Advanced HIPAA Privacy Compliance Strategies: Those Nagging Issues That Don't Seem to Go Away

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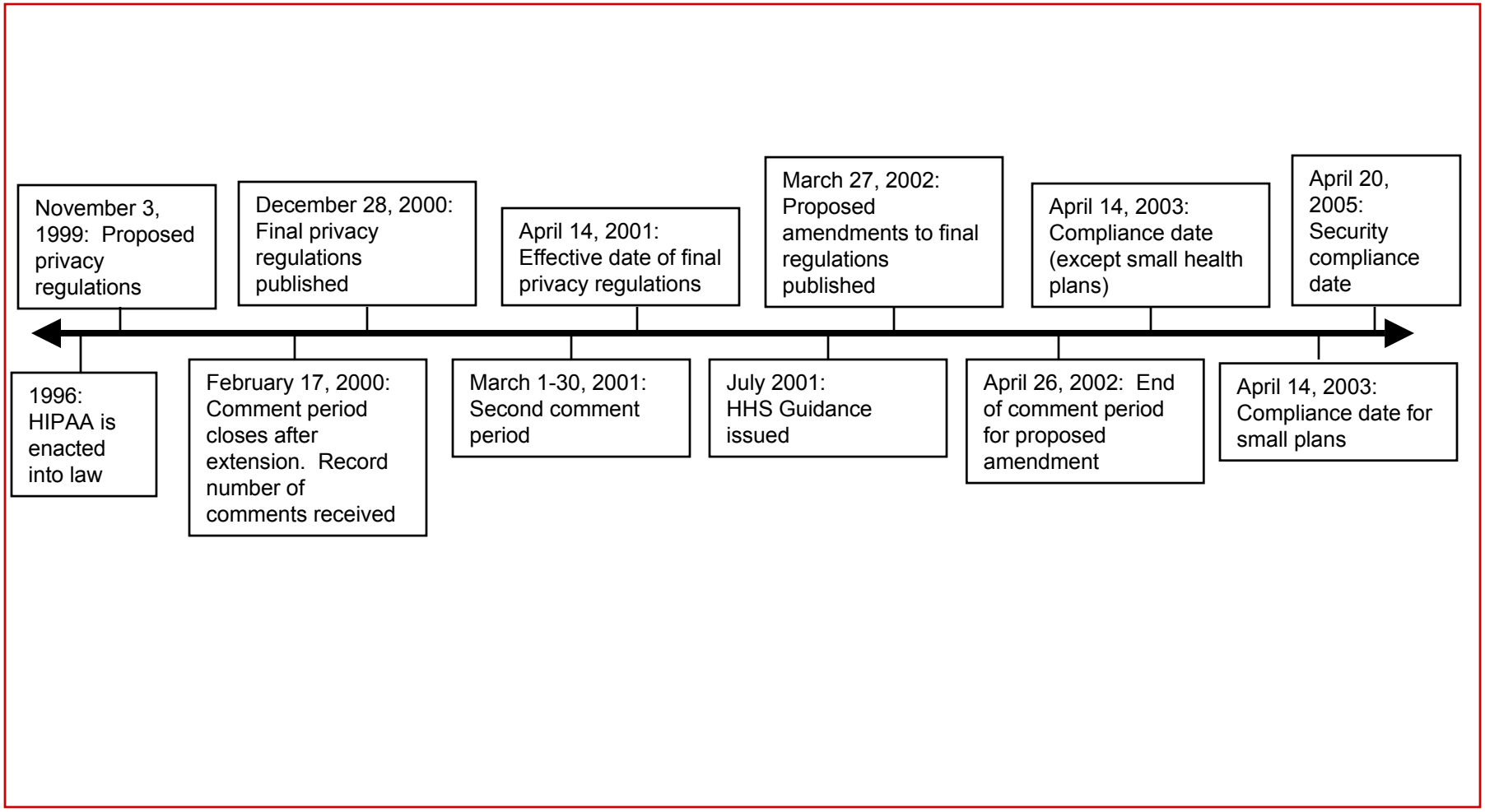
HIPAA Privacy — A Timeline



