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Analysis of Final HIPAA Omnibus Rule: Research, GINA, Hybrid Entities and Other Miscellaneous Provisions

This is the seventh in a series of publications analyzing the changes of the HIPAA omnibus rule (Final Rule) released January 17, 2013, and published January 25, 2013 (78 Fed. Reg. 5566). The Final Rule adopts many of the proposed changes and made some additional modifications related to research, genetic information, hybrid entities, deceased individuals and immunizations.

Research

The Final Rule creates an exception to the general prohibition on compound authorizations, and permits a covered entity to combine conditioned authorizations for research (i.e. authorizations that condition the provision of research-related treatment on obtaining an authorization to disclose personal health information (PHI) for research purposes) and unconditioned authorizations for research, provided the authorization clearly differentiates between the conditioned and unconditioned research components, and allows the individual to opt in to the unconditioned research activities.

Covered entities are also permitted to do the following with respect to research authorizations:

- Describe the unconditioned research activity on a separate page of a compound authorization, and cross-reference relevant sections of a compound authorization to minimize the potential for redundant language; and
- Use a separate checkbox to signify that an individual has opted in to the unconditioned research activity using one signature line for the authorization, or in the alternative provide a distinct signature line for the unconditioned authorization.

The Department of Health and Human Services (HHS) also noted in the comments that their previous interpretation that research authorizations must be study specific was modified, thus permitting a research authorization to include future research. An authorization for future research must describe the purpose of the authorization so that the individual would reasonably expect that his or her PHI could be used or disclosed for future research. Covered entities have the option of obtaining a new authorization for future research any time after the effective date of this final rule, or they may continue to use study-specific authorizations for research.

GINA

The Final Rule includes changes to comply with the Genetic Information Nondiscrimination Act of 2008 (GINA). The Final Rule adopts the prohibition on the use of genetic information for underwriting purposes. However, the use of genetic information is permitted when an individual is seeking a particular

benefit under the plan and the health plan needs genetic information to determine the medical appropriateness of providing the benefit to the individual.

It should be noted that this prohibition *expands* the prohibition under GINA by prohibiting *all entities included in the definition of "health plan," except for long term care plans*, from using genetic information for underwriting purposes. The prohibition does *not* apply to providers. The prohibition applies to all genetic information from the compliance date of the Final Rule forward, regardless of when or where the genetic information originated.

The Final Rule includes the following changes/clarifications to the definitions related to GINA:

- Adopts the definition of "genetic information" in GINA, which includes with respect to any individual, information about: (1) such individual's genetic tests; (2) the genetic tests of family members of such individual; and (3) the manifestation of a disease or disorder in family members of such individual (*i.e. family medical history*).
- Clarifies that tests such as HIV tests, blood counts, cholesterol or liver function tests, or tests to detect the presence of alcohol or drugs, are not genetic information.
- Defines genetic information to include information about a fetus or embryo.
- Specifically excludes age and sex from the definition of genetic information.
- Expressly includes genetic information in the definition of health information.
- Adopts the GINA definition of "underwriting," which includes (1) determination of eligibility (including enrollment and continued eligibility) for benefits; (2) the computation of premium or contribution amounts under the plan, *including reduced cost sharing amounts or rewards under a wellness program*; (3) the application of any pre-existing condition exclusion under the plan; and (4) other activities related to the creation, renewal or replacement of a contract of health benefits.

Hybrid Entities

A hybrid entity is an organization that performs both covered functions and non-covered functions. For example, an insurance company that offers health insurance and life insurance can designate itself as a hybrid entity and define its covered functions, and thereby avoid the application of HIPAA to its life insurance lines of business. The Final Rule requires that a hybrid entity that performs business associate functions include the business associate functions in the covered functions of the hybrid entity.

Deceased Individuals

The Final Rule limits the time period that PHI of deceased individuals must be protected to 50 years (there previously was no limit). The comments note that this is not a record retention requirement, but if a covered entity chooses to retain records for 50 years or more, the protections of the privacy rules continue to apply for 50 years, but not longer. The Final Rule also permits a covered entity to disclose a deceased individual's PHI to family members and others who were involved in the care or payment for care of the individual prior to death, unless doing so would be inconsistent with any prior expressed preference of the individual.

Immunizations

The Final Rule permits a covered entity to disclose proof of immunization to a school where the school is required by law to have such information prior to admitting the student. While written authorization will no longer be required to permit this disclosure, covered entities will be required to obtain either written or oral agreement from a parent or guardian (or from the individual, if the individual is an adult or emancipated minor) to document the agreement. A signature is not required, which allows covered entities the flexibility to determine what appropriate documentation is. For example, an email from the parent, or a notation of a phone call in the child's medical record or elsewhere would suffice as documentation.

This joint e-Alert is the seventh in a series analyzing the final HIPAA Omnibus Rule. Please watch for our future e-Alerts on additional topics covered under the Final Rule, and for the announcement of our new tool to help you make changes to your HIPAA compliance program required by the Final Rule.

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