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HIPAA and HITECH – Getting Down to Business with Business Associates



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Agenda

- Identifying business associates under the new definition
- Things to consider prior to entering into a business associate relationship
- Points of negotiation in BAAs
- Sticky issues
- The business associate's perspective
- Compliance for business associates
- Considerations in BAA drafting
- Case study

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Business associates and HITECH

- A whole new world starting on September 23, 2013
- BAs may use or disclose PHI only as permitted or required by the BAA or as required by law
- BAs will be directly liable under the HIPAA Rules and subject to civil and criminal penalties for failing to comply with the BAA or the Security Rule

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New Definition of Business Associate

- A BA “creates, receives, maintains, or transmits PHI”
- Government has stated informally that entities that store only encrypted PHI are still BAs.
- Business associate definition includes health information organizations, e-prescribing gateways and others that provide data transmission and that access PHI on a routine basis
- Includes PHR vendors that act on behalf of CE
- Includes subcontractors that create, receive, maintain, or transmit PHI on behalf of a business associate

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Who is not a business associate?

- Health care provider when disclosure is for treatment
- Plan sponsor for disclosures allowed under HIPAA
- Government agency that is determining government plan eligibility or enrollment, as authorized by law
- OHCA member acting on behalf of OHCA

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Subcontractors/business associates/service providers

- Shredding companies
- Law firms
- 78 Fed. Reg. 5574: “Disclosures by a business associate pursuant to §164.504(e)(4) and its business associate contract for *its own* management and administration or legal responsibilities do not create a business associate relationship with the recipient of the protected health information because such disclosures are made outside of the entity’s role as a business associate.” **However...**

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Subcontractors/business associates/service providers(continued) . . .

- 78 Fed. Reg. 5574: “We also clarify that the same interpretations that apply to determining whether a first tier contractor is a business associate also apply to determining whether a subcontractor is a business associate.”
- Whether a subcontractor or a service provider, you must obtain “reasonable assurances” from the data recipient

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Organized Health Care Arrangements (OHCAs)

- BA does not include a covered entity participating in an OHCA that performs a function or activity for or on behalf of the OHCA.
- Is the CE acting on behalf of the OHCA as a whole, or on behalf of a component of the OHCA?

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Who is a business associate?

- *Decision tree from Workgroup for Electronic Data Interchange (WEDI.org):*
 - http://www.wedi.org/forms/uploadFiles/35FE700000DC.filename.7.26_BA-Decision-Tree_V2.pdf

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Who is a business associate? (from WEDI.org)

- Is PHI being disclosed to a person or entity other than a member of the workforce? If no, then no BAA needed. If yes, then . . .
- Is PHI being disclosed to a health care provider for treatment? If yes, then no BAA needed. If no, then . . .
- Is the PHI being disclosed to a health plan for payment purposes, or to a health plan sponsor with respect to disclosures by a group health plan? If yes, then no BAA needed. If no, then . . .

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Who is a business associate? (continued)

- Is PHI being disclosed to a government agency pursuant to an investigation? If yes, then no BAA needed. If no, then . . .
- Is the PHI disclosed to another covered entity part of an OHCA with the originating covered entity? If yes, then no BAA needed. If no, then . . .
- Does the other person/entity create, receive, maintain, or transmit PHI for a function or activity regulated by HIPAA? If yes, then BAA is needed. If no, then . . .

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Who is a business associate? (continued)

- Does the other person/entity provide legal, actuarial, account, consulting, data aggregation, management, administrative, accreditation, or financial services where the provision of the services involves disclosure of PHI? If yes, then a BAA is needed, if no, then . . .
- Will the other person or entity be able to access PHI on a routine basis, and/or is there a possibility that the PHI in the person/entity's custody could be compromised (e.g. data storage vendor, shredding company)? If yes, then BAA needed. If no, then

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Who is a business associate? (continued)

- Is the entity a Health Information organization, E-prescribing gateway, data transmission vendor with routine PHI access, PHR vendor acting on behalf of the covered entity? If yes, then BAA needed. If no, then the entity may not be a BAA, but *make sure HIPAA otherwise permits the disclosure.*

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Beyond the Forms – Things to consider up front

- Due diligence
 - Questionnaires
 - Investigations
 - Exclusions list
- Is the entity a business associate at all?

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Underlying agreement and BA particulars

- What will the BA be doing exactly?
- Does HIPAA allow it?
- Does Florida law allow it?
- Do you have the correct corporate names?
- Did the services already start, or what's the start date?
- What's the notice address?
- Who will be signing?

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Indemnification

- Is it already addressed in the underlying agreement?
- Will it be mutual?
- How much indemnification do we need?
- Is there any insurance?

