

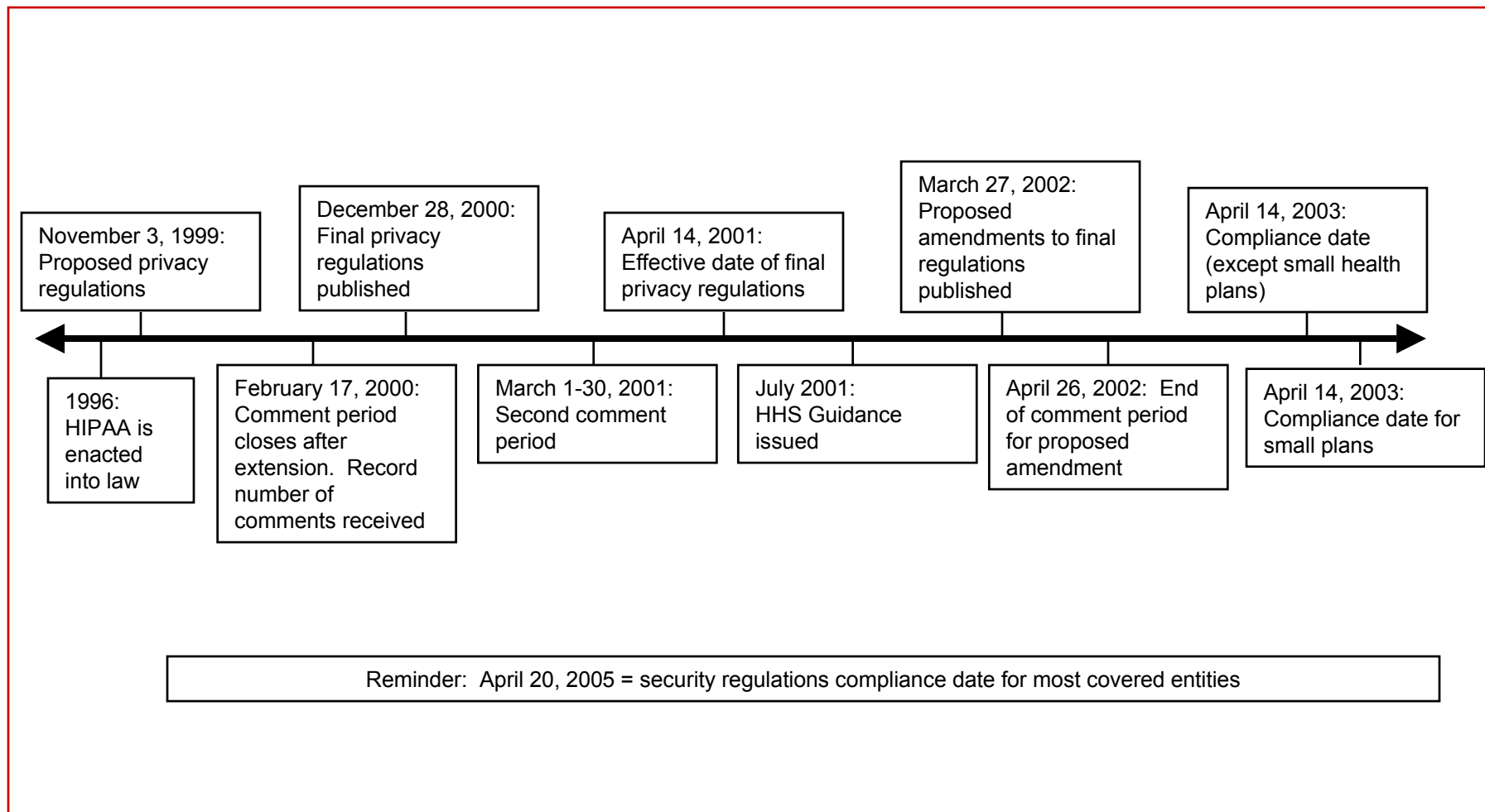
HIPAA Privacy: Those Nagging Issues That Don't Seem to Go Away

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HIPAA Privacy — A Timeline



HIPAA Roulette



Business Associates

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



Who is a Business Associate?

