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Fourth National HIPAA Summit
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Implementation of a HIPAA Data Management Strategy

Safeguarding privacy interests while
making data available for
research, public health and
health care operations

Hogan & Hartson, L.L.P.

American Hospital Association

Session Overview

- Research Uses of Data--Donna A. Boswell, Hogan & Hartson, L.L.P.
- The “De-identification Safe Harbor” -- Marcy Wilder, Hogan & Hartson, L.L.P.
- Hospitals’ Shared Health Care Operations -- Melinda Hatton, American Hospital Association
- The Business Associate Approach to Shared Health Care Operations --Melissa B. Levine, Hogan & Hartson, L.L.P.
- IRB waiver of authorization for Research and Public Health Analysis -- Bartley Barefoot, Hogan & Hartson, L.L.P.
- Panel Discussion of a new safe harbor: The Data Use Agreement for Public Health, Research, and Health Care Operations

Research Uses of Data

Donna A. Boswell

- The public interest in--
 - epidemiologic analyses and registries
 - outcomes research
- Patient identity is not needed by researcher
 - dates, geographical, and health information are needed but not direct identifiers
 - case codes to create longitudinal and cross-situational data sets are needed

A Balancing of Interests

- Measures that promote research but fail to protect the privacy interests of individuals do not serve the public interest because they undermine public trust in the motives of the research community.
- Measures that protect privacy interests by creating too much potential liability or cost for providers do not serve the public interest because they create disincentives for the public to support research.

The “De-identification Safe Harbor”

Marcy Wilder

- The “de-identification safe harbor”--
 - assumes widespread, unsupervised use and distribution of “de-identified” data -- including use in activities designed to identify and target data subjects.
 - was not intended to be used for research, public health or health care operations.
- The 18 “identifiers” are the criteria that, in today’s world, would be used by a database jockey in attempting to identify individuals.

The Safe Harbor Does Not Work For Research or Public Health Uses

- The statistical alternative to safe harbor allows a covered entity to estimate and assume the risk of potential unauthorized use from release of a data set with some of the identifiers on the safe harbor list.
- A statistician is unlikely to be able to make the certification of “very low probability” so long as the fields needed by public health and research entities, e.g., birth date and zip code, are included.
- The uncertainty regarding the liability of a covered entity where the de-identification process is allegedly defective, makes it unlikely that researchers could rely on this method in asking covered entities to contribute data to the large data sets necessary for research and public health purposes.

Shared Health Care Operations

Melinda Hatton

Data pooled from multiple providers in a region is necessary for--

- Using others' experience to "benchmark" one's own performance for self-study and goal setting in
 - financial collections and administration
 - reducing dependence on public payers
 - improving the quality of care
- Community health planning
 - determining unmet community health needs
 - developing business plans to make efficient use of health care resources.

Excess Liability or Cost of Data Analysis Activities for Covered Entities ...

- Is not an appropriate balancing of the public interest in high quality, efficient care and the privacy interests of individual patients
- Shifts dollars from patient care to administrative concerns
- Creates disincentives to develop community planning initiatives and shared quality improvement initiatives.

The Business Associate Approach

Melissa B. Levine

- The rule permits CEs to each contract separately with a BA to aggregate PHI
- The BA that they have in common can use the PHI from all of the participating CEs to do analyses for the health care operations of the participating CEs
- However, the reports available to each CE cannot include any PHI from another CE.

Why BA Agreements Fail to Provide the Appropriate Balance for Health Care Operations...

- The need for a third party to do all analyses makes it too costly--
 - No pooling of data permitted by CEs without a third party: Can one CE be the BA of all others
 - Patient specific data that includes the “suspect” fields is PHI
 - No disclosure of PHI to another covered entity (even under the NPRM such disclosure is extremely limited)

Waiver of authorization for Research and Public Health Analysis

Bartley Barefoot


- Individual authorization for research use of PHI, unless waived by an IRB or privacy board.
- Waiver of authorization
 - is based on subjective criteria
 - must be documented as prescribed by the regulation to show that the CE verified that the criteria have been met.
 - must be annotated with respect to each record made available in order for the CE to be able to provide the data subject with an “accounting” of disclosures.

Why Waiver of Authorization Does Not Provide an Appropriate Balance for Research and Public Health

- Public health analyses, such as those used in epidemiology or for identifying exposure to a pathogen such as anthrax, need large data sets compiled from multiple sources.
- The need to obtain multiple waivers of authorization, and the need for each CE to be satisfied that the “minimum necessary” data are being made available, may introduce corruption into the data set, as well as excess cost.

The Need for a New Safe Harbor Panel and Audience Discussion

- A data use agreement imposing obligations on the recipient regarding appropriate use of the data only for public health, research, and health care operations and not in activities to identify or contact data subjects.
- A requirement that the CE arrange for deletion of “direct identifiers” to protect the privacy of individuals while the data are in routine, authorized use.

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Proposal for a Safe Harbor

Data Use Agreement governing use
of a “Limited Data Set”

plus

Creation of Limited Use Data Set by
stripping Direct Identifiers

In a Data Use Agreement, the recipient must agree ...

- To use the Limited Data Set only for public health, research and health care operations
- Not to use the data to identify or contact data subjects
- To arrange for secure, supervised use of the data, and not to disclose or transfer the data for other purposes.

A Limited Data Set could be ...

- Any set of PHI stripped of “direct identifiers”
- “Direct identifiers” are --
 - name
 - street address
 - email address
 - telephone number
 - fax number
 - certificate/license #s
 - social security number
 - vehicle IDs/serial #s
 - Web URLs
 - IP addresses
 - Full face photos

Implementation Issues: The Data Use Agreement Safe Harbor...

- Is a proposal for discussion only
- HHS requested comments in the preamble to the NPRM
- May or may not be adopted in the final rule
- If it is not established by HHS in the August final rule--
 - CEs, researchers and public health personnel will need to be prepared to bear the costs and limitations of using BAs and IRB waivers if the quality and efficiency of our health care system is not to be compromised by the rule's prohibitions and limitations on use of data for health care operations, research and public health analyses.

HOGAN & HARTSON, L.L.P.



555 13th Street NW
Washington, DC 20004
202-637-5600