VBP CONTRACTING WEBINAR SERIES

Webinar
Data Sharing and Confidentiality – Part 1

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Care Transitions Network
for People with Serious Mental Illness

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Agenda

- HIPAA Confidentiality
- Business Associate Agreements
- Key Questions

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Introduction to HIPAA Confidentiality

The HIPAA Rules

HIPAA Privacy Rule (2000)

- Focuses on uses/disclosures of protected health information (PHI) and individual rights to understand/control how their PHI is used

HIPAA Security Rule (2003)

- Establishes federal protections for electronic PHI (ePHI) that is created, received, or maintained by a covered entity

HIPAA Enforcement Rule (2003)

- Creates framework for HIPAA-investigations and civil monetary penalties

HIPAA Final Omnibus Rule (2013)

- Changes HIPAA as required under the HITECH Act (HITECH)

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HIPAA Covered Entities

Covered Entities

- Health care providers who submit HIPAA transactions (like claims) electronically
- Health plans
- Health care clearinghouses

Covered Entities Guidance Tool

- https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/HIPAA-ACA/Downloads/CoveredEntitiesChart20160617.pdf

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HIPAA Privacy

- Covered entities may not use/disclose PHI, except as **permitted by Privacy Rule** or as **authorized by individual** who is the subject of the PHI

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HIPAA Privacy

Covered entities **<u>are permitted</u>** to use or disclose PHI:

1. To the individual (unless required for access or accounting of disclosures)
2. For **treatment, payment, and health care operations**
3. Incidental use and disclosure
4. With **authorization of individual**
5. Use or disclosure with opportunity to agree or object
6. Public interest and benefit activities
7. Limited data set

See 45 CFR §§164.502(a)(1), 164.512

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Treatment, Payment and Health Care Operations

- **Treatment**: The provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another.
- **Payment**: Encompasses activities of health care providers to obtain payment or be reimbursed for their services and of a health plan to obtain premiums, to fulfill their coverage responsibilities and provide benefits under the plan, and to obtain or provide reimbursement for the provision of health care.

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Treatment, Payment and Health Care Operations

- **Health Care Operations**: Certain administrative, financial, legal, and quality improvement activities of a covered entity that are necessary to run its business/support core functions of treatment and payment.
- Examples:
  - Conducting quality assessment and improvement activities, population-based activities relating to improving health or reducing health care costs, and case management and care coordination.
  - Business planning and development, such as conducting cost-management and planning analyses related to managing and operating the entity.

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Treatment, Payment and Health Care Operations

In general, before a covered entity can share PHI with another covered entity for purposes of health care operations, the following three requirements must also be met:

1. Both covered entities must have or have had a relationship with the patient (can be a past or present patient)
2. The PHI requested must pertain to the relationship
3. The disclosing covered entity must disclose only the minimum information necessary for the health care operation at hand

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Treatment, Payment and Health Care Operations

- Any use or disclosure of PHI for treatment, payment, or health care operations **must be consistent with the covered entity's notice of privacy practices**. A covered entity is required to provide the individual with adequate notice of its privacy practices, including the uses or disclosures the covered entity may make of the individual's information and the individual's rights with respect to that information.

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Patient Right to Request Restrictions

Individuals have a right to request covered entities restrict the use or disclosure of their PHI for treatment, payment, or health care operations or to notify family members/others:

- Covered entity is under no obligation to agree to the restriction, but must adhere to the restriction if it agrees, except in the case of an emergency.
- Restriction may be terminated if:
  - Individual agrees to or requests termination in writing;
  - Individual orally agrees to termination and oral agreement is documented; or
  - Covered entity informs individual that it is terminating its agreement, effective only re: PHI created or received by a covered entity after it has so informed the individual.

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Patient Authorizations

A covered entity must obtain the individual's written authorization for any use or disclosure of PHI that is not for treatment, payment or health care operations or otherwise permitted or required by the Privacy Rule.

- Core elements and required statements for a valid authorization can be found at 45 CFR §164.508
- Specific authorization requirements under HIPAA for:
  - Psychotherapy notes
  - Marketing purposes
  - Sale of PHI

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Minimum Necessary Standard

- When using, disclosing, or requesting PHI, a covered entity must make reasonable efforts to limit PHI to the **minimum amount necessary** to accomplish the intended purposes of the use, disclosure, or request.
  - Does not apply to disclosures to or requests by a health care provider for treatment or those made pursuant to an authorization.
  - A covered entity must develop policies and procedures that reasonably limit its disclosures of, and requests for, PHI for payment and health care operations to the minimum necessary.

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Organized Health Care Arrangements

"Organized health care arrangement" means:

1.A clinically integrated care setting in which individuals typically receive health care from more than one health care provider…

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Organized Health Care Arrangements

2. An organized system of health care in which more than one covered entity participates and in which the participating covered entities:

- Hold themselves out to the public as participating in a joint arrangement; and
- Participate in joint activities that include at least one of the following:
  - Utilization review…
  - Quality assessment and improvement activities…
  - Payment activities, if the financial risk for delivering health care is shared, in part or in whole, by participating covered entities through the joint arrangement and if protected health information created or received by a covered entity is reviewed by other participating covered entities or by a third party on their behalf for the purpose of administering the sharing of financial risk…

45 CFR § 160.103

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Organized Health Care Arrangements

A covered entity that participates in an organized health care arrangement may disclose protected health information about an individual to other participants in the organized health care arrangement for any health care operations activities of the organized health care arrangement.