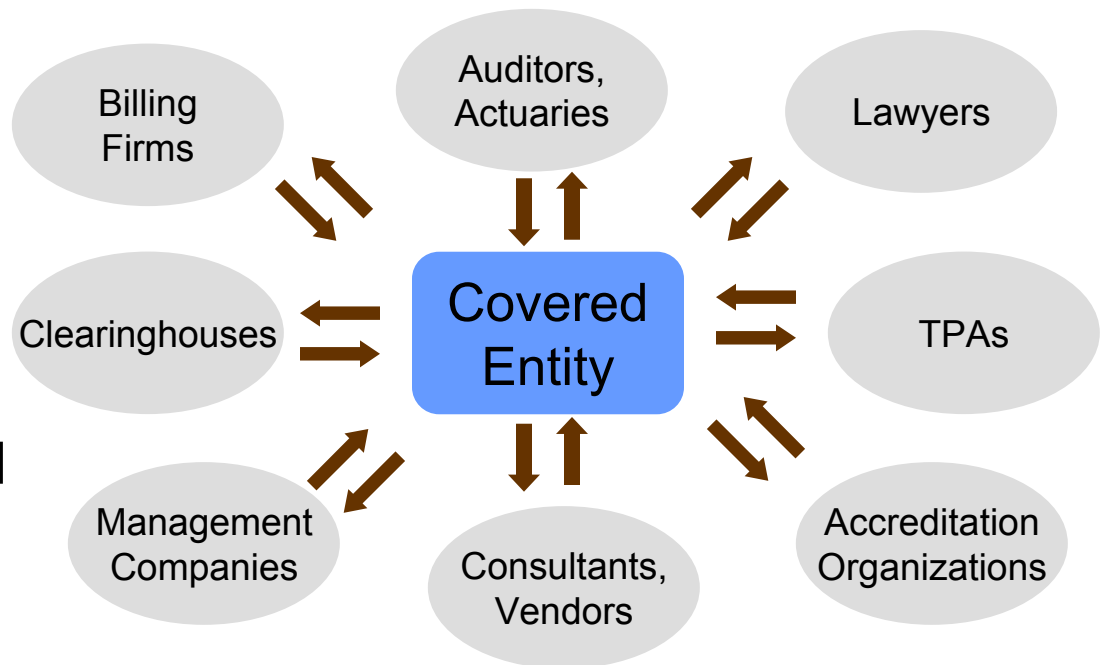
◆ A person who, on behalf of a covered entity or OHCA —

❖ Performs or assists with a function or activity involving

■ Individually identifiable health information, or

■ Otherwise covered by HIPAA

❖ Performs certain identified services



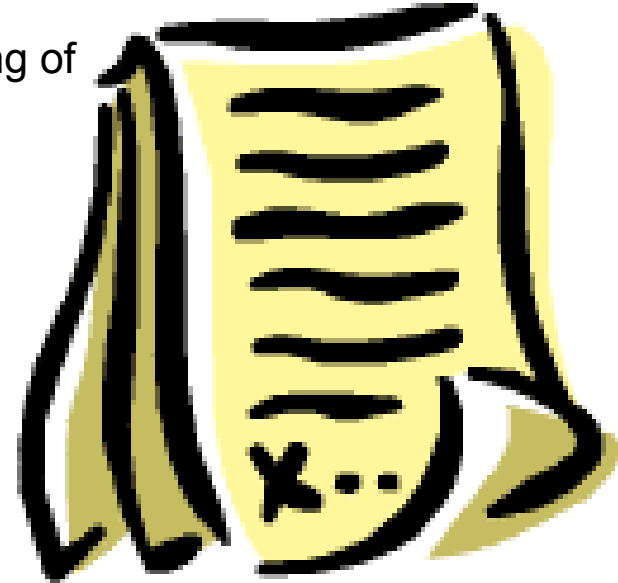
Who Are Business Associates?

- ◆ 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



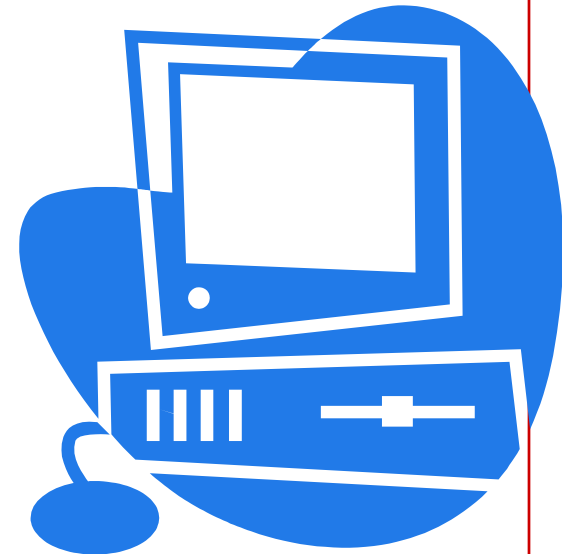
What Must Be in a Business Associate Contract — Privacy Rule

- ◆ 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: Establish an approach under security regulations
- ◆ Process to:
 - ❖ Revisit existing relationships and contracts
 - ❖ Address future relationships
- ◆ Build off of existing approach
 - ❖ Templates
 - ❖ Rules of the road
 - ❖ Elevate issues as needed