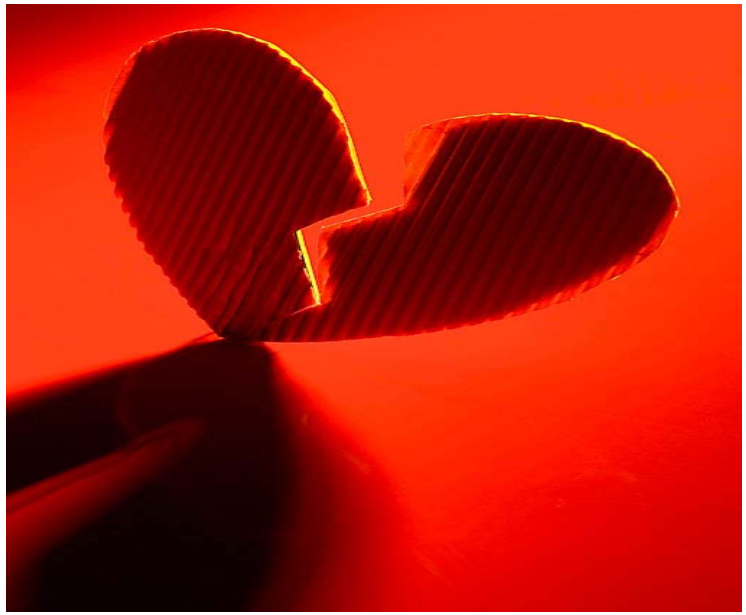
HIPAA Roulette

The Ex-Factor

- Breaking Up is Hard to Do
- When Good Employees Go Bad

The Ex-Factor

- Top risks for intentional misuse, improper disclosures and false accusations:
  - Ex-relationships: divorces, custody disputes, break-ups, new significant others, and so on and so on
  - Ex-employees
- Also be attuned to:
  - VIPs
  - Fellow workforce members



Response to Ex-Factor and Other Violations: Complaint Process

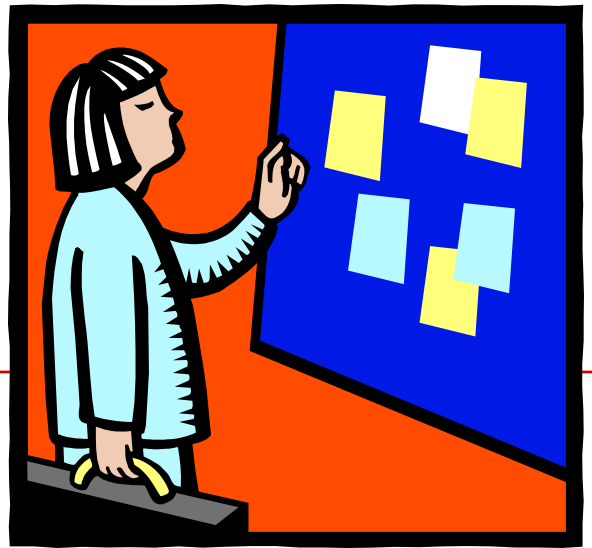
- Must provide process to receive complaints
- Must document all complaints and their disposition
- Tip: Make it easy for a patient to complain
  - Written only vs. any medium
- Tip: When there is "history," dig a little deeper
- Tip: Privacy Officer should be attuned to "gossip"
- Tip: Be aware of direct complaints that may become OCR complaints

Consumer Breach Notification

- Increasing number of state laws
- Possible federal law

Consumer Breach Notification

- Many state laws mandate notification
- A new wrinkle to mitigation
  - Covered entities have a duty to mitigate
  - Can be difficult once a breach has occurred
- Does mitigation include notification?
- Does a breach have to be included in accounting?
  - Incidental disclosure v. breach

