ARNOLD & PORTER LLP

CONFIDENTIALITY COALITION

The HIPAA Privacy Rule and Research: *Tensions and Innovations*

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Overview

- Confidentiality Coalition
  - Mission
  - Members
- New Research Initiatives
- The HIPAA Privacy Rule and Proposed Changes to the Common Rule

Confidentiality Coalition

- A broad group of organizations working to ensure that we as a nation find the right balance between the protection of confidential health information and the efficient and interoperable systems needed to provide the very best quality of care.

Members

Aetna
America's Health Insurance Plans
American Hospital Association
American Pharmacists Association
American Society for Radiation Oncology
AmerisourceBergen
Amgen
AMN Healthcare
Anthem
Ascension
Association of American Medical Colleges
Association of Clinical Research Organizations
athenahealth
Augmedix
Baylor Scott & White Health
Bio-Reference Laboratories
Blue Cross Blue Shield Association
BlueCross BlueShield of Tennessee
Boehringer Ingelheim
C.R. Bard
Cardinal Health
Change Healthcare
Cigna
Cleveland Clinic
College of American Pathologists
Cotiviti
CVS Health
Eli Lilly and Company
Express Scripts
Federation of American Hospitals
Franciscan Missionaries of Our Lady Health System
Genetic Alliance
Golden Living
Health Information Trust Alliance
Healthcare Leadership Council
IMS Health
Indiana University Health
Intermountain Healthcare
Johnson & Johnson
Kaiser Permanente
Leidos
Marshfield Clinic Health System
Maxim Healthcare Services
Mayo Clinic
McKesson Corporation
Medical Group Management Association
Medtronic
MemorialCare Health System
Merck
MetLife
National Association of Chain Drug Stores
National Association of Psychiatric Health Systems
NewYork-Presbyterian Hospital
NorthShore University HealthSystem
Novartis Pharmaceuticals
Novo Nordisk
Owens & Minor
Pfizer
Pharmaceutical Care Management Association
Premier healthcare alliance
Privacy Analytics
Quest Diagnostics Incorporated
Sanofi US
SCAN Health Plan
Select Medical
State Farm
Stryker
Surescripts
Takeda Pharmaceuticals
Texas Health Resources
Teladoc
TransUnion
VHA
Walgreens
Weight Watchers International
Workgroup for Electronic Data Interchange
ZS Associates

The Landscape for Research

- New data-driven era of healthcare
- New sources of data
- New abilities to aggregate data
- New consumer expectations of innovation
- **Rules and regulations have not caught up**

Precision Medicine Initiative

- Building a national research cohort of one million or more U.S. participants
- “Policies will need to be developed to address participant inclusion; Institutional Review Board (IRB) review and consent; privacy, misuse of information, and security; sharing of data and specimens with researchers; and sharing of data and research results with participants.”

- PMI Working Group Report to NIH

Cancer Moonshot Initiative

- $1 billion initiative from the White House
- “The cancer initiative will encourage data sharing and support the development of new tools to leverage knowledge about genomic abnormalities, as well as the response to treatment and long-term outcomes.”

CMS Data Releases

- Allowing the use of huge amounts of data for research
- Significant restrictions
- Needs uniform approach with other agencies

Multiple Overlapping Regulations

- HIPAA Privacy Rule
- HITECH Act
- The Privacy Act of 1974
- CLIA
- HHS meaningful use regulations
- FDA genomic tech framework
- FDA medical device regulations
- The Common Rule
- NIH grant, data-sharing and dissemination policies
- State laws as applicable

The HIPAA Privacy Rule and Proposed Changes to the Common Rule

HIPAA Privacy Rule Provisions Relevant to Research

HIPAA: Protected Information

- The HIPAA Privacy Rule governs uses and disclosures of "protected health information" ("PHI"), *i.e*:
  - Health-related Information in any form
  - Created, received, or maintained by a HIPAA covered entity, *and*
  - Identifies or reasonably could be used to identify an individual

- Examples of PHI:

  - Blood sample with donor's initials
  - Tissue specimen with donor's date of birth

How Can PHI Be "De-Identified"?