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Process for managing negotiation and documentation

- Central control of negotiations and drafting vs. giving everyone a template form?
- Centralized recordkeeping? Will departments keep copies?
- How much negotiation will there be? Should we send document in Word or as a pdf?
- Do you want stand alone BAAs or will they be incorporated into other contracts?

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Battle of the forms – Preliminary considerations

- How risky is the arrangement?
- Do we need a confidentiality agreement for other information?
- Should the BA be allowed to re-disclose? Maintain PHI? Destroy PHI?

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10 Things a BA Must Address

1. Establish the permitted and required uses and disclosures of PHI by BA
2. Provide that BA will not use or further disclose the information other than as permitted or required by the contract or as required by law
3. Require the BA to implement appropriate safeguards to prevent unauthorized use or disclosure of the PHI, including compliance with the Security Rule for ePHI

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What a BA must contain (continued)

4. Require reporting to CE any improper use or disclosure, including breaches
5. Require BA to make PHI available for access and amendment, and require information for accounting
6. Require Privacy Rule compliance, to the extent applicable
7. Require BA to make books and records available to HHS

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What a BA must contain (continued)

8. Require return or destruction of PHI at termination, if feasible
9. Require the BA to ensure that subcontractors agree to the same restrictions and conditions
10. Authorize termination of the contract by CE if the BA violates a material term

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Didn't we just do this in 2009?

- If we are happy with the current BAA, what's the minimum that needs to change?
- OCR template language?
- Reference to privacy rule compliance?
- Minimum necessary rule?
- Breaches?

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Sticky issues

- Cloud storage
 - Encrypted PHI
 - Just where is this “cloud”?



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Sticky issues (continued) . . .

- “**ensure** that any subcontractors that create, receive, maintain, or transmit protected health information on behalf of the business associate agree to the **same restrictions and conditions** that apply to the business associate with respect to such information . . .”.



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Staffing services



- Are they business associates?
- Maybe part of an OHCA?
- Workforce?
- Will they need PHI?

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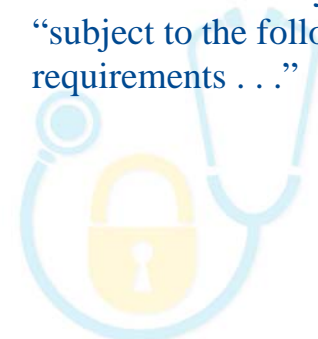
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Minimum necessary rule

- OCR language: “consistent with the covered entity’s minimum necessary policies and procedures” or “subject to the following minimum necessary requirements . . .”



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Minimum necessary rule (continued)

- FAQ 252: “A **covered entity**’s contract with a business associate may not authorize the business associate to use or further disclose the information in a manner that would violate the HIPAA Privacy Rule if done by the covered entity. See **45 CFR 164.504(e)(2)(i)**. Thus, a **business associate contract must limit** the business associate’s uses and disclosures of, as well as requests for, protected health information to be **consistent with the covered entity’s minimum necessary policies and procedures**. Given that a business associate **contract must limit a business associate’s requests for protected health information on behalf of a covered entity to that which is reasonably necessary to accomplish the intended purpose**, a covered entity is permitted to reasonably rely on such requests from a business associate of another covered entity as the minimum necessary.”

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Security incidents

- BAs must report any “security incident” of which it becomes aware
- “Security incident” includes “attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an information system”

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New restrictions on sale of PHI

- Rule provides specific guidance regarding sales that require authorization
- Information can be sold for public health, treatment and payment, or for the sale of an entity
- Information can be sold for research, but remuneration must be reasonable and cost-based
- Remuneration can flow from a covered entity or business associate.
- Business associates and covered entities can also receive remuneration for other lawful purposes, but the fee must be only a “reasonable, cost-based fee to cover the cost to prepare and transmit” the PHI or for a “fee otherwise expressly permitted by other law”

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Sale of PHI

- Warning – Use extreme caution if PHI and remuneration are flowing in opposite directions. Does an exception apply?



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De-identification of PHI

- OCR has indicated that a CE can use a BA to create de-identified data or a limited data set, even if for the BA's own use (FAQ 468, 67 Fed. Reg. 53237 (Aug. 14, 2002), but be careful about the remuneration flow.
- Individually identifiable health information from which **any and ALL** identifiers of the individual, relatives, employers, or household members are removed:

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De-identification safe harbor

- (A) Names;
- (B) Street address, town or city, county, precinct, zip code, and equivalent geo codes;
- (C) All elements of dates (except year) for dates directly related to an individual and all ages over 89;
- (D) Telephone numbers; —
- (E) Fax numbers; —
- (F) Electronic mail addresses;
- (G) Social security numbers;
- (H) Medical record numbers;
- (I) Health plan ID numbers;
- (J) Account numbers;
- (K) Certificate/license numbers
- (L) Vehicle identifiers and serial numbers, including license plate numbers; —
- (M) Device identifiers/serial numbers; —
- (N) Web addresses (URLs);
- (O) Internet IP addresses; —
- (P) Biometric identifiers, incl. finger and voice prints;
- (Q) Full face photographic images and any comparable images; and
- (R) Any other unique identifying number, characteristic, or code.

