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CONFIDENTIALITY COALITION

HIPAA Privacy and Medical Research: *Opportunities and Challenges*

March 30, 2017

Nancy L. Perkins, MPP, JD
Counsel, Arnold & Porter Kaye Scholer LLP
Washington, D.C.

Tina Olson Grande, MHS
Chair, Confidentiality Coalition
SVP, Healthcare Leadership Council

Overview

- Confidentiality Coalition Mission & Members
- HIPAA Privacy Rule Research Provisions
- 21st Century Cures Act HIPAA Provisions
- Precision Medicine Initiative
- Common Rule HIPAA-Related Changes
- Confidentiality of Substance Abuse Records

The Confidentiality Coalition, convened by the Healthcare Leadership Council (HLC), is a broad group of organizations working to ensure that policymakers balance appropriately the protection of confidential health information with the efficient and interoperable systems needed to provide high quality care.

We advocate for policies and practices that safeguard the privacy of patients and healthcare consumers while, at the same time, supporting policies that enable the essential flow of patient information that is critical to the timely and effective delivery of healthcare. Timely and accurate patient information leads to both improvements in quality and safety and the development of new lifesaving and life-enhancing medical interventions.

Confidentiality Coalition 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
Baxter
Bio-Reference Laboratories
Blue Cross Blue Shield Association
BlueCross BlueShield of Tennessee
Bristol-Myers Squibb
C.R. Bard
Cardinal Health
Change Healthcare
Cigna
Cleveland Clinic
College of American Pathologists
Cotiviti'
CVS Health
dEpid/dt Consulting Inc.
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
Intermountain Healthcare
Johnson & Johnson
Kaiser Permanente
Leidos
Mallinckrodt Pharmaceuticals
Marshfield Clinic Health System
Maxim Healthcare Services
Mayo Clinic
McKesson Corporation
Medical Group Management Association
Medidata
Medtronic
MemorialCare Health System
Merck
MetLife
National Association of Chain Drug Stores
National Association of Psychiatric Health Systems
Nestlé Health Science
NewYork-Presbyterian Hospital
NorthShore University HealthSystem
Novartis Pharmaceuticals
Novo Nordisk
Pfizer
Pharmaceutical Care Management Association
Premier healthcare alliance
Privacy Analytics
QuintilesIMS
Sanofi US
SCAN Health Plan
Select Medical
State Farm
Stryker
Surescripts
Takeda Pharmaceuticals
Texas Health Resources
Teladoc
TransUnion
Vizient
Walgreens
Workgroup for Electronic Data Interchange
ZS Associates

HIPAA Privacy Rule Provisions Relevant to Research

Scope of HIPAA Regulation of Research

- The HIPAA Privacy Rule restricts uses and disclosures of "protected health information" ("PHI") for research
- "Research" means "a systematic investigation . . . designed to develop or contribute to *generalizable knowledge*
- PHI in the research context includes, *e.g.*:
  - Blood sample with donor's initials
  - Tissue specimen with donor's date of birth

"De-Identifying" Health Information for Research

- Two methods to de-identify health information (to make it no longer PHI):
  - Remove all of 18 individual identifiers, *or*
  - Rely on a qualified statistician to certify that the information cannot reasonably be used to identify an individual.
- NCVHS now questions these de-identification methods and recommends:
  - More stringent controls to prevent re-identification
  - Tracking disclosures of de-identified data
  - Imposing privacy-related responsibilities on recipients of de-identified data sets

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.

21st Century Cures Act
HIPAA-Related Provisions

Streamlining Research Authorizations

- Requires HHS to issue guidance on authorizations for use and/or disclosure of PHI for future research
  - How much needs to be said about the type of future research?

- HHS must also clarify whether individuals who signed authorizations for use and/or disclose of their PHI for research are entitled to *annual notices* of their right to revoke the authorization.

Reviews of PHI Preparatory to Research

- Requires HHS to issue guidance clarifying that, under the HIPAA Privacy Rule, researchers may be granted remote access to electronic "protected health information" (PHI) to conduct reviews preparatory to research, provided the researcher:
  - keeps the PHI secure
  - makes no copies, and
  - does not otherwise retain it.
- This guidance is consistent with HHS's current interpretation of the "preparatory to research" exception to the general requirement for an individual authorization to disclose PHI

Working Group on PHI in Research

- Requires HHS to convene a working group to study and issue a report, within one year, on the use of PHI for research purposes within the constraints of the HIPAA Privacy Rule.
- The working group must include representatives from:
  - NIH, CDC, FDA, and the HHS OCR
  - The research and patient communities
  - Experts in privacy rights, date security, and HIT
  - Health care providers; bioethists
- The report must address, among other things, the rights of individuals to authorize or preclude the use of their PHI for research, and the manner and timing of such authorizations
- The report must be submitted to Congress and made public

Privacy Under the Precision Medicine Initiative

- HHS must issue certificates of confidentiality to researchers engaged in federally funded research involving subjects' identifiable, sensitive information
- "Identifiable, sensitive information" is information:
  - identifiable to an individual, or
  - for which there is at least a "very small risk" that the information combined with other available data sources could be used to deduce the identity of an individual
- The certificates will prohibit the researcher from disclosing the sensitive information to anyone not connected to the research (with very limited exceptions)

Precision Medicine Update

- Recently released Precision Medicine Initiative (PMI) Data Security Principles Implementation Guide
- President's proposed budget **calls for a $5.8 billion cut** to the NIH in 2018, representing the largest chunk of the $15 billion reduction to the entire Department of Health and Human Services.

HIPAA Privacy-Related Changes to Federal Common Rule

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

Proposed Common Rule Changes
WITHDRAWN

- Extend Common Rule coverage to research involving *non-identified biospecimens*
- Require new security safeguards to protect biospecimens or identifiable private information from:
  - Anticipated threats or hazards to security
  - Impermissible use, release or disclosure
- Make it harder to obtain a waiver of the Common Rule requirements for obtaining consent for use and disclosure of identifiable biospecimens

Approved Common Rule Changes

- Periodically assess new technologies that may make unidentified biospecimens identifiable
- Exempt from Common Rule's coverage secondary research that involves only activities that, under the HIPAA Privacy Rule, are either:
  - Research, or
  - Health care operations
- Permit obtaining a broad, one-time consent to the gathering, storing, and use of identifiable specimens and other identifiable private information for secondary research (subject to certain conditions)

42 CFR Part II

- Confidentiality of Alcohol And Drug Abuse Patient Records
- Lack of alignment with HIPAA has long been problematic
  - Opioid epidemic
  - Alternative payment models
- Long-awaited SAMHSA final rule took some steps to modernize Part 2 but did not go far enough

42 CFR Part II Action

- Legislative action is necessary to modify Part 2 and bring the sharing of substance use records into the 21st century.
- Partnership To Amend 42 CFR Part 2: *A coalition of over 20 health care stakeholders committed to aligning 42 CFR part 2 (part 2) with HIPAA to allow appropriate access to patient information that is essential for providing whole-person care.*

Questions?

Nancy L. Perkins
Arnold & Porter Kaye Scholer LLP
601 Massachusetts Ave., NW
Washington, DC 20001
Nancy.Perkins@apks.com
www.apks.com

Tina Olson Grande
Chair, Confidentiality Coalition
750 9th Street, NW, Suite 500
Washington, DC 20001
tgrande@hlc.org
www.confidentialitycoalition.org