

HIPAA Privacy Modification Rule - Final Harvard Colloquium

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Tom Hanks

Director Client Services

Health Care Practice

Tom.Hanks@us.pwcglobal.com

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Privacy Modification Rule - Components

- **Use & Disclosure of PHI**
 - Consent & Notice
 - Authorization
- **Minimum Necessary Provision**
- **Business Associates**
- **Parental Rights**



Privacy Modification Rule - Components

- **Marketing Communications**
- **Research & De-identification**
- **Technical Modifications**
 - Accounting for disclosures
 - Hybrid Entities
 - Sales of covered entities
 - Security/Safeguards



Using And Disclosing PHI – Consent

- **Removes consent requirement for use & disclosure for TPO**
 - Retains right to request restrictions
 - Requires good faith effort to obtain acknowledgement of notice
 - Layered notices preferred



Using And Disclosing PHI – Sharing PHI for TPO

- **Treatment – unlimited between all providers**
- **Payment - between covered entities and non-covered providers**
- **HCO – only between covered entities (limited)**



Using And Disclosing PHI – Authorization

- **Simplifies Authorization**
 - Eliminates special authorizations based on purpose
 - Sets core criteria
 - Sets minimum requirements for informational statements



Using And Disclosing PHI – Authorization (cont'd)

■ Core Criteria

- i. A description of the information to be used or disclosed,*
- ii. The identification of the persons or class of persons authorized to make the use or disclosure of the protected health information,*
- iii. The identification of the persons or class of persons to whom the covered entity is authorized to make the use or disclosure,*



Using And Disclosing PHI – Authorization (cont'd)

- **Core Criteria**

- iv. A description of each purpose of the use or disclosure,*
- v. An expiration date or event,*
- vi. The individual's signature and date, and*
- vii. If signed by a personal representative, a description of his or her authority to act for the individual.*



Using And Disclosing PHI – Authorization (cont'd)

- **Informational statements**

- i. A statement that the individual may revoke the authorization in writing, and either a statement regarding the right to revoke, and instructions on how to exercise such right or, to the extent this information is included in the covered entity's notice, a reference to the notice.*



Using And Disclosing PHI – Authorization (cont'd)

ii. A statement that treatment, payment, enrollment, or eligibility for benefits may not be conditioned on obtaining the authorization if such conditioning is prohibited by the Privacy Rule or, if conditioning is permitted, a statement about the consequences of refusing to sign the authorization,



Using And Disclosing PHI – Authorization (cont'd)

iii. As appropriate, a statement about the potential for the protected health information to be re-disclosed by the recipient. This statement could inform the individual that the information will be disclosed to another covered entity where it would still be protected, or disclosed to a non-covered entity for which protections may not be available under HIPAA. However, if disclosed to an entity that is subject to other privacy laws or privacy policies, those laws and/or policies that may provide further protection may be stated.



Using And Disclosing PHI – Authorization (cont'd)

- **Conditioning payment of claim is no longer allowed**
- **Removes individual's right to revoke in certain circumstances**
- **Prevents requiring an individual to list a purpose for disclosure for their own purposes**



Using And Disclosing PHI – Authorization (cont'd)

- **Disclosing remuneration only required for marketing.**
- **Mandates authorization for all marketing**
- **Clarifies no disclosure of psych notes without authorization**



Minimum Necessary Provision

- **Permits incidental disclosures**
- **Clarifies role-based access**
- **Requires policies & procedures for processing non-routine disclosures**
- **Clarifies MNP does not apply to release of PHI to the individual**



Minimum Necessary Provision – (cont'd)

- **Affirms “reasonable standard”**
 - eliminates the term “reasonably ensure”
- **Clarifies the MNP is intended to be flexible**
 - Facility redesigns & expensive computer upgrades not required
- **Clarifies Sign-in sheets may be OK**



Business Associates

- **Allows BA's to operate under existing contracts until April 14, 2004**
- **Offers sample language for BAC**
- **Oops – maintains the requirements for mitigation**



Parental Rights & Unemancipated Minors

- **Clarifies that state laws govern disclosure of PHI of minors**
 - If laws specifically address the issue
 - If laws leave disclosure to discretion of the provider
- **Establishes a neutral position when parent is not the personal representative or law is silent or unclear**



Marketing Communications

- **Simplifies by removing special marketing provisions**
 - New marketing definition
 - New marketing exclusions
- **Requires authorization for any use of PHI for marketing**



