



United States Department of
Health & Human Services

Office of the Secretary
Office for Civil Rights (OCR)

HIPAA Privacy Rule and Secondary Uses of Health Information

*NCVHS Ad Hoc Workgroup for Secondary Uses of Health
Data*

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Presentation Topics

- Scope of the Ad Hoc Workgroup Inquiry
- HIPAA Goals for Secondary Uses of PHI
- What Are the Secondary Uses and Disclosures of PHI Allowed by HIPAA
- HIPAA Crosswalk to Certain Secondary Uses and Disclosures:
 - Payment
 - Health Care Operations (Quality Indicators)
 - Marketing
 - Research
 - Public Health
- Preemption and State Law; Federal Law



Scope: What is a Secondary Use

- Important to Define the “What”
- What Is a “Primary” Use?
 - Treatment or Direct Care
- What Is a Secondary Use?
 - Everything Else?
 - Only “health related” uses/disclosures? What is the rest?
 - Are there “super” categories of data outside this discussion – ie, public health, required by law?



Scope: Why Revisit Secondary Uses

- Important to Know the “Why”
- HIPAA Privacy Rule Defines Balance Today
 - Is there a workability problem or need for greater clarity that causes us to revisit this issue? If so, is this an issue for all or just a few?
 - Does NHIN provide new pathways or sharing environment that causes us to reassess today’s balances? If so, what is the new functionality and which uses/disclosures are most affected?
- Focus on NHIN Unique Factors to Expedite Process



HIPAA Privacy Rule Overview

Goals for Defining Uses/Disclosures

- HIPAA Privacy Rule Dealt with All
- Different Categories (Not Primary/Secondary)
 - Core Functions: Treatment, Payment, Healthcare Operations
 - Informal Health Care Related Uses and Disclosures
 - Public Policy Uses and Disclosures
 - Individual Authorization
- Goals
 - Individual Control (Choice) Balanced with Need for the Information and Feasibility of Administration
 - Value Neutral on Uses and Disclosures (authorizations required whenever feasible to do so, not because the disclosure was deemed “unworthy” or a “bad” use of the data)



Secondary Uses v. TPO

- HIPAA Permits Use/Disclosure of PHI for TPO without Individual Consent or Authorization
 - Exception: “Marketing” requires authorization
- Treatment: generally classified as “primary” use
- Secondary Uses May Include:
 - Payment
 - Analysis/Quality/Patient Safety Measurement
 - Provider Certification/Accreditation
 - Marketing, other Business or Commercial Use



Payment

- HIPAA Privacy Rule permits uses and disclosures of PHI for payment purposes subject to minimum necessary § 164.506
- Payment includes:
 - Billing, claims management, collection
 - Eligibility and coverage determinations
 - Medical necessity, utilization reviews.



Health Care Operations (1)

- HIPAA Privacy Rule permits uses and disclosures of PHI for the covered entity's own HCOps subject to minimum necessary
§ 164.506
- Permits disclosures for certain HCOps of others if both have relationship with individual and PHI requested pertains to such relationship
§ 164.506(c)(4)



Health Care Operations (2)

- HIPAA Definition of HCOps includes following AMIA secondary uses:
 - Analysis/Quality/Patient Safety Measurement § 164.501 (¶1)
 - Provider Certification/Accreditation § 164.501 (¶2)
- These disclosures may also be permitted as health oversight activities §164.512 (d)



Health Care Operations (3)

- Health Care Ops Definition also includes limited business related operations:
 - ¶ 5 Business planning and development
 - ¶ 6 Business management and general administrative activities
- HIPAA Privacy Rule permits use and disclosure of PHI for these business activities when related to the covered functions of the covered entity



Marketing (1)

- HIPAA Privacy Rule defines Marketing as:
 - Making a communication about a product or service that encourages the purchase or use of such product or service
 - or
 - An arrangement between a CE and another entity where CE discloses PHI to the other entity in exchange for remuneration for that entity to market its products or services to individuals



Marketing (2)

- Marketing Excludes (§ 164.501):
 - A covered entity communicating with individuals about the entity's own health-related products and services
 - Communications related to treatment
 - Communications related to case management, care coordination, or alternative treatments, therapies, care providers or care settings



Marketing (3)

- HIPAA Privacy Rule requires the individual to sign a valid authorization for any use or disclosure of PHI for marketing purposes, with limited exceptions § 164.508(a)(3)
- Authorizations must disclose any remuneration received by the CE in connection with the marketing activity



