

Federal Preemption, and State Healthcare Privacy and Data Security Law and Regulation

Fifth National HIPAA Summit

October 30 – November 1, 2002

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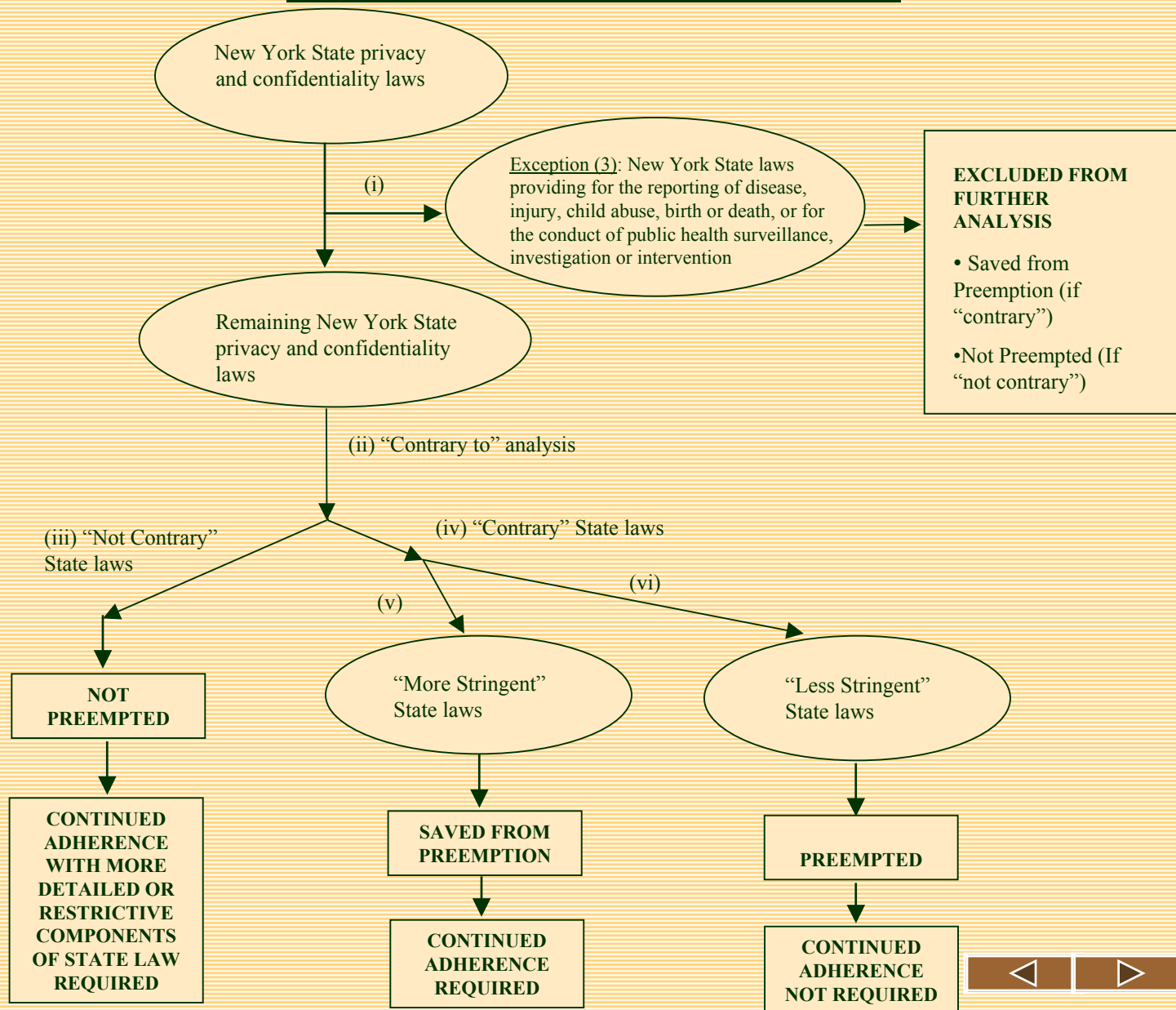
Introduction: Importance of Preemption Analysis

