

## H I P A A I m p l e m e n t a t i o n T i p s

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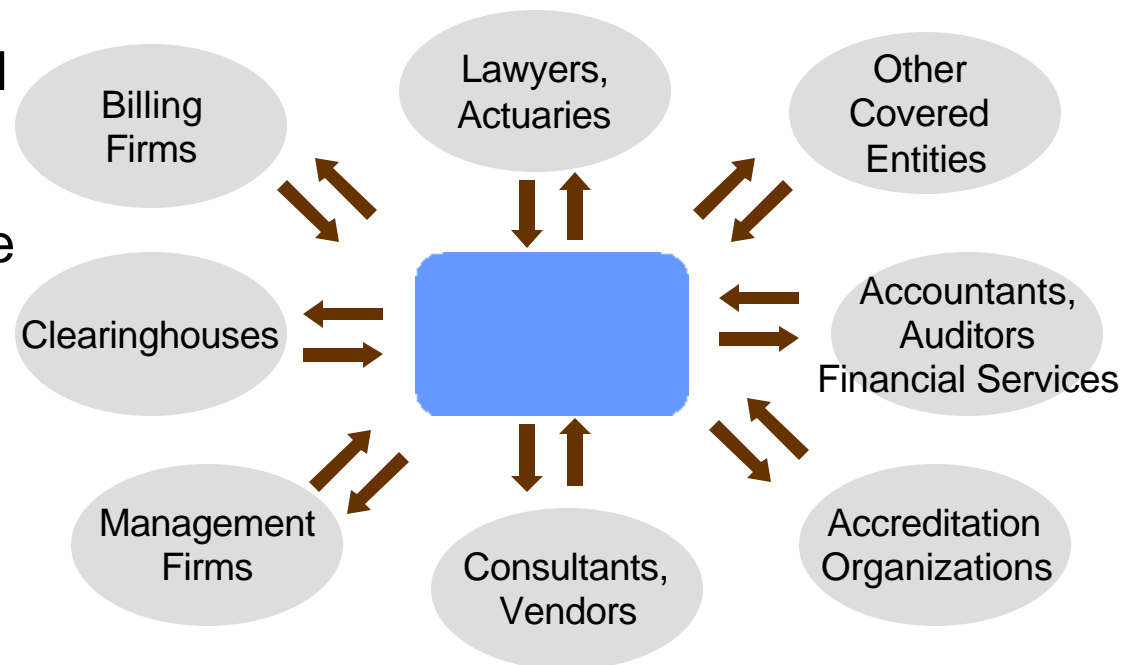
**Davis Wright Tremaine LLP**



# Use and Disclosure —

## Who is a Business Associate?

- ◆ A person who receives individually identifiable health information and —
  - ❖ On behalf of a covered entity performs or assists with a function or activity involving use or disclosure of information or otherwise covered by HIPAA
  - ❖ Provides certain identified services to a covered entity
- ◆ May be a covered entity



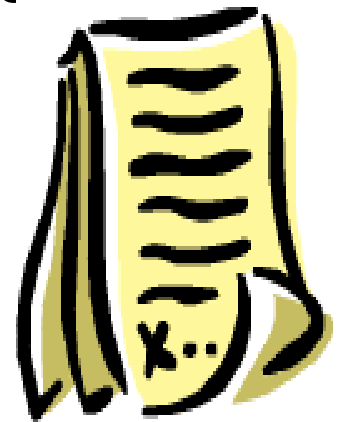
## No Business Associate Relationship

- ◆ Workforce
- ◆ Provider and plan
- ◆ Provider and provider for treatment
- ◆ Hospital and medical staff member
- ◆ Group health plan and plan sponsor
- ◆ Financial institutions
- ◆ Due diligence activities
- ◆ Members of  
“organized health care arrangements”
- ◆ “Conduits” (mail services and electronic equivalents)
- ◆ Special arrangements may create a business associate relationship



## Use and Disclosure — Business Associate Contracts

- ◆ A covered entity may disclose protected health information to business associates if:
  - ❖ Obtains “satisfactory assurance” that business associates will appropriately safeguard the information
- ◆ Business associate contract required
- ◆ Form agreement included in manual
  - ❖ Informational purposes/not legal advice
  - ❖ Any form must be adapted and individualized