Marketing Communications – (cont'd)

- **Broadens “marketing” definition**
 - i. “to make a communication about a product or service that *encourages* recipients of the communication to purchase or use the product or service”

OR



Marketing Communications – (cont'd)

- ii. “an arrangement between a covered entity and any other entity whereby the covered entity discloses PHI to the other entity, in exchange for direct or indirect remuneration, for the other entity or its affiliate to make a communication about its own product or service that encourages recipients of the communication to purchase or use that product or service”**
- Clarifies that remuneration does not define marketing**



Marketing Communications – (cont'd)

- **Clarifies marketing exceptions**
 - i. Participating providers and health plans in a network, the services offered by a provider, or the benefits covered by a health plan.*



Marketing Communications – (cont'd)

- ii. Individual's treatment*
- iii. Case management or care coordination for that individual, or directions or recommendations for alternative treatments, therapies, health care providers, or settings of care*



Research & De-Identified Information

- **Simplifies IRB/Privacy Board waiver criteria**
 - Aligns with Common Rule
 - Evidence of adequate plans to protect & destroy identifiers & prohibit reuse or re-disclosure
 - Ability to perform research without the waiver



Research & De-Identified Information - (cont'd)

- **Standardizes authorization requirement**
 - Eliminates expiration date
- **Clarifies that research entities can continue to use PHI collected after authorization revocation**
- **Clarifies use of re-identification codes**



Research & De-Identified Information - (cont'd)

- **Consolidates transition period to grandfather prior permissions**
- **Adds limited data set alternative**
 - Prescription number cannot be included in limited data set
 - Includes Dates & Geographic Info (State & Zip)



Research & De-Identified Information - (cont'd)

■ Limited Data Set Excludes

- i. Names;
- ii. Postal address information, other than town or city, State, and zip code;
- iii. Telephone numbers;
- iv. Fax numbers;
- v. Electronic mail addresses;
- vi. Social security numbers;
- vii. Medical record numbers;
- viii. Health plan beneficiary numbers;
- ix. Account numbers;
- x. Certificate/license numbers;
- xi. Vehicle identifiers and serial numbers, including license plate numbers;
- xii. Device identifiers and serial numbers;
- xiii. Web Universal Resource Locators (URLs);
- xiv. Internet Protocol (IP) address numbers; Biometric identifiers, including finger and voice prints; and
- xv. Full face photographic images and any comparable images.



Research & De-Identified Information - (cont'd)

- **Who can use a Limited Data Set**
 - May only be used for the purposes of health care operations, public health and research
 - Not for use between health plans and plan sponsors
 - Requires Data Use Agreement for use of Limited Data Set



Research & De-Identified Information - (cont'd)

- **Terms of Data Use Agreement**
 - i. Not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law;
 - ii. Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement;



Research & De-Identified Information - (cont'd)

- iii. Report to the covered entity any use or disclosure of the information not provided for by its data use agreement of which it becomes aware;
- iv. Ensure that any agents, including a subcontractor, to whom it provides the limited data set agrees to the same restrictions and conditions; and,
- v. Not identify the information or contact the individuals



Accounting for Disclosures

- **Removes requirements to account for disclosures made under authorizations**
- **Excludes uses or disclosures of Limited Data Set**



Hybrid Entities

- **Removes non-covered entity restrictions**
 - Designate covered/non-covered components
 - Create “firewalls”
 - Include components that would be business associates
 - “Firewalls required to protect information in BA components that serve both covered & non-covered components



Hybrid Entities - (cont'd)

- **Excludes health information in covered entities' employment records from PHI**
 - Employment records not limited to specific “physical” files – context based
- **Treats sharing of PHI between covered & non-covered components as it would separate legal entities**



Hybrid Entities - (cont'd)

- **Non-health care components cannot be included in covered components unless act as business associates**
- **Treats sharing of PHI between covered & non-covered components as it would separate legal entities**



Hybrid Entities - (cont'd)

- **Employers, plan sponsors and group health plans cannot be treated as separate components of a hybrid entity**
 - Separate legal entities



Sale of a Covered Entity

- **Allows PHI to be disclosed to the purchasing entity without authorization**



Enrollment Information

- **Clarifies that enrollment information can be shared between a health plan and plan sponsor**



