Health Law Advisory: New Proposed HIPAA Rules May Benefit Researchers

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On July 8, 2010, the Department of Health and Human Services (HHS) published proposed modifications to the Health Insurance Portability and Accountability Act (HIPAA) Privacy, Security and Enforcement Rules (the Proposed Rules) implementing the Health Information Technology for Economic and Clinical Health Act (HITECH) provisions of the American Recovery and Reinvestment Act of 2009.

The purpose of the Proposed Rules is to strengthen the privacy and security of protected health information (PHI) and to clarify the HIPAA rules, but they also contain two key provisions of particular interest to researchers. The adoption of one provision would permit authorizations for future, unspecified research; the other would permit compound authorizations for research-related uses and disclosures of PHI. HHS collaborated with the Office for Human Research Protections (OHRP) to develop the research proposals and will coordinate any changes with the Food and Drug Administration (FDA).

Authorizations for Future Research

The first proposal has the potential to facilitate secondary research and improve the utility of research databases and repositories. HIPAA does not permit blanket authorizations for unspecified future research because of the concern that a patient would lack the specific information necessary for an informed decision about future use of his or her PHI. As a result, HHS has interpreted the current HIPAA privacy rule to require that authorization for research be study specific, which could include authorization of the use of PHI to create a tissue repository. However, each future use of PHI from the repository could require a separate authorization if a waiver for that use could not be obtained from an institutional review board or privacy board.

Researchers have expressed concern to HHS that the current regulatory scheme encumbers secondary research and requires patients to be repeatedly contacted for additional studies—even for future studies targeting the same disease as the original study.

In the Proposed Rules, HHS did not suggest specific modifications to the prohibition on future research, but instead solicited comments on several options. The options and issues being considered include permitting:

1. an authorization for future uses that adequately informs the individual that his or her PHI could be used in the future and that adequately describes the potential uses;

2. an authorization for future research only to the extent the description of the future research included certain elements or statements specified by the privacy rule; or
3. the first option as a general rule, but requiring certain disclosure statements in cases where the future research could encompass sensitive research activities, such as genetic analyses or mental health research.

In addition to comments on these options, HHS invited other proposals to address the issue.

Compound Authorizations

HIPAA generally prohibits "compound authorizations" or authorizations for the use or disclosure of PHI that are coupled with any other legal permission. In particular, HIPAA prohibits a Covered Entity from combining an authorization that conditions the receipt of treatment (i.e., no authorization/no treatment) with an authorization that is not so conditioned (no change in the treatment or benefits for a patient who elects to not sign).

HIPAA, nevertheless, allows researchers to use compound authorizations in some circumstances. For example, researchers may combine a research-related authorization with another written permission for a study—such as a consent to participate. However, this exception does not permit a researcher to combine a treatment-conditioned authorization with a non-conditioned authorization. This prohibition has created problems for some researchers. For example, researchers cannot combine a tissue banking authorization with an authorization necessary for study-related treatment.

HHS is proposing to amend HIPAA to permit the combination of conditioned and non-conditioned authorizations for research. In addition to seeking comments on this proposed change, HHS is seeking comments on structure and formatting changes that would support research participant understanding.

Comments will be accepted by the Office of Civil Rights until September 13, 2010.

For assistance in this area please contact one of the attorneys listed below or any member of your Mintz Levin client service team.

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