De-Identification

- ◆ How
- ◆ When to use



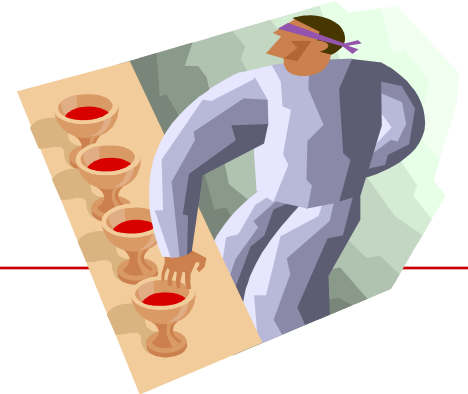
De-Identification

◆ 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 amount of records/information
 - ❖ Beware small communities
- ◆ Identify what workforce needs to know de-identification rules. For example,
 - ❖ Marketing
 - ❖ Medical staff who lecture



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 de-identified
- ◆ Special rules apply



Data Use Agreements

- ◆ A covered entity may use or disclose a limited data set if recipient signs data use agreement but only for
 - ❖ Research,
 - ❖ Public health or
 - ❖ 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 health care 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 few requests to date
- ◆ 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)



Complaints and the Ex-Factor



- ◆ Top risk areas include
 - ❖ Intentional misuse and improper disclosures related to ex-relationships, divorces, custody disputes, new significant others
 - ❖ VIPs
 - ❖ Fellow workforce members

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: Be aware of local complaints that may become OCR complaints
- ◆ Tip: Privacy Officer should be attuned to “gossip”



Legal Proceedings



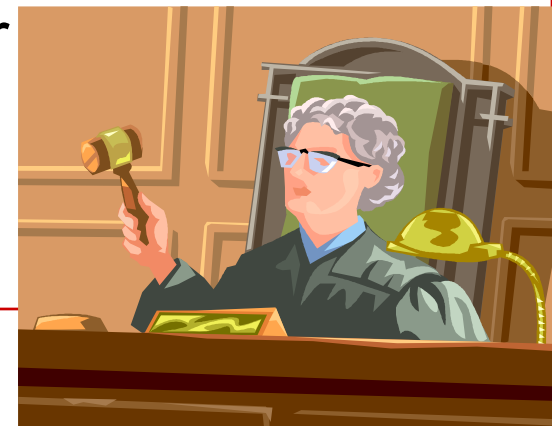
Disclosures for Legal Proceedings

- ◆ If a party to litigation/proceeding
 - ❖ May use and disclose PHI for own health care operations (as well as other exceptions)
 - ❖ Operations includes 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



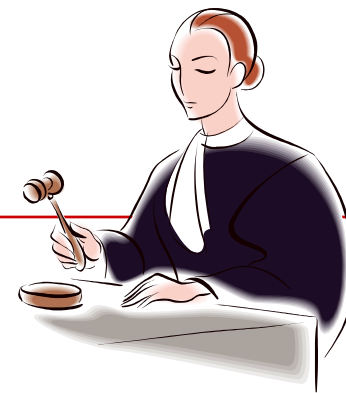
Disclosures for Legal Proceedings

- ◆ 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
- ◆ Don't assume a lawyer knows the law (with HIPAA at least)
- ◆ Is a business associate contract for outside counsel needed?
- ◆ Accounting of Disclosures
 - ❖ Depends on exception
 - ❖ No: health care operations, payment, authorization
 - ❖ Yes: subpoena, health care oversight



Disclosures to Law Enforcement



Disclosures to Law Enforcement

- ◆ When required by law
- ◆ Pursuant to court orders, subpoenas or other process
- ◆ To respond to an administrative request
- ◆ To respond to a request about a victim of a crime, upon agreement or law enforcement representation (not used against victim/and necessary)
- ◆ To report child abuse or neglect
- ◆ To report adult abuse, neglect or domestic violence (limited)
- ◆ To report a death in suspicious circumstances
- ◆ To report a crime on the premises



Disclosures to Law Enforcement

- ◆ To report criminal activity in off-site medical emergencies
- ◆ To avoid serious and imminent threat
- ◆ To respond to a request for purposes of identifying a suspect, fugitive, material witness or missing person (limited)
 - ❖ Name, address, date and place of birth, SSN, ABO blood type and rh factor, type of injury, date and time of treatment, date and time of death, description of distinguishing features
- ◆ To report a person who has admitted to a violent crime (limited)
- ◆ For specialized governmental law enforcement (intelligence, inmate)



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 work force
 - Detailed approach for those making the decisions
- ◆ Tip: Consider a community meeting with providers and law enforcement to agree on ground rules



Misunderstandings and Unrealistic Expectations



Misunderstandings and Unrealistic Expectations

- ◆ Must train workforce
- ◆ Should train/educate patients
- ◆ Areas of confusion
 - ❖ Opting out of facility directory
 - Approach to 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”
 - Approach to promote consistency
 - ❖ Accounting of disclosure