- As of April 14, 2003 Covered Entities need to be in compliance with both the Privacy Rule *and* with state privacy laws that are not preempted (or saved from preemption)
- Preemption analyses identify components of state privacy laws with which Covered Entities must continue to comply
- Results of preemption analyses should be incorporated into Covered Entities' policies and procedures to accurately reflect the requirements of the Privacy Rule, surviving state privacy laws and any other applicable federal laws
- Results of preemption analyses supplement the gap analysis presently being performed at many hospitals

The Preemption Rule

- Section 160.203 of the Privacy Rule (“PR”)
- A State law that is “contrary” to the PR will be “preempted,” unless “saved” by virtue of falling into one of the four following categories of exceptions
 - (1) determination by the Secretary that the state law is not preempted
 - (2) state law is “more stringent” than the PR
 - (3) state law “provides for the reporting of disease, injury, child abuse, birth or death, or for the conduct of public health surveillance, investigation or intervention
 - (4) state law governs accessibility to, or the reporting of, information in the possession of health plans.

DIAGRAMMATIC REPRESENTATION OF PREEMPTION ANALYSES



Laws Saved by Exception (3) and Disclosures Required by Law – Step (i)

- Exception (3) laws:
 - Because NY State laws encompassed by exception (3) are “categorically” saved from preemption, these laws may be identified and excluded from further analysis.
 - Example: NY Public Health Law §2001 imposes the duty to “report the existence of Alzheimer’s disease to the department when the physician...diagnoses or confirms the presence of that illness.”
 - Result: Because Alzheimer’s falls within the “disease” category of exception (3), continued compliance with section 2001 is required.
 - Providers must continue to comply with all State laws falling within exception (3)

Laws Saved by Exception (3) and Disclosures Required by Law – Step (i)

- Disclosures Required by Law:
 - Providers must also continue to comply with all “mandatory” NY State reporting laws not captured by exception (3).
 - Compliance with these laws is “required” by State law and “permitted” by the PR under section 164.512(a). Therefore, they are “not contrary” to, and hence “not preempted” by, the PR.

“Contrary to” Analysis – Step (ii)

- A State law will be “contrary” to the PR where [45 CFR§160.202]:
 - (i) It is “impossible” for a provider to comply with both State law and the PR (“Impossibility Test”).
 - (ii) State law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of the PR” (“Obstacle Test”).
- Provisions of State law and PR standards fall into one of three categories:
 - (1) they **require** a use or disclosure of PHI
 - (2) they **prohibit** a use or disclosure of PHI
 - (3) they **permit** a use or disclosure of PHI

“Contrary to” Analysis – Step (ii) (cont.)

- All possible combinations between State law and the PR are summarized in the following chart:

	A. Final Privacy Rule REQUIRES	B. Final Privacy Rule PROHIBITS	C. Final Privacy Rule PERMITS
1. State law REQUIRES	Not Contrary	Contrary (Impossibility Test)	Not Contrary
2. State law PROHIBITS	Contrary (Impossibility Test)	Not Contrary	Contrary (Obstacle Test)
3. State law PERMITS	Not Contrary	Contrary (Obstacle Test)	Not Contrary

“Contrary to” Analysis – Step (ii) (cont.)

➤ Example of “Not Contrary” State laws (step iii):

A use or disclosure is “required” by NY State law, and is “permitted” by the PR

➤ Example:

NY State law = “requires” providers to grant individuals access to specified PHI

PR = “permits” providers to grant individuals access to the same specified PHI

➤ Result: “Not contrary” since the intent of both laws is the same, and providers can comply with both laws by providing access

“Contrary to” Analysis – Step (ii) (cont.)