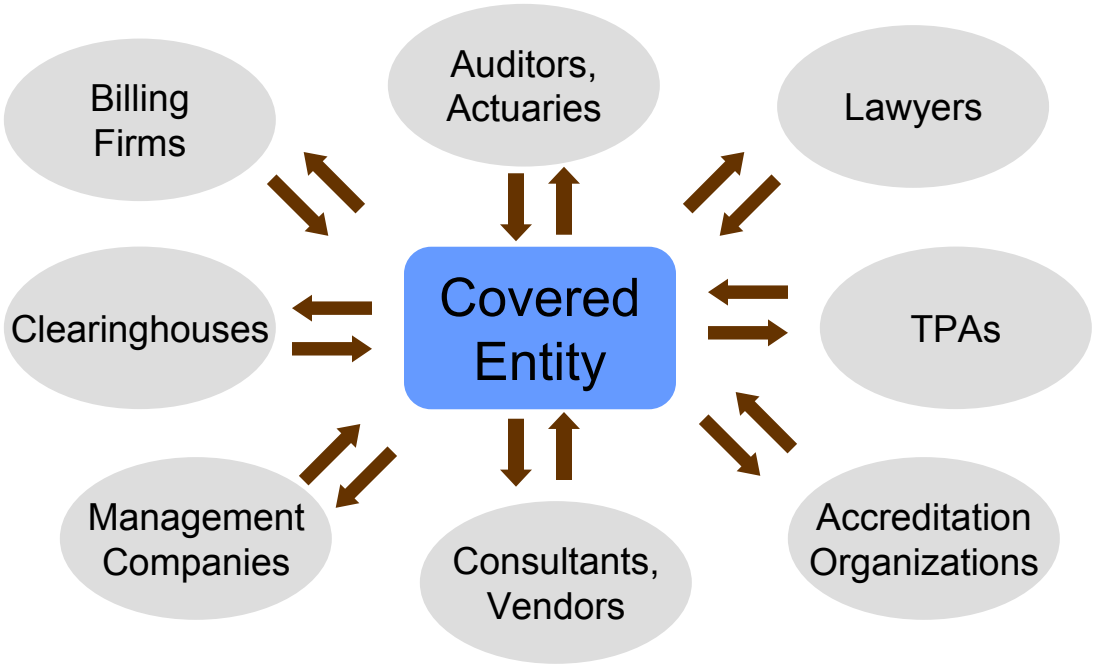


Business Associates

- Identifying business associates
- Disagreements on BA status
- Negotiation
- Tracking contracts

Who is a Business Associate?

- A person who, on behalf of a covered entity or OHCA —
  - Performs or assists with a function or activity
    - Involving PHI or
    - Otherwise covered by HIPAA
  - Performs certain identified services

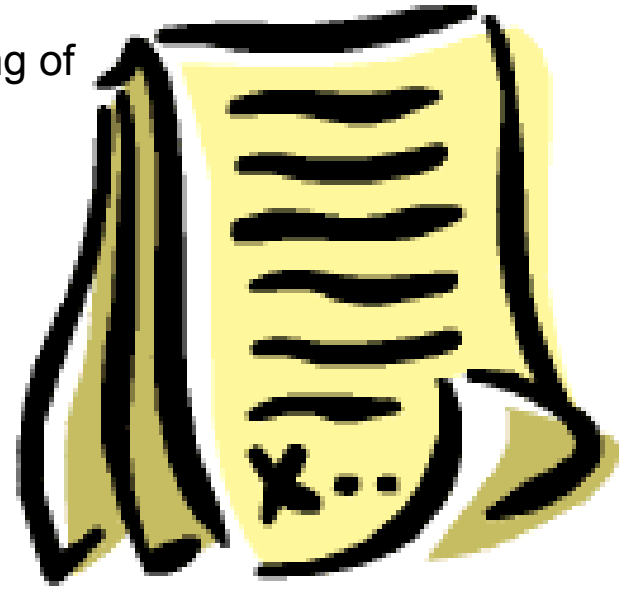


Who Are Business Associates?

- Medical device company . . . Probably not
- Research sponsor . . . Usually not – Follow research rules
- Record storage/destruction . . . Depends
- Accreditation organizations . . . Yes
- Software vendor . . . Maybe
- Collection agencies . . . Yes
- Lawyers . . . Definitely maybe

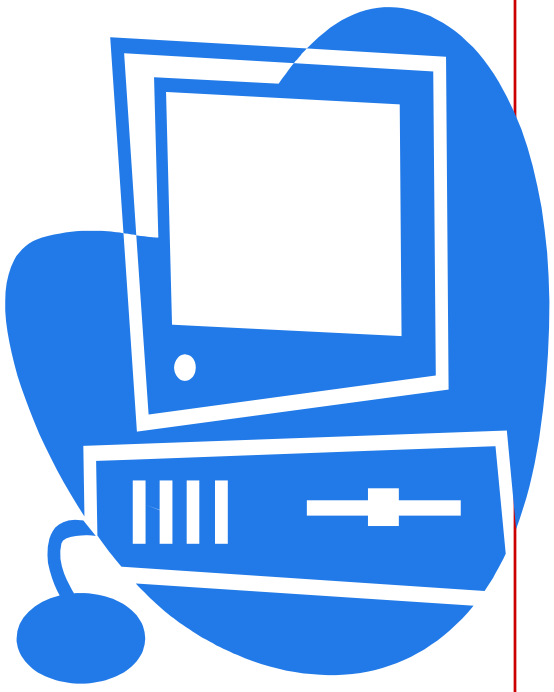
What Must Be in a Business Associate Contract — Privacy Rule