# Business Associate Contracts — Required Terms

- ◆ Use and disclose information only as authorized in the contract
  - ❖ No further uses and disclosures (Section 2a)
  - ❖ Such uses and disclosures may not exceed what the covered entity may do under HIPAA (2b)
  - ❖ Data aggregation services exception (Exhibit A, 7)
- ◆ Implement appropriate privacy and security safeguards (2c)
- ◆ Report unauthorized disclosures to covered entity (2d)
- ◆ Make available protected health information under access, amendment and accounting of disclosures rights (2f)
- ◆ Incorporate any amendments to PHI (2g)



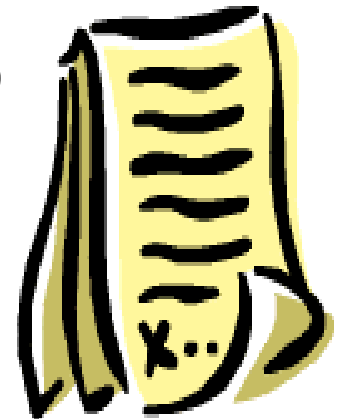
# Business Associate Contracts — Required Terms

- ◆ Make available its records to HHS for determination of covered entity's compliance (2h)
- ◆ Return/destroy protected health information upon termination of arrangement, if feasible (5d)
- ◆ Ensure agents and subcontractors comply (2e)
- ◆ Authorize termination by covered entities (5)



# Business Associate Contracts — Provisions to be Considered

- ◆ Right to review contracts between business associates and their subcontractors/agents
- ◆ Business associates insurance (2i)
- ◆ Indemnification (6)
- ◆ Use for management and administration (Ex A, 5)
- ◆ Effective date and “placeholder” provisions



## Liability for Business Associates

- ◆ If covered entity knows of a pattern of activity constituting a breach by the business associate, then
  - ❖ Must take reasonable steps to
    - Cure the breach or
    - End the violation
  - ❖ If unsuccessful,
    - Must terminate if feasible or
    - Report to DHHS
- ◆ Reprieve from proposed regulations
- ◆ How much monitoring is required?
  - ❖ Affirmative representations by business associate
  - ❖ Due diligence and questionnaire





## Business Associate Considerations

- ◆ Identify likely business associates
  - ❖ Start by listing everyone who receives individually identifiable health information
  - ❖ Determine who is/likely to be a business associate
  
- ◆ Allow for educational lead time



# Contract Compliance Considerations

- ◆ Decide on scope (may vary depending on relationship)
  - ❖ Addendum
  - ❖ Integration of key provisions into contract
  - ❖ Stand-alone contract
- ◆ Proactive or reactive approach
- ◆ What to do now
  - ❖ Contract/relationship inventory
  - ❖ Review existing contracts
  - ❖ New contracts
    - If term is longer than 2 years
    - “HIPAA compliance” language



## Individual Rights — Right to Access Own Protected Health Information

- ◆ Regardless of who created the information
- ◆ Non-duplicative information
- ◆ Form and format requested by the individual
  - ❖ If readily producible
  - ❖ Otherwise, readable hard copy or other mutually acceptable form
- ◆ Timely production (30 to 60 + 30 days)
- ◆ May require written request (included in Notice)



# Individual Rights — Right to Access/Denial of Access

## Non-Reviewable Grounds

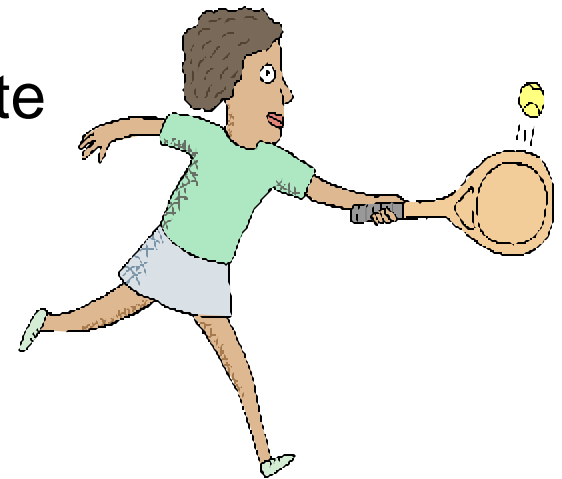
- ◆ Psychotherapy notes
- ◆ Compiled in reasonable anticipation of civil, criminal or administrative action
- ◆ Prohibited by CLIA
- ◆ Inmates
- ◆ Certain research data (limited)
- ◆ Protected by Privacy Act
- ◆ Information given under promise of confidentiality

## Reviewable Grounds

- ◆ Likely to endanger life/physical safety
- ◆ Reference, if disclosed, likely to harm third person
- ◆ To personal representative if likely to cause harm to individual or third person