Example of “Contrary” State laws (step iv):

A State law “prohibits”, expressly or by implication, a specified use or disclosure that is “permitted” by a standard, requirement or implementation specification of the PR, or vice versa

➤ Example:

State law = “prohibits” disclosure to X without authorization of Y

PR = “permits” disclosure to X without authorization of Y

➤ Result: “Contrary” since the intent of the laws are diametrically opposed

(1) disclosure pursuant to the PR would entail a violation of State law

(2) lack of disclosure in accordance with State law would frustrate (stand as an obstacle to) the accomplishment and execution of the full purposes and objectives of the PR

Stringency Analysis – Steps (v) and (vi)

- The term “more stringent” is defined at section 160.202 of the PR
- In general, State laws are “more stringent” than the PR where they:
 - (i) are more restrictive with respect to the use and disclosure of PHI by Covered Entities
 - (ii) offer greater rights of access to or amendment of PHI to individuals who are the subjects of the PHI
- “More stringent” State laws = “Saved” from Preemption (step v)
- “Less stringent” State laws = Preempted (step vi)

Stringency Analysis (cont.)

➤ Example:

NY State law = “prohibits” release of HIV-related information pursuant to a general subpoena of medical records

PR = “permits” disclosure of PHI pursuant to a general subpoena

➤ Result:

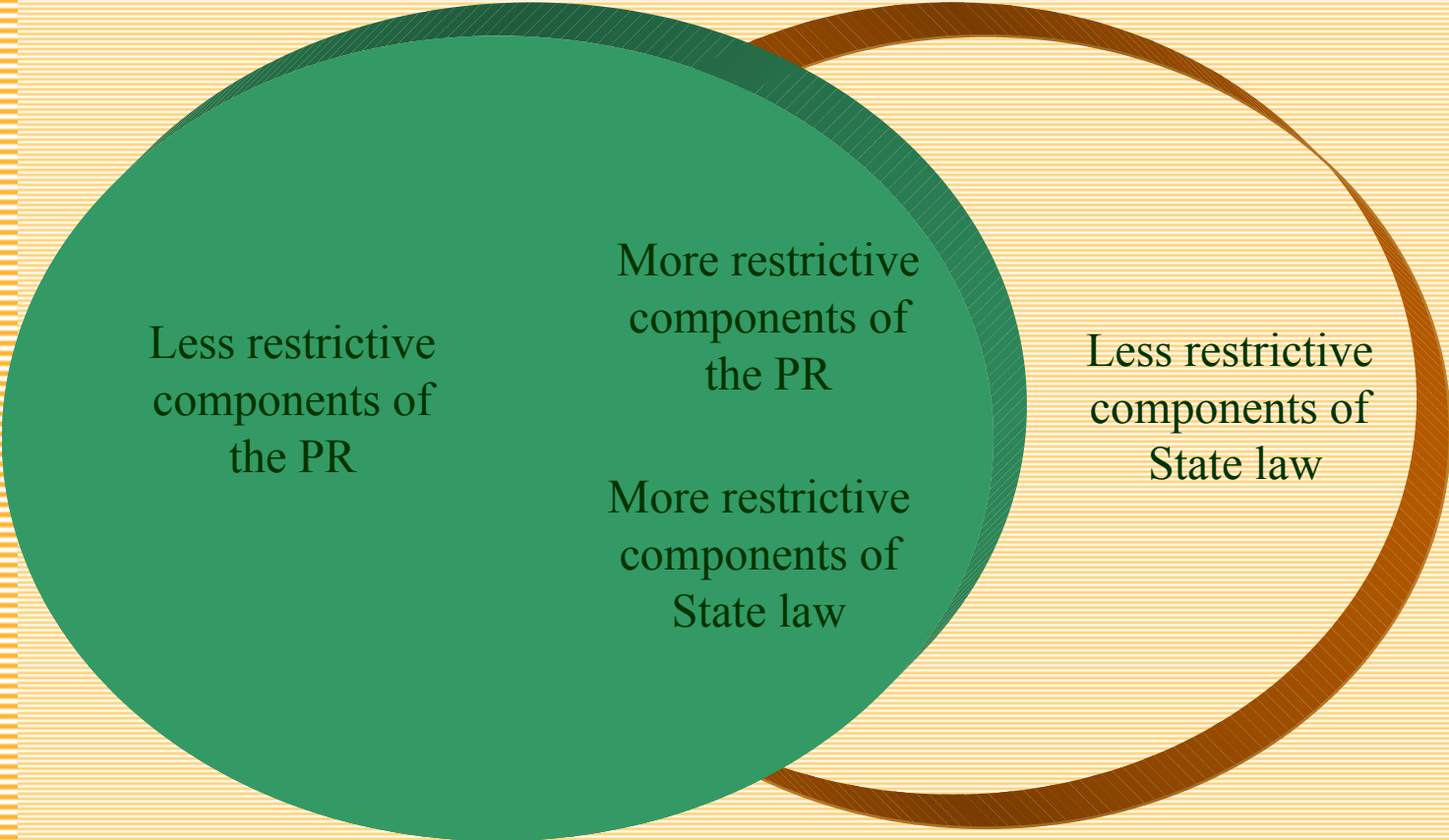
(1) the laws are “contrary” to each other under the Obstacle Test

