety, or welfare;" or compelling need that outweighs the privacy intrusion as determined by the Secretary.

2. Regulates controlled substances

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EXCEPTIONS/CARVEOUTS (cont'd)

Privacy Analysis

- B. Privacy of health information laws that are more stringent than the federal law

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EXCEPTIONS/CARVEOUTS (cont'd)

Carve Outs

- C. Public health reporting, surveillance, investigation, intervention
- D. Health plan reporting for regulatory compliance

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ANALYSIS

Analysis to Decide "Which Rule Rules"

1. Individual's information, or HHS in connection with a compliance inquiry
2. "State Law"
3. "Contrary"
4. Carve Out?
5. Exception Determination?
6. "More Stringent"
7. Federal Law

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STATE LAW

- ❑ State Law: "...a constitution, statute, regulation, rule, common law, or other State action having the force and effect of law."
- ❑ Privacy of Individually Identifiable Health Information - State law specific purpose to protect privacy of health information or affects the privacy of health information in a direct, clear, and substantial way.

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STATE LAW

- ❑ Constitution
- ❑ Medical records laws and regulations
- ❑ Genetic testing laws and regulations
- ❑ HIV laws and regulations
- ❑ Privacy laws and regulations
- ❑ Patients Bill of Rights
- ❑ Mental health/substance abuse laws and regulations
- ❑ Pharmacy laws and regulations
- ❑ Licensure laws and regulations
- ❑ Case law on privacy protections
- ❑ Local codes

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CALIFORNIA

- ❑ California Constitution Privacy Provision
- ❑ Confidentiality of Medical Information Act
- ❑ Health and Safety Code
- ❑ Lanterman-Petris-Short Act
- ❑ HIV test confidentiality
- ❑ Insurance Information Privacy Protection Act
- ❑ Information Practices Act
- ❑ Gramm-Leach-Bliley
- ❑ Case Law
- ❑ Local municipal codes

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CONTRARY

State Law is contrary when:

1. A covered entity would find it impossible to comply with both the State and federal requirements; or
2. The State law is an obstacle to implementation of the HIPAA administrative simplification requirements.

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CARVE OUT

Public Health: Public health reporting, surveillance, investigation, intervention

Compliance/Enforcement: Health plan reporting for regulatory compliance

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EXCEPTION DETERMINATION

- ❑ Federal DHHS decides the legal impact of a State privacy law, and determines preemption
- ❑ Anyone may request
- ❑ State request must be from Governor or designee
- ❑ Exception criteria used in determination
- ❑ Exception remains in effect until federal or state law changes, or criteria no longer met

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EXCEPTION CRITERIA

- A. Where DHHS determines the law:
1. Is necessary to: a) prevent fraud and abuse in payment for healthcare; b) ensure state regulation of insurance under state law; c) allow State reporting of healthcare delivery or costs; d) serve "compelling need related to public health, safety, or welfare;" or compelling need that outweighs the privacy intrusion as determined by the Secretary.
 2. Regulates controlled substances

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MORE STRINGENT

- ❑ State Law contrary to HIPAA
- ❑ Related to Privacy of Individually Identifiable Health Information
- ❑ No Carve-Out or Exception Determination
- ❑ State law that is “more stringent” will not be preempted
- ❑ Greater privacy protection for individual

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MORE STRINGENT

- ❑ Use or Disclosure
- ❑ Individual Access or Amendment
- ❑ Information provided to an Individual
- ❑ Authorization or Consent form or substance
- ❑ Record keeping our accounting
- ❑ Greater privacy protections

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FEDERAL LAWS

- ❑ Privacy Act of 1974
- ❑ Freedom of Information Act
- ❑ Substance Abuse Confidentiality requirements
- ❑ ERISA
- ❑ Electronic Signatures in Global National Commerce Act (“E-Sign”)
- ❑ Gramm-Leach-Bliley
- ❑ OSHA
- ❑ Food, Drug and Cosmetic Act

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FEDERAL LAWS

- ❑ Americans with Disabilities Act
- ❑ Rehabilitation Act of 1973
- ❑ Family Educational Rights Privacy Act
- ❑ Clinical Laboratory Improvement Amendments
- ❑ U.S. Safe Harbor Privacy Principles (EU Directive on Data Protection)
- ❑ Federally Qualified Health Centers
- ❑ Family planning
- ❑ Maternal and Child Health

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FEDERAL LAWS

“Implied Repeal Analysis”

- ❑ Two potentially conflicting Statutes
- ❑ Both Statutes applied to a situation
- ❑ Legislative intent to repeal earlier statute
- ❑ General/specific language

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