



JCAHO

Joint Commission on Accreditation of Healthcare Organizations
Setting the Standard for Quality in Health Care

NCQA

Measuring the Quality of America's Health Care

**PRIVACY
CERTIFICATION
FOR BUSINESS ASSOCIATES**

Functioning as a Business Associate Under HIPAA

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Background: JCAHO/NCQA and HIPAA

- JCAHO and NCQA are business associates to the organizations they accredit
- NCQA is also a researcher – using data gathered as a BA
- JCAHO and NCQA have developed the Privacy Certification for Business Associates (PCBA) program
- See BA issues from both sides

HIPAA Myths

- Business associates do not have to comply with the federal HIPAA regulations
- Business associates only have to have contracts with covered entities
- How many have heard these?
- How many believe it?

Why Comply with HIPAA?

- Enforcement Issue
 - Federal government may not enforce BA compliance, but states that adopt the federal regulations as the standard of care are likely to apply them to all organizations
- PR Issue
 - Public breaches of privacy or security could damage or destroy a company's reputation
- Business Issue
 - Covered entities need partners they can trust
- Not to mention – it's the right thing to do!

How to Comply with HIPAA?

- According to the Privacy and Security regulations:
 - **Business associates have to provide “satisfactory assurances” that they will “appropriately safeguard” PHI (45 CFR 164.308 (b) (1) and 45 CFR 164. 502 (e) (1))**
- In both cases, specific BA provisions are scarce
 - **Include establishing allowable uses and disclosures, implementing “appropriate safeguards,” reporting breaches to the covered entity, ensuring agents and subcontractors follow suit and cooperating with investigations**

What Do BA Requirements Really Require?

- Terminology is vague, definitions may come in the future
- Must determine on our own the reasonable steps for a BA to take to work effectively with covered entities
- HIPAA regulations can be expected to create minimum “best practices” that all organizations can be expected to follow
- What to do?



Privacy Certification for Business Associates

- A joint initiative of NCQA and JCAHO
- A voluntary, private evaluation mechanism to provide business associates with a method of demonstrating satisfactory assurances of PHI protections to covered entities

Proposed Standards

- Closely track HIPAA privacy regulations
- Also include security requirements required by privacy
- Developed with input from multistakeholder Advisory Committee
- Categories include:
 - **Administration**
 - **Use and Disclosure**
 - **Individual Rights**

Use the Same Framework

- In creating our program, we asked the questions:
 - How can the BA “back-up” the provisions of the BA contract?
 - What areas of a BA/covered entity relationship not addressed in the contract?
 - What processes must BAs have, no matter
 - How do you comply with differing covered entity requirements?
 - To what standard do you hold BAs?

Basic BA Requirements

- Create infrastructure for PHI protection
- Determine routine business needs involving use, disclosure and storage of PHI
- Implement policies, procedures and processes for those routine business needs
- Coordinate with covered entities to determine unique needs
- Monitor, test, revise and refine processes over time
- BAs should be expected to meet same standards as covered entities, when performing the same functions

Creating Infrastructure

- Analyze business processes
 - Where is PHI coming in from covered entities?
 - How is PHI being transmitted to covered entities, agents, subcontractors and workforce members?
 - How/where is PHI stored?
 - Can PHI be inadvertently sent during routine business processes?
- Gaps? – close them
- Risk identified? – set up plan to deal with them

Creating Infrastructure - II

- Create Infrastructure to protect PHI
 - Determine documentation requirements for the BA's processes
 - Set up physical and electronic access controls
 - Set oral PHI standards
 - Implement procedures for visitors
 - Create process to identify and mitigate PHI protection breaches
 - Set sanction policy for those breaches

Creating Infrastructure - III

- Train staff on general requirements
 - Overall PHI/HIPAA training
 - Include basic privacy and security
 - Explain why this affects your business
 - Include all workforce members
- Implement specific training
 - Based on role, type of PHI accessed, uses and disclosures of PHI needed
 - Tailor to departmental/unit needs
- Create reminder system

Setting Daily P&P

- Focus on areas of routine use and disclosure of PHI
- Establish policies, procedures and processes to handle
- Set minimum necessary standards for internal uses and disclosures to agents and subcontractors
 - **May need to adapt for specific covered entity requirements**

Authorizations

- Determine if any routine business needs require authorizations
- If so, work with covered entities – who is responsible for obtaining?
- If covered entity responsible, BA should set up process to check whether authorization in place before disclosing
- If BA responsible, create authorization form and process for ensuring they are obtained when needed

Consumer/Individual Rights

- Individuals can access PHI, and request amendments, restrictions, confidential communications and accountings of disclosures
- BAs, depending on business processes, will have to deal with at least some of these
 - **Accountings of disclosures**
 - **Restrictions on use/disclosure agreed to by covered entity**

Consumer/Individual Rights - II

- Analyze business processes
 - Does the BA contact consumers?
 - May get requests directly – where do you send them?
 - Confidential communications – how do you account for these?
 - How will restrictions on use and disclosure affect BA's processes?
 - Do you have a system to track and handle these – when agreed to by covered entity?

Consumer/Individual Rights - III

- Analyze business processes
 - Does the BA hold any portions of the designated record set?
 - How will BA provide access?
 - How will amendments be incorporated?
 - How will amendment denials be incorporated?
 - Does the BA disclose PHI?
 - How are disclosures tracked?
 - How will accountings be generated?

Consumer/Individual Rights - IV

- **Coordination is the Key**
 - **Work with covered entities to determine which organization is responsible for different aspects of consumer rights**
 - **Set up processes accordingly, remembering**
 - **The covered entity could disappear tomorrow – what happens if the BA is the only holder of the PHI?**
 - **Even if BA does not directly deal with consumers, covered entity decisions on restrictions, amendments and other rights can affect BA's business**

Contracts/Agreements

- Covered entities responsible for obtaining contracts/agreements
- BAs can help by internally tracking:
 - **Are there existing covered entity clients/customers without contracts at all?**
 - **When are contracts up for renewal?**
 - Before or after April 2004?
 - **Which covered entities have contacted the BA with a BA contract or addendum?**
- Should the BA have its own contract?

Contracts/Agreements - II

- Study contract provisions
 - Are there any that will interfere with routine business operations?
 - Are there other options to provide same protection but streamline BA's processes?
 - Are there areas covered entity should have included but didn't?
- Set up system to alert staff to specific covered entity requirements

Questions?