(2) Since State law prohibits a disclosure that would otherwise be permitted by the PR, it is “more stringent” than, and hence “not preempted” by, the PR

Overall Effect of Preemption

- The practical effect of preemption is that providers must comply with the standards, implementation specifications and requirements of the PR in addition to, or as modified by, the more stringent requirements of contrary State laws and the more restrictive requirements of not-contrary State laws.

Overall Effect of Preemption (cont.)



■ = State laws providers must comply with

■ = State laws

■ = PR

State And Court As Final Arbiters

- The application of this preemption analysis is not the final authority on preemption.
- Whether a provision of state law is “contrary” to the PR will not be definitively answered until addressed by the State legislature or adjudicated by a court of competent jurisdiction.

Example of a Recurring Preemption Theme: Personal Representatives

- What is a personal representative?: The PR defines the term “personal representative” as any person who has authority *under applicable law* to make health care decisions on behalf of:
 - (i) an individual who is an adult or emancipated minor; or
 - (ii) a parent, guardian, or other person acting *in loco parentis* with respect to an unemancipated minor.

Example of a Recurring Preemption Theme: Personal Representatives (cont.)

- Interaction between personal representatives under State law and personal representatives under the PR: Whether a person identified as a personal representative under State law will likewise qualify as a personal representative under the PR depends on whether State law grants to that person the authority to make “health care decisions” on behalf of the individual who is the subject of the PHI.

Example of a Recurring Preemption Theme: Personal Representatives (cont.)

- For Example: Health care proxies under New York State law are personal representatives under the PR:
 - NY State proxy law defines the proxy decision maker as “an adult to whom authority to make health care decisions is delegated under a health care proxy.”
 - This is coterminous with the definition of personal representative under the PR.
 - The proxy’s/personal representative’s authority commences upon a determination by the attending physician that the individual lacks capacity to make health care decisions.
- Preemption Conclusion:
 - NY State laws permitting disclosure of PHI to health care proxies are “not contrary” to, and hence “not preempted” by the PR.

Preemption Example: Denial of Access (NY)

- PR: Under the PR, providers may deny access when access is likely to endanger the life or physical safety of the individual or another person
 - preamble to the PR notes that providers may not deny access under this ground “on the basis of the sensitivity of the health information or the potential for causing emotional or psychological harm.”
 - but under the PR providers may deny access when PHI references another individual and access is reasonably likely to cause substantial harm to such other person, including substantial physical, emotional, or psychological harm (according to the Preamble).

Preemption Example: Denial of Access (NY)

- NY State law: Under NY State law, providers may deny patients access where review of information reasonably expected to cause “substantial and identifiable harm” to patients or others
 - nothing in NY State law expressly prevents a provider from denying access because it is reasonably expected to cause emotional or psychological harm to the patient or to the other person
 - nothing in NY State law requires that the “other person” harmed by the access to PHI be referenced in the PHI

Preemption Example: Denial of Access (NY)

- Result: Providers can comply with both laws by:
 - (1) not denying access to the patient because it is reasonably likely to cause only emotional or psychological harm to the patient
 - (2) denying access to the patient when it is likely to cause physical harm to the patient
 - (3) continue to deny access when reasonably likely to cause substantial harm, including emotional or psychological harm, to another person referenced in the PHI

Integrating Preemption Results Into Compliance Planning

- PR compliance cannot be based solely on implementation of HIPAA standards
- PR compliance must integrate preemption analysis
- Compliance efforts should focus on more restrictive components of the PR and the more restrictive components of State law (see slides 13,14)