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Limited Data Set

- PHI that excludes **direct identifiers**. Limited data set is still PHI since it may contain identifiable information.
- PHI may be used or disclosed, for purposes of research, public health, or health care operations, without obtaining either an individual's Authorization or a waiver or an alteration of Authorization for its use and disclosure, with a data use agreement.
- CE may use and disclose a limited data set for research activities conducted by itself, another covered entity, or a researcher who is not a covered entity if the disclosing covered entity and the limited data set recipient enter into a **data use agreement**.
- **Limited data sets** may only be used or disclosed for **research, public health, or health care operations purposes**.

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Limited Data Set (LDS)

- ~~(A) Names;~~
- ~~(B) Street address, town or city, county, precinct, zip code, and equivalent geo-codes;~~
- **(C) All elements of dates (except year) for dates directly related to an individual and all ages over 89;**
- ~~(D) Telephone numbers;~~
- ~~(E) Fax numbers;~~
- ~~(F) Electronic mail addresses;~~
- ~~(G) Social security numbers;~~
- ~~(H) Medical record numbers;~~
- ~~(I) Health plan ID numbers;~~
- ~~(J) Account numbers;~~
- ~~(K) Certificate/license numbers~~
- ~~(L) Vehicle identifiers and serial numbers, including license plate numbers;~~
- ~~(M) Device identifiers/serial numbers;~~
- ~~(N) Web addresses (URLs);~~
- ~~(O) Internet IP addresses;~~
- ~~(P) Biometric identifiers, incl. finger and voice prints;~~
- ~~(Q) Full face photographic images and any comparable images; and~~
- **(R) Any other unique identifying number, characteristic, or code.**

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Data Use Agreement

- An agreement into which the **covered entity enters with the intended recipient of a limited data set** that establishes the **ways in which the information** in the limited data set **may be used and how it will be protected.**
- Establishes the means by which a covered entity obtains satisfactory assurances that the recipient of the limited data set will use or disclose the PHI only for specified purposes.
- Agreement must be in place between CE and limited data set recipient.

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Data Use Agreement

- Sets out the permitted uses and disclosures of the PHI in the LDS
- Identifies who is permitted to use or disclose the information
- Provides that the recipient will
 - Properly safeguard the data
 - Not use the information in a manner inconsistent with the DUA
 - Report any improper uses or disclosures to the CE
 - Not use the information to attempt to identify or contact individuals based on the information in the LDS
 - Require all agents and subcontractors to comply with the terms of the DUA

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Federal common law of agency

- Agents vs. independent contractors
- 2002: “The Privacy Rule does not require a covered entity to actively monitor the actions of its business associates nor is the covered entity liable for the actions of its business associates.” 67 Fed. Reg. 53252 (Aug. 14, 2002)

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Federal common law of agency (continued)

- 45 CFR 160.402(c): CE “is liable, in accordance with the Federal common law of agency, for a civil money penalty for a violation based on the act or omission of any agent of the covered entity, including a workforce member or business associate, acting within the scope of the agency.”

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Federal common law of agency

- “[W]hether a business associate is an agent will be fact specific and consider the totality of the circumstances involved in the ongoing relationship between the parties.”
- BA would generally not be an agent if the only avenue of control would be to amend the BAA.
- Could be an agent if CE could direct the BA after the relationship was established. 78 Fed. Reg. 5581 (Jan. 25, 2013)

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Qualified Service Organization Agreements

- QSOs provide services to a 42 CFR Part 2 program, including data processing, bill collecting, medical services, etc.
- QSOs must enter into a written agreement with a program under which that person:
 - Acknowledges that it is fully bound by 42 CFR Part 2
 - If necessary, will resist in judicial proceedings any efforts to obtain access to patient records, except as permitted by the regulations

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QSO Agreements (continued)

- Substance Abuse and Mental Health Services Administration (SAMHSA) has indicated that QSOs can disclose patient data only under very limited circumstances to a “contract agent.” The agent is bound by Part 2.
- HIPAA allows business associates to re-disclose for broader purposes

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BA and Subcontractor agreements – Getting started

- Obtain or create a thorough inventory of business associates or subcontractors
- Figure out which agreements need to be amended
- Update templates for new agreements
- Agents vs. independent contractors
 - Delegation of HIPAA obligations
 - Manner and method of control over the BA
- Consider the OCR template

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Business associate's perspective



- Some covered entities are also BAs
 - Separate policies and procedures?
 - Adequate separation?
 - Risk analysis?
 - Training?