- Use and disclose information only as authorized in the contract
  - No further uses and disclosures
  - Not to exceed what the covered entity may do
- Implement appropriate safeguards
- Report unauthorized disclosures to covered entity
- Facilitate covered entity's access, amendment and accounting of disclosures obligations
- Allow HHS access to determine CE's compliance
- Return/destroy protected health information upon termination of arrangement, if feasible
  - If not feasible, extend BAC protections
- Ensure agents and subcontractors comply
- Authorize termination by covered entity



What Must Be in a Business Associate Contract — Security Rule

- Implement administrative, physical and technical safeguards that reasonably and appropriately protect the
  - Confidentiality,
  - Integrity and
  - Availability
  - Of *electronic* protected health information
- Ensure any agent implements reasonable and appropriate safeguards
- Report any security incident
- Authorize termination if the covered entity determines business associate has breached



Business Associate Contracts

- Tip: Contract management system
- Tip: Do not forget the security requirements
  - When ePHI is involved, the privacy version is not enough
- Process to identify business associates
  - Revisit existing relationships and contracts
  - Address future relationships
- Process to effectively deal with contracting
  - Templates
  - Rules of the road
  - Elevate issues as needed

De-Identification

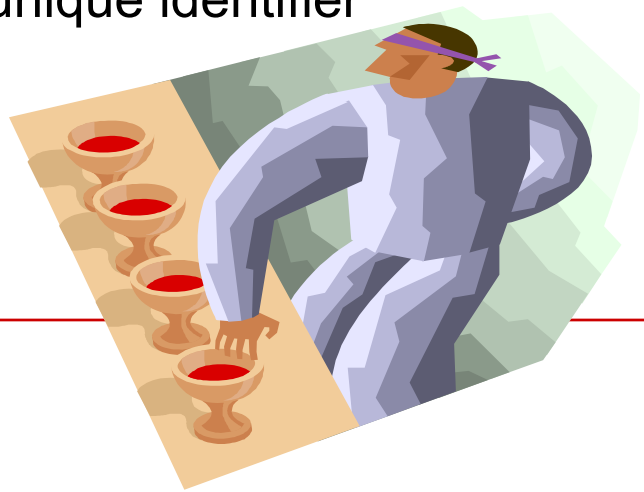
- How
- When to use

De-Identification

- Information is presumed de-identified if—
  - Qualified person determines that risk of re-identification is “very small” or
  - The following identifiers are removed:

Name	Address	Relatives	Employer
Dates	Telephone	Fax	e-mail
SSN	MR#	Plan ID	Account #
License #	Vehicle ID	URL	IP address
Fingerprints	Photographs	Other unique identifier	

  - And the CE does not have actual knowledge that the recipient is able to identify the individual



De-Identification

- Beware the “other unique identifier” requirement
  - Especially difficult with large number of records
  - Beware small communities
- Identify what workforce needs to know de-identification rules. For example,
  - Marketing
  - Medical staff who lecture or publish

Limited Data Sets

- What are they
- When to use limited data sets
- How to disclose limited data sets

Limited Data Set — Not Quite De-Identified

- Limited Data Set = PHI that excludes direct identifiers except:
  - Full dates
  - Geographic detail of city, state and 5-digit zip code
- Not completely de-identified
- Special rules apply

Data Use Agreements

- Limited Purposes:
  - Research,
  - Public health
  - Health care operations
- Recipient must enter into a Data Use Agreement:
  - Permitted uses and disclosures by recipient
  - Who may use or receive limited data set
  - Recipient must:
    - Not further use or disclose information
    - Use appropriate safeguards
    - Report impermissible use or disclosure
    - Ensure agents comply
    - Not identify the information or contact the individuals

