C-Change Progress on HIPAA: webinar

July 17, 2013
Webinar Logistics

• This webinar will be recorded and available through C-Changetogether.org website tomorrow and

• The Q&A session will occur at the end. Please submit your questions via the questions function.
Research

#1. Promoting Clinical Trials
- Too many dying
- 2.3% in clinical trials
- Groups under-represented

- Access to trials
- Diversity in trials
- Therapies...
- Longer lives
- Privacy protected

Clinical Trials Guidance

Policy Focus

- What's next?
- HIPAA
  - IOM
  - No protection for people
  - Not helpful for promoting research

Analysis...

LAW

How can we change the law?
Options for change

Collaboration with I.U.

ARRA grant

Change

How law needs to change
Legislative fix

LAW - Draft Model Legislation

LAW - Draft Model Legislation

Regulations
January 2013
Stanley Crosley, JD

- Co-Chair of Research Advisory Committee
- Director of Indiana University Center for Law, Ethics and Applied Research (CLEAR)
- Principal in Crosley Law Offices, LLC
Melissa Bianchi, JD

- Partner, Hogan Lovells
- Expertise includes the HIPAA and HITECH regulations
Roy Jensen, MD

- Co-chair of Research Advisory Committee
- Director of the University of Kansas Cancer Center
- Research focus: BRCA1 gene in the growth control of normal and malignant cells
C-Change Actions to Date

• Articulated the problem through the report “The Costs of HIPAA”

• Advocated for change
  – Comments to HHS
  – Draft legislation
C-Change Actions to Date

- Consistent messages in comments to HHS
  - Accounting for disclosures under HITECH
  - Modifications to the HIPAA Privacy, Security, and Enforcement Rules Under HITECH
  - PCAST report: Realizing the full potential of HIT
  - Advanced Notice for Proposed Rulemaking on Human Subjects Research Protections
Melissa Bianchi, JD

- Partner, Hogan Lovells
- Expertise includes the HIPAA and HITECH regulations
Under HIPAA, may use PHI for research with:

- an individual’s written authorization
  - Must be study-specific
  - No compound authorizations
  - May not authorize future unspecified research

- a waiver of authorization by an Institutional Review Board ("IRB") or privacy board,
- a data use agreement regarding a limited data set,
- de-identified information
- a certification for data reviews preparatory to research, or
- special provisions for research using decedent’s information.
Major changes in the HITECH final rule

- Study-specific limitation/future unspecified research
- Compound authorizations
Research: Study-Specific Limitation

- HHS prior position = research authorizations may not authorize future unspecified research
- The Privacy Rule requires authorizations to describe the “purpose” of the requested use and disclosure. Historically, HHS has interpreted this as requiring study-specific descriptions of the purpose, and prohibiting authorization for use or disclosure of PHI for future, unspecified research.
New approach to describing future research

• HITECH Final Rule modifies HHS’s prior position:
  – As of March 26, 2013, a HIPAA authorization may permit future research if the authorization adequately describes the future research such that it would be reasonable for the individual to expect that his/her PHI could be used or disclosed for that purpose.
  – Certain ongoing studies grandfathered
Research: Compound Authorization

- The Privacy Rule prohibits compound authorization for use/disclosure of PHI that authorizes (i) research activities for which treatment is conditioned on signing the authorization ("conditioned") and (ii) research activities for which treatment is not conditioned on signing the authorization ("unconditioned").

- **Under old interpretation, a clinical trial associated with corollary research activities (e.g. biospecimen banking), required separate authorizations for the clinical trial participation (conditioned authorization) and participation in the corollary activity (unconditioned authorization).**
New approach to compound authorizations

• The Final Rule permits such compound authorizations for research purposes provided:
  – (1) the authorization clearly differentiates between the conditioned and unconditioned research components;
  – (2) the authorization provides a clear opportunity for individuals to opt-in to the unconditioned component; and
  – (3) the research does not involve psychotherapy notes
What does this mean for research?

• Significant change in interpretation provides greater flexibility to conduct research
• Removes some of the road blocks for research
  – Important for researchers, study sponsors
  – C-Change advocated for these changes to the authorization process
What are covered entities doing now?

- Revising template HIPAA research authorizations to permit future research
- Considering compound authorizations for protocols involving multiple research activities (e.g., investigational treatment and tissue banking of specimens)
- Amending policies and procedures for implementing requests to revoke authorization
- Reviewing ongoing studies that involve the possibility of future research to determine eligibility for grandfather status
De-Identification

- HITECH Final Rule does not change the HIPAA de-identification standard
- September 2012 guidance document providing more information about de-identification
Sale of PHI

- Sale of PHI: disclosure of PHI by a covered entity (CE) or business associate (BA), where the CE or BA directly or indirectly receives remuneration from or on behalf of the recipient of the PHI in exchange for the PHI
- Several exceptions, including disclosures for:
  - Research (allows a reasonable cost-based fee to cover the cost to prepare and transmit data)
  - Public Health (costs not limited to cost-based fee)
  - Grants, contracts, other similar arrangements
    - Example: Grant funding from government that requires CE to report PHI for program oversight ≠ Sale of PHI
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*Associated offices
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Proposed Next Steps

1. Develop and promote the following best practice documents that should be endorsed by organizations both inside and outside of cancer:
   – Common language and standards for consent forms, including their use
   – Standards for research incorporating the new rules, including those related to data repositories
Proposed Next Steps

2. Monitor implementation of research related components of the new rule, assess if the changes ultimately are having the intended positive impact on clinical outcomes, and ascertain problems in implementation as they arise

- Request feedback from: AACI, AACR, ASCO, USCAP, CAP and similar orgs
Proposed Next Steps

• C-Change will re-assess the decision to advocate for these issues in the future if necessary
Questions

• Please ask your questions using the question function
Thank You

• Please complete the evaluation!

• This webinar is recorded and will be available tomorrow through www.c-changetogether.org and on 🌐/twitter/facebook.

• If you have additional questions, please email pshah@c-changetogether.org.