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Lawyers as business associates

- Law firms are likely “business associates”
- Law firms probably have “subcontractors”
- Firms need to update their HIPAA compliance programs, including the risk analyses, policies and procedures, etc.
- Law firms need to update training and be sure all attorneys and staff with access to PHI are trained
- Ethical issues regarding BAAs
- Self-insured health plans

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Compliance for business associates

- Security official – responsible for the development and implementation of policies and procedures required by the Security Rule
- Should BAs have a privacy official?
- No notice of privacy practices needed (FAQ 390)

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Compliance for business associates (continued)

- Risk analysis – “an accurate and thorough assessment of the potential risks and vulnerabilities” to ePHI
- Risk mitigation – “sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level”

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Compliance for business associates (continued)

- Policies and procedures
 - Sanction policies
 - Workforce clearance procedures
 - Termination procedures
 - Disaster recovery plan
 - Other policies to ensure BAA compliance

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Compliance for business associates (continued)

- Subcontracts
- Training
- Firewalls
- Monitoring and auditing

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Considerations in BAA drafting and negotiation

- General legal considerations – Is there a meeting of the minds? Is there mutual consideration? Has the CE agreed to do anything?
- Definition section – May not need to repeat the regulatory definitions. Consider the OCR template.
- Does the BAA need to consider other laws and rules dealing with substance abuse, nonpublic personal financial information, etc.?

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BAA drafting (continued)

- Will the BA be maintaining PHI in a designated record set?
- Is the BA a law firm that may need to protect the attorney/client privilege?
- How will CE ensure that BA follows its “minimum necessary” policies and Notice of Privacy Practices?

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BAA drafting – Covered Entity perspective

- Have you obtained patient authorization sufficient to allow BAs and subcontractors to re-disclose for their own proper management and administration and other purposes?
- Should the underlying agreement terminate if the BAA terminates?
- CE should make sure that BA is obligated to report more than just “breaches.”

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BAA drafting – CE perspective (continued)

- Will the BA be retaining PHI? Why?
- Does the CE want to allow the BA to destroy PHI at termination of the BAA?
- Do you need/want indemnification?
- Do you want to physically audit or inspect?
- Does the CE want to require the BA to provide patients with notice if BA commits a breach?

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BAA drafting – CE perspective (continued)

- Make sure the CE is defined properly if you have a hybrid entity, affiliated covered entity, etc.
- Consider whether CE should add specificity regarding BA's obligations with respect to access, amendment, and accounting.
- Are you exercising so much control that BA may become an "agent"?
- Do you want to require that data not go offshore?
- Do you want to be able to amend unilaterally?

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Considerations from Business Associate perspective

- Subcontractors must agree to the same restrictions and conditions. How will that be handled? Will CE agree to use BA's form?
- Can the parties agree that the BAA constitutes a sufficient report of certain unsuccessful security incidents?

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BAA drafting – BA perspective (continued)

- Does the BAA allow BA to disclose for its proper management and administration?
- Does the BAA address data aggregation? De-identification? Limited data sets?
- Consider requiring CE to notify BA of restrictions, minimum necessary policies, etc.
- Consider requiring CE to obtain state law authorizations that may be necessary to allow BA to re-disclose.

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BAA drafting – BA perspective (continued)

- BAs may want to try to limit liability, such as for incidental, indirect or consequential damages.
- BA may not want the underlying agreement to terminate if the BAA terminates, but this may not be feasible.
- BA may want assurances that CE will also comply with HIPAA and other applicable law.

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Case study

Hospital wants to hire Vendor to help it respond to patient complaints. In addition to these services, Vendor will combine the PHI it receives on behalf of Hospital with the PHI it receives from its other customers and prepare aggregate quarterly reports showing trends in patient complaints, which will be used for quality assessment and improvement.

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Case study (continued)

Vendor offers Hospital a discounted rate for its services in exchange for the right to de-identify the PHI and use the information to publish a monthly newsletter that will summarize the typical types of complaints hospitals received in the previous month. Vendor indicates that it has hundreds of Hospital clients, and a number of subcontractors, so it's really important that Hospital consider signing Vendor's BAA.

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Case study (continued)

Vendor also needs access to Hospital's EHR database so Vendor can look up patient contact information and see if the services the patients may complain about were really provided. Time is of the essence to get a business associate agreement in place, because Vendor started receiving PHI from Hospital last week.

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Case study analysis

- Date services began
- BAA must specify the services
- Minimum necessary
- Sale of PHI
- De-identification
- Terms flowing down to subcontractors
- Research
- Marketing

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