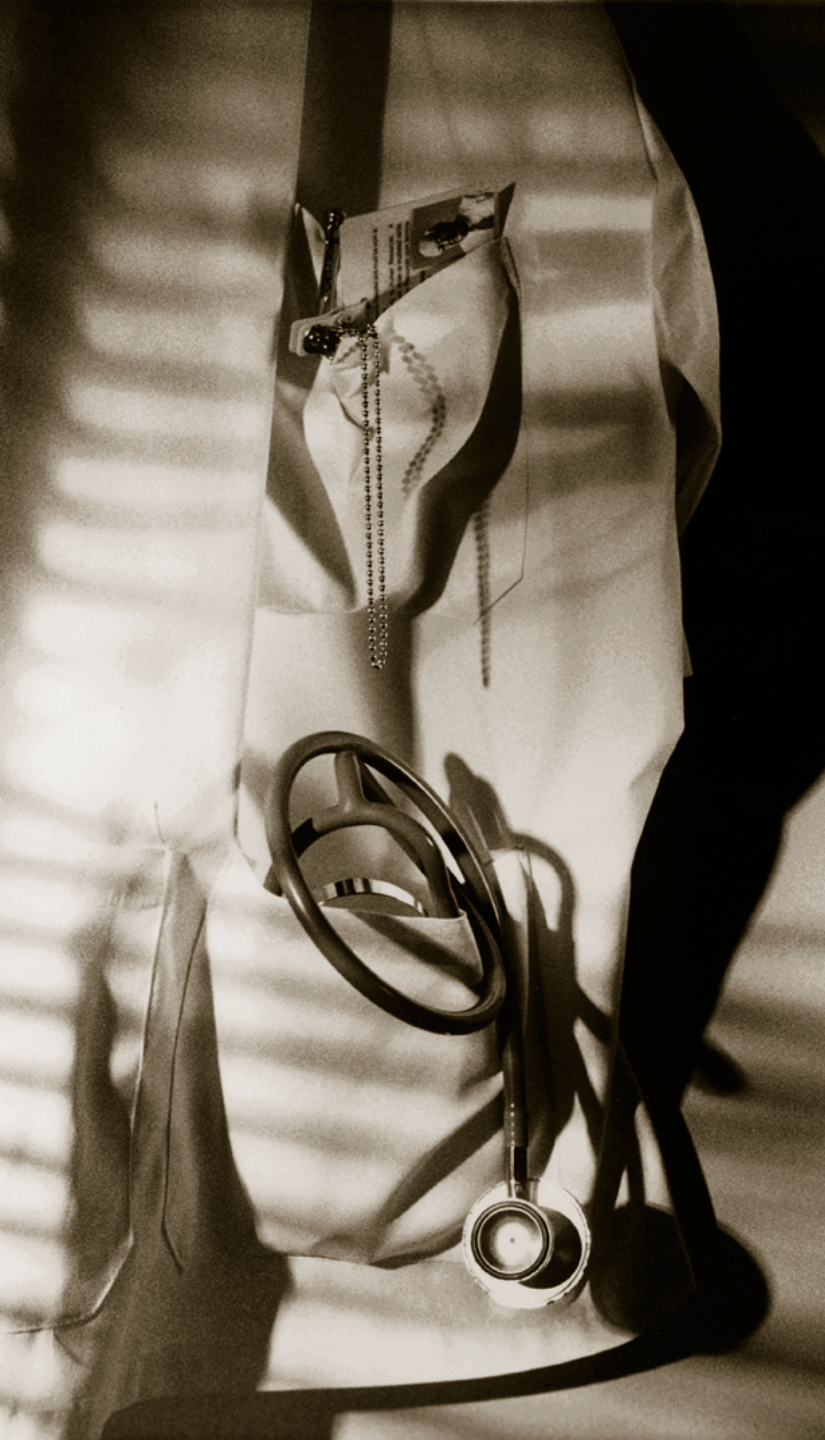
Protects Disclosures to FDA

- **Ensures that covered entities can disclose PHI to FDA**
- **Clarifies that Privacy rule not intended to disrupt flow of information to FDA**



Security and Privacy

- **Clarifies no potential conflict between Privacy & Security rules**
 - Privacy covers all PHI
 - Security only covers PHI maintained or transmitted electronically
- **All safeguards required under Privacy apply regardless of Security rule**



Questions?

Tom Hanks
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Tom.Hanks@us.pwcglobal.com