Secondary Uses v. Public Priorities

- HIPAA Privacy Rule permits use/disclosure of PHI for public priorities without authorization only if the use or disclosure comes within one of the listed exceptions and follows its conditions.
- Secondary Uses/Disclosures may include:
 - Research
 - Public Health

§164.512



Research (1)

- The HIPAA Privacy Rule permits the use or disclosure of PHI for research purposes as follows:
 - with individual authorization (§ 164.508)
 - with IRB or Privacy Board waiver of authorization (§ 164.512(i)), or
 - in limited circumstances, without either individual authorization or IRB/PB waiver of authorization (§§164.512(i)(1)(ii)-(iii), 164.514(a)-(c), 164.514(e))



Research (2)

- *Research With Patient Permission*

HIPAA authorization requirements intended to align with Informed Consent process

- May be combined with informed consent
- May be no expiration date or event or may continue until “end of research study”
- Can condition provision of research-related treatment
- Individual has right to revoke, except to extent Covered Entity already acted in reliance
 - Not required to retrieve PHI already disclosed
 - Limited continued use of PHI allowed to protect integrity of research, e.g., to account for individual’s withdrawal from study



Research (3)

- *Research With a Waiver of Authorization*

Obtain documentation that an independent, neutral arbiter (i.e., IRB or Privacy Board) has approved alteration to or waiver of authorization based on 3 waiver criteria (adapted from Common Rule):

- The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals
- The research could not practicably be conducted without the alteration or waiver
- The research could not practicably be conducted without access to and use of the PHI



Research (4)

- *Research Without Patient Permission or Waiver*
 - Preparatory to research;
 - Research on decedents; or
 - Limited data set
 - Only use or disclose limited data set/“indirect identifiers” (e.g., zip codes, dates of service, age, death)
 - Requires data use agreement
 - Intended to be consistent with information that is not “personally identifiable information” under the Common Rule and thus, allows researchers access to same level of information without IRB review



Public Health Activities (1)

- HIPAA Privacy Rule permits use or disclosure of PHI for Public Health (§ 164.512(b))
 - To Public Health Agency for public health activities
 - To FDA or persons subject to FDA jurisdiction
 - To report child abuse or neglect to appropriate authorities
 - To persons at risk of exposure to communicable diseases
 - To employer for workforce surveillance activities
- Minimum necessary applies to public health uses and disclosures



Public Health Activities (2)

- Some public health disclosures may also be permitted as required by law (§ 164.512(a)); minimum necessary does not apply to disclosures required by other law
- If “public health” is taken off list of secondary uses and disclosures because of overriding need for data, consider:
 - Only those disclosures “required by law”
 - What constitutes “public health”
 - Public recipient of data or private partners as well



Secondary Uses v. Other Non-direct Care Disclosures

- HIPAA permits the use or disclosure of PHI for the following purposes without patient permission:
 - As required by other law (§ 164.512(a))
 - Disclosures about victims of abuse, neglect or domestic violence (§ 164.512(c))
 - Uses and disclosures for health oversight activities ((§ 164.512(d))
 - Uses and disclosures about decedents (§ 164.512(g))
 - Uses and disclosures for cadaveric organ, eye, tissue donation (§ 164.512(h))



Secondary Uses v. Other Permissible Disclosures

- HIPAA permits the use or disclosure of PHI to third parties for the following purposes (not related to care) without patient permission:
 - Disclosures for judicial and administrative proceedings (§ 164.512(e))
 - Uses and disclosures to law enforcement (§ 164.512(f))
 - Uses and disclosures to avert a serious, imminent threat to health or safety (§ 164.512(j))
 - Uses and disclosures for specialized governmental functions (§ 164.512(k))
 - Uses and disclosures for workers' compensation purposes (§ 164.512(l))
- Minimum necessary applies, except where required by law



Preemption and State Law

- HIPAA Preempts Contrary State Law
 - Except where State law is “More Stringent” that is, more protective of privacy
 - Need to consider State law requirements on when health data may be disclosed, particularly in specialized areas such as mental health, procreation, substance abuse, HIV, etc.
- HIPAA Permits Disclosures Required by State Law
- HIPAA May Refer to State Law for Other Permissions
 - Determination of parent/minor rights and access



HIPAA and Other Federal Law

- HIPAA Does Not Supersede Other Federal Law
 - 42 CFR Part 2
 - Privacy Act/FOIA
 - FERPA
 - CLIA
 - ADA
 - ERISA
- HIPAA Permits Disclosures Required by Federal Law



OCR Web Site

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