# Individual Rights — Right to Amend

- ◆ Request for amendment (may require writing)
- ◆ Covered entity may accept or deny request
  - ❖ Grounds for denial
    - Not created by entity
    - Information is accurate and complete
    - Information is not subject to access
    - Not part of designated record set
- ◆ Statement of disagreement
- ◆ Rebuttal statement
- ◆ Record-keeping/linking/informing others



# Individual Rights — Accounting of Disclosures

## ◆ Accounting includes:

- ❖ Date of disclosure
- ❖ Recipient's name and address
- ❖ Description of information disclosed
- ❖ Purpose of disclosure

## ◆ Exceptions include disclosures for:

- ❖ Treatment, payment and health care operations
- ❖ Individual access, directories, persons involved in care
- ❖ National security or intelligence
- ❖ Correctional facilities or law enforcement officials
- ❖ Prior to compliance date



## Individual Rights — Right to Request Additional Protections

- ◆ Right to request additional privacy protections
  - ❖ Covered entity may refuse
  - ❖ If agrees → bound (except in emergency)
- ◆ Right to request to receive communications in alternative fashion
  - ❖ Accommodate reasonable request



## Individual Rights — Right to Notice of Privacy Practices

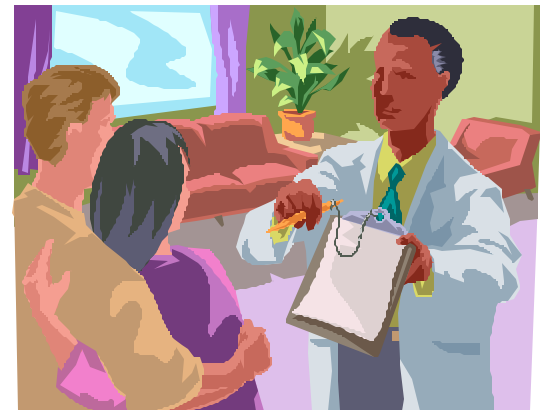
- ◆ Bound by notice: actions must be consistent with notice
- ◆ Sufficient detail to put the patient on notice of practices (as opposed to policies)
- ◆ Written in plain language (with examples in some cases)
  - ❖ Short sentences and active voice
  - ❖ Organized in logical order and short sections
- ◆ Single notice for affiliated covered entities
- ◆ Joint notice for organized health care arrangement





# Individual Rights — Right to Notice of Privacy Practices

- ◆ Specific content requirements, including —
  - ❖ “THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.”
  - ❖ Use and disclosures
  - ❖ Individual rights
  - ❖ Covered entity’s duties
  - ❖ Complaints and contacts
- ◆ Reserve right to change notice
- ◆ May not be combined with a consent



# Individual Rights — Right to Notice of Privacy Practices

## ◆ Dissemination of Notice

### ❖ For providers with direct treatment relationship

- Provide notice by first date of service
- Posted in clear and prominent location
- Available at facility



### ❖ For plans

- By compliance date
- At enrollment and within 60 days of material revision
- Inform beneficiaries every 3 years about availability
- To name insured

### ❖ Clearinghouses, when not business associates

### ❖ Website

## Administrative Requirements

- ◆ Implement administrative, technical and physical safeguards to protect health information from intentional or accidental misuse
- ◆ Designate privacy official
  - ❖ Identify job responsibilities and reporting lines
  - ❖ Recommend oversight committee
- ◆ Implement administrative systems
- ◆ Complaint mechanism with contact person



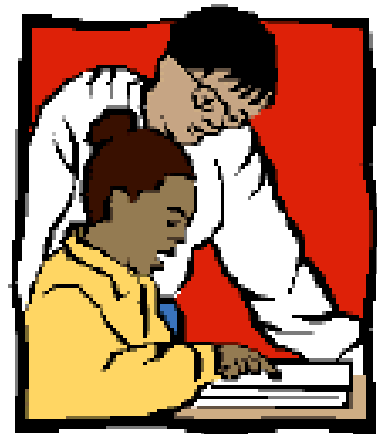
## Administrative Requirements

- ◆ Mitigation of harmful effects of improper use or disclosure
- ◆ No intimidation/retaliation for exercising rights
- ◆ No requirement to waive rights
- ◆ Documented policies, procedures and systems
  - ❖ Update as necessary



# Administrative Requirements — Workforce Training and Sanctions

- ◆ Privacy and security awareness training to —
  - ❖ Entire workforce by compliance date
  - ❖ New employees following hire
  - ❖ Affected employees after material changes in policies
- ◆ Document training
- ◆ Systems of sanctions — consistent enforcement



## Questions?

For more information, contact

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