Davis Wright Tremaine LLP

HIPAA - Issues in Agreements with Business Associates

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What's the Context - Who's Doing Whom?

- Covered Entities
- Business Associates
 - Claims, IT vendors
 - Managers
 - Lawyers; Accountants
- Exceptions
 - Hospital-Physician
 - Financial Institutions
 - Health Plan-Plan Sponsor
 - Organized Healthcare Arrangement



HIPAA Mandatory Provisions

- Not to use PHI other than as permitted by agreement, law (public health, subpoena, data aggregation)
 - purposes of the disclosure by CE to BA
 - PHI to be disclosed by CE to BA
 - BA's permitted uses and disclosures of PHI
- Use appropriate confidentiality safeguards
- Report to CE any impermissible use or disclosure
- Ensure subcontractors agree to same restrictions as BA



HIPAA Mandatory Provisions

- Make PHI available to CE to permit it to carryout its obligations to patients regarding access and accounting of disclosures
- Return or destroy PHI on termination of BAC
- Provide DHHS with BA's internal practices, books as to use and disclosure of PHI
- IF CE knows (or should know) of violation, CE to take reasonable steps to cure/end a violation



Oversight and Due Diligence of BAs

- BA to "use appropriate safeguards to prevent [impermissible] use or disclosure of PHI"
- Due diligence
 - Contingency Planning
 - Written policies and procedures
- Use of representations and warranties
 - Maintain security and confidentiality safeguards
 - In-service education
 - Reporting



BA's Subcontractors

- Second and third-tier agreements agents and subs must be subject to same limitations as BA
- Active monitory
 - Significant risks
 - Less significant risks
- Use common sense
- Ensure CE and BA have contractual rights to inspect and object
- CE's obligation to mitigate harmful effects of disclosure

Specific Provisions -Liability, Indemnification and Insurance

- Limitations on liability factors:
 - amount of the contract
 - impact of available insurance proceeds
 - consequential damages
- Indemnification two elements
 - pay damages
 - provide a defense
- Insurance online security loss coverage; other available coverage

Specific Provisions - Assignment, Administration, Integration

- **BA** sells its business or the applicable business unit
 - Assumption
 - Diligence
 - Right to terminate
- Use of PHI for BA's administrative purposes
 - Defining service areas
 - Defining nature of BA's business
- Integration and the Battle of the Forms

Specific Provisions - Breach and Enforcement

- BA's obligation to notify of breach
- Audit and inspection by CE (two edged)
- Suspension pending investigation
- Cure/end violations
- Impact of governmental enforcement as to BA
- Liquidated damages
- Return of data
- Receivership (unusual circumstances)

Specific Provisions - Dispute Resolution

- Informal meet and confer
- More formal mediation
- More formal arbitration
- More formal injunction
- Who reads this stuff until there's a problem?

Specific Provisions - Effective Date and Placeholders

- April 14, 2003
- Agreements to negotiate
- Agreement to abide by CE's boilerplate
- Termination if you do not agree
- Whose fault is it and who pays?



Final Thoughts

- Make sure you know who you are
- Know what you have to have
- Know what you need to have
- Be there first and most comprehensively
- Make sure those responsible for contracting understand why you need what you need
- Make sure those responsible for performance know the contract
- Toward some standardization lessons from the Uniform Commercial Code