Data Use Agreements

- Likely uses
  - State hospital associations
  - Public health agencies (for non-mandatory reporting)
  - Research where identifiers are not necessary
- Not included in an accounting of disclosures

Accounting of Disclosures

- What is covered
- What is the best way to track
- Communications with patients

Accounting of Disclosures

- Patient has the right to receive an accounting of disclosures of the patient's PHI
- Accounting includes:
  - Date of disclosure
  - Recipient name and address
  - Description of information disclosed
  - Purpose of disclosure

Accounting of Disclosures

- Exceptions:
  - Treatment, payment and operations
  - Individual access
  - Directories, persons involved in care
  - Pursuant to authorizations
  - National security or intelligence
  - Incidental disclosures
  - Limited date set
  - Prior to April 14, 2003

Accounting of Disclosures – Problems

- Cumbersome process with relatively few requests
- Patients often want information that is excepted
- Tricky issues
  - Date ranges acceptable (e.g., access to a universe of records during limited time)
  - For disclosures made routinely within set time:
    - Intervals acceptable (e.g., “gunshot wound within 48 hours after treatment” plus date of treatment)
- Dealing with Business Associates

Accounting of Disclosures — Approaches

- Different potential approaches
  - Log all disclosures at time of the disclosure
  - Do analysis at time of any patient request
  - Abbreviated accounting
- Tip: clarify the request before beginning (but do not discourage request)

Disclosures to Law Enforcement

Disclosures to Law Enforcement

- Required by law
- Court orders, subpoenas . . .
- Administrative request
- Request about a crime victim
- Child abuse or neglect
- Adult abuse, neglect or domestic violence (limited)
- Death in suspicious circumstances
- Criminal activity in off-site medical emergencies
- Crime on the premises
- Avoid serious and imminent threat
- Identification of suspect, fugitive, material witness or missing person (limited)
- Admission to a violent crime (limited)
- Specialized law enforcement

Disclosure to Law Enforcement

- Preemption considerations
  - State law plays a critical role in analysis
- Develop detailed policies and procedures
  - Tip: Identify go-to people
  - Tip: Two tier approach
    - Basic approach for majority of workforce
    - Detailed approach for those making the decisions
- Tip: Consider a community meeting with providers and law enforcement to agree on ground rules

Legal Proceedings

Disclosures for Legal Proceedings

- If a party to litigation/proceeding
  - May use and disclose PHI for own health care operations (as well as other exceptions)
  - "Operations" include conducting or arranging for legal services to the extent related to health care functions
    - Defendant in malpractice suit
    - Plaintiff in collection matter (also payment)
  - Minimum necessary
    - De-identification
    - Qualified protective order
  - Business associate contract for outside counsel needed

Disclosures for Legal Proceedings

- If covered entity is not a party, find an exception
  - Required by law (e.g., court order)
  - Health care oversight (e.g., licensure hearing)
  - Authorization
  - Response to subpoena or other lawful process
    - Satisfactory assurances that requestor made reasonable efforts either to notify relevant patients or secure a qualified protective order
    - Covered entity may do the same
    - Specific requirements for each

Disclosure for Legal Proceedings

- Preemption Considerations: Beware state law
- Accounting of Disclosures
  - Depends on exception
  - No: health care operations, payment, authorization
  - Yes: subpoena, health care oversight
- Tip: Don't assume a lawyer knows the law (with HIPAA at least)

Misunderstandings and Unrealistic Expectations

- HIPAA does not always live up to expectations

Misunderstandings and Unrealistic Expectations

- Must train workforce
  - Biggest threat
  - Greatest resource
- Training needs to be relevant and tailored
- Assess levels of awareness (you cannot manage what you cannot measure)
- Abuse of legitimate access
  - Difficult to detect on audit
- Encourage workforce awareness
- Facilitate workforce reporting of suspicions and making suggestions

Misunderstandings and Unrealistic Expectations

- Should train/educate patients
- Areas of confusion
  - Opting out of facility directory
    - Foster understanding of consequences
  - Requests for additional privacy protections
    - Patient has right to ask
    - Covered entity has right to say “No”
    - Covered entity is bound by a “Yes”
    - Promote consistency
  - Accounting of disclosure
- Not all disclosures without authorization are improper

Questions