- PHI will be deemed "de-identified" and thus categorically no longer PHI if either:
  - It is stripped of all of 18 individual identifiers *and* there is no actual knowledge that the resulting information could be used alone or in combination with other information to identify an individual, *or*
  - A qualified statistician has certified that the information cannot reasonably be used to identify an individual.

Use and Disclosure of PHI for Research

- General Rule: Covered entities must obtain an individual's authorization to use or disclose PHI for research purposes.
- Exceptions:
  - If an IRB or Privacy Board waives the authorization requirement
  - For reviews preparatory to research
  - For research on decedents' PHI
  - If the PHI constitutes a "limited data set"
- An IRB or Privacy Board waiver is permissible only if:
  - Research use or disclosure of PHI involves no more than minimal risk to privacy
  - Research could not be conducted practicably without waiver

Individual Authorizations for Research

- Must comply with general authorization requirements, but:
  - May be combined with study Informed Consent
  - May state that there is no expiration date or event, or that authorization continues until the end of the research study.
  - May state that access by individual to PHI will be denied during study.
- Must specify the study for which the PHI will be used or disclosed – cannot contain open-ended authorizations (*e.g.*, *"…* and for other research purposes" is not acceptable).
- ***But, to align with Common Rule,*** may cover non-study-specific future research so long as the authorization is sufficiently descriptive such that it would be reasonable for the individual to expect that his or her PHI could be used or disclosed for such future research.

Common Rule Coverage and Proposed Privacy-Related Changes

Scope of HIPAA Privacy Rule and Common Rule

HIPAA Privacy Rule

- Applies only to HIPAA covered entities and their business associates
- Exclusively focuses on protection of PHI

Common Rule

- Applies to researchers conducting studies for or with support from federal agencies
- Protects safety and privacy rights of human research subjects

Common Rule: Current Data Protection Scope

- Governs research involving *human subjects*
- "Human subject": a living individual about whom an investigator (whether professional or student) conducting research obtains:
  - Data through intervention or interaction with the individual, or
  - *Identifiable private information*.
- "Identifiable private information"
  - Information provided for specific purposes by an individual who can reasonably expect the information will not be made public,

  if
  - "the identity of the subject is or may readily be (i) ascertained by the investigator or (ii) associated with the information."

Major Proposed Change to the Common Rule

- Extend coverage to research involving *non-identified biospecimens*
- Redefine “human subject” to mean:
  - A living individual about whom an investigator obtains, uses, studies, or analyzes:
    - Data through intervention or interaction with the individual,
    - Identifiable private information, or
    - ***Biospecimens***.

Proposed Regulation of Biospecimen Collection, Storage and Use

- Require informed consent for research involving biospecimens, *regardless of identifiability*
  - Very limited exceptions, *e.g.*:
    - If IRB waives consent
    - If research will generate only confirming, not previously unknown, information
- Permit "broad" informed consent for use of biospecimens collected for certain research or non-research purposes

Proposed Requirements for Broad Informed Consents for Secondary Research

- Informed consents to storage of biospecimens or identifiable private information and use of those biospecimens/information for secondary research must state, *inter alia*:
  - the types of secondary research that may be conducted and the information that is expected to be generated from the research
  - who might conduct the secondary research
  - the period of time during which biospecimens or information will be collected (may not exceed 10 years from date of consent)
  - the period of time during which an investigator may continue to use the biospecimens/information for secondary research
  - that participation is voluntary and consent may be withdrawn at any time, but that information or biospecimens already distributed for research use may not be retrieved if consent is withdrawn

New Proposed Security Requirements

- Institutions and investigators involving collection, storage or use of biospecimens or identifiable private information must implement protective safeguards to prevent:
  - Anticipated threats or hazards to security
  - Impermissible use, release or disclosure
- Acceptable safeguards:
  - Measures to be detailed by HHS, *or*
  - Safeguards that meet the standards of the HIPAA Security Rule

Industry Reaction

- NPRM on Federal Policy for Protection of Human Subjects
- Need for harmonization of federal and state laws
- Applaud recent approaches to achieve consent for research

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Questions?

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