45 CFR § 164.506(b)(5)

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HIPAA Security Rule: Safeguards

Covered entities must maintain reasonable and appropriate administrative, technical and physical safeguards for protecting e-PHI:

- Ensure the confidentiality, integrity, and availability of all e-PHI they create, receive, maintain or transmit;
- Identify and protect against reasonably anticipated threats to the security or integrity of the information;
- Protect against reasonably anticipated, impermissible uses or disclosures; and
- Ensure compliance by their workforce.

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HIPAA Security Rule Safeguards

Covered entities must have:

- **Administrative Safeguards** (e.g., workforce security, information access management, and security awareness and training)
- **Physical Safeguards** (e.g., workstation use, device and media controls)
- **Technical Safeguards** (e.g., access controls, audit controls, authentication)

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HIPAA Security Rule Safeguards

Business Associate Contracts and Other Arrangements: A covered entity may permit a business associate to create, receive, maintain, or transmit e-PHI on covered entity's behalf only if covered entity receives satisfactory assurances that business associate will appropriately safeguard the information.

- **Written contract or other arrangement (required):**
  - Document satisfactory assurances through written contract or other arrangement that meets requirements of Security Rule.

45 CFR § 164.308(b)

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HIPAA Security Rule Safeguards

Transmission Security: Implement technical security measures to guard against unauthorized access to e-PHI that is being transmitted over an electronic communications network.

- Integrity controls (addressable): Implement security measures to ensure that electronically transmitted e-PHI is not improperly modified without detection until disposed of.
- Encryption (addressable): Implement a mechanism to encrypt e-PHI whenever deemed appropriate.

45 CFR § 164.312(e)

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Business Associate Agreements

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Business Associates

- Business associate: Generally defined as “a person who performs functions or activities on behalf of, or certain services for, a covered entity that involve the use or disclosure of [PHI].”

- The HIPAA Rules require that covered entities obtain satisfactory assurances that the business associate will appropriately safeguard the PHI it creates or receives on behalf of the covered entity. Typically, this is done through a “business associate agreement” (BAA).

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Business Associates

Definition of “business associate”

- A person or entity who performs functions or activities on behalf of, or certain services to, a covered entity involving the use or disclosure of protected health information.
- A person who is a member of the covered entity’s workforce, *i.e.*, an employee, volunteer, trainee and other person whose conduct is under the direct control of the covered entity, is not a business associate.
- A physician or other provider who receives protected health information for treatment purposes is also not a business associate.

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Business Associates

Examples of functions performed by business associates may include:

- Claims processing or administration
- Data analysis processing or administration
- Utilization review
- Quality assurance
- Billing
- Benefit management
- Practice management

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Business Associates

Business associate services include:

- Legal
- Actuarial
- Accounting
- Consulting
- Data aggregation
- Management
- Administrative
- Accreditation
- Financial

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Business Associates

- The HIPAA Final Rule expanded the "business associate" definition by adding various categories of individuals and entities into the definition:
  - Patient Safety Organizations
  - Health Information Organizations, E-prescribing Gateways, or other persons that provide data transmission services with respect to PHI to a covered entity and that require routine access to such PHI, and persons who offer personal health records to one or more individuals on behalf of a covered entity.
  - Subcontractors: Person to whom a business associate delegates a function, activity or service.

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Business Associates

- Business associates are directly liable for their own HIPAA violations.
- Business associate agreements must meet the requirements of 45 CFR §164.504(e). For example, it must:
  - Limit the business associate's uses and disclosures of PHI consistent with the covered entity's minimum necessary standards.
  - Require business associates report breaches to the covered entity.
  - Require the business associate to ensure any subcontractors that create, receive, maintain or transmit PHI on behalf of the business associate agree to the same restrictions and conditions.
- When the covered entity delegates Privacy Rule responsibilities to business associate, the business associate must comply to same extent as the covered entity.
- Covered entities and business associates may contract with regard to issues outside the realm of the HIPAA Privacy and Security Rules
  - *e.g.*, indemnification clauses

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Key Questions

Key Questions – Understanding the Data Flow

- What patient information will be disclosed?
- For what purpose(s) will the information be disclosed?
- Is patient authorization required for such disclosures under HIPAA or state law?
- Does the covered entity require patient authorization for such disclosures?
- Will individuals “opt-in” or “opt-out” of participation?
- Does the relationship meet the definition of an “organized health care arrangement”?
- How does the information flow (HIE, etc.)?

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Key Questions – Business Associates

- What function or service is the business associate performing on behalf of or for the covered entity?
- Are the permitted uses and disclosures identified in the contract or the business associate agreement?
- How and when will the covered entity be notified of breaches?
- How will PHI be returned, destroyed or protected at the termination of the contract?

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Questions and Comments

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Additional Webinars in this Series

All Webinars Scheduled for 1:00 - 2:00pm ET

Webinar 7: Data Sharing and Confidentiality Part 2; Wednesday, August 15

Webinar 8: Employment & Professional Services Agreements; Wednesday, August 29

Webinar 9: Forming Provider Networks to Participate in VBP Arrangements; Wednesday, September 12

Webinar 10: Contracting for EHR Systems; Wednesday, September 26

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