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HIPAA OMNIBUS FINAL RULE

Webinar Series – Part II
Research and Marketing
April 9, 2013

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I. BACKGROUND

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Background

- > HIPAA Omnibus Final Rule:
 - Announced on January 17, 2013
 - Published in Federal Register on January 25, 2013
 - <http://www.gpo.gov/fdsys/pkg/FR-2013-01-25/pdf/2013-01073.pdf>
 - Effective on March 26, 2013
 - Compliance date of September 23, 2013
 - HHS will begin enforcing the Final Rule's provisions on the compliance date

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Overview of Webinar Topics

- > Part I of this Webinar Series covered HIPAA changes related to business associates, business associate agreements, and notices of privacy practices.
- > Part II covers HIPAA changes related to research and marketing.
- > Part III (April 16, 2013, same time) will cover breach issues, including changes to the definition of "breach," breach notification requirements, and breach risk assessments.
- > To sign up for Part III, please e-mail Diane.Olsen@dbr.com.

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II. RESEARCH

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Compound Authorizations – Current Rule

- > Current HIPAA Privacy Rule generally prohibits compound authorizations
- > Compound authorization = authorization for use and disclosure of PHI that is combined with any other legal permission
- > Exception: Permissible to combine an authorization for use and disclosure of PHI in a research study with any other written permission for the same study, including an informed consent to participate in the research

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Compound Authorizations – Current Rule

- > Not permissible to combine a “conditioned authorization” and an “unconditioned authorization”
- > Conditioned authorization = an authorization or permission that conditions treatment, payment, enrollment in a health plan or eligibility for benefits on the individual's provision of the authorization
- > Unconditioned authorization = an authorization or permission that does not contain such a condition
- > Purpose is to ensure that individuals may decline the activity described in the unconditioned authorization while still receiving the treatment, services, or benefits in the conditioned authorization.

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Compound Authorizations – Current Rule

- > Example:
 - Clinical trial includes:
 - Investigational drug
 - Standard-of-care treatment
 - Optional blood sample to be banked
 - Must use 2 separate authorizations
 - Conditioned authorization for investigational drug/standard-of-care treatment
 - Unconditioned authorization for collection/banking of blood sample

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Compound Authorizations – New Rule

- > Final Rule allows conditioned authorizations and unconditioned authorizations for research to be combined in the same form.
- > Must clearly differentiate between conditioned and unconditioned components and clearly allow the research subject the option to participate in unconditioned research activities.

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Compound Authorizations – New Rule

- > Covered entities, researchers, and IRBs have discretion to determine how authorizations distinguish between conditioned and unconditioned research activities.
- > HHS noted in commentary to the Final Rule that a check box or extra page explaining the unconditioned activity may be appropriate.

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Authorization for Future Research – Old Rule

- > Research authorization must be study-specific and cannot include authorization for future research
- > Old Rule encumbered secondary research and diverged from Common Rule standards regarding informed consent for future research

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Authorization for Future Research – New Rule

- > Authorization for use and disclosure of PHI for research does not have to be study-specific.
- > Authorization for future research purposes must describe those purposes in a manner such that it would be reasonable for an individual to expect that his/her PHI could be used or disclosed for such future research.

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Authorization for Future Research – New Rule

- > Covered entities, researchers, and IRBs have flexibility to determine how to adequately describe the future research purpose, the information to be used/disclosed, and the recipients of PHI for the future research.
- > Description of PHI to be used for future research may include information collected beyond the time of the original study.
- > Permissible to rely on an IRB-approved consent form obtained prior to the effective date of the Final Rule that reasonably informs individuals about future research, as long as the informed consent is combined with a HIPAA-compliant authorization.
- > Look for additional guidance from HHS on revocations of authorizations for future research uses.

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Decedents' PHI

- > Definition of PHI no longer includes information related to persons deceased for more than 50 years

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Purchase/Licensing of Research Data from a Covered Entity

Old Rule:

- > A covered entity was not prohibited from receiving remuneration in exchange for PHI if the purpose of the use or disclosure was otherwise permissible.
- > Permissible disclosures might include, e.g.,
 - Limited data set for research.
 - Preparatory to research.
 - Pursuant to IRB waiver of authorization.
 - Research on decedents' information

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Sale of PHI

New Rule as of September 23, 2013:

- > Disclosure of PHI in exchange for remuneration prohibited without authorization, with certain exceptions.
 - Authorization must state that the disclosure will result in remuneration to the covered entity.
- > Exceptions include:
 - for public health activities
 - for research where disclosure is otherwise permitted by the Privacy Rule and where the only remuneration received by the covered entity or business associate is a reasonable cost-based fee to cover the cost to prepare and transmit the PHI for such purposes.

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Sale of PHI – Research Exception (I)

- Fee may include direct and indirect costs, including:
 - labor, materials, and supplies for generating, storing, retrieving, and transmitting PHI
 - labor and supplies to ensure PHI is disclosed in a permissible manner;
 - related capital and overhead costs.
- Fees charged to incur a profit from the disclosure of PHI are not allowed.

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Sale of PHI – Research Exception (II)

- HHS does not consider this provision to encompass payments a covered entity may receive in the form of grants, or contracts or other arrangements to perform programs or activities, such as a research study.
- Payment by a research sponsor to a covered entity to conduct a research study is not considered a sale of PHI even if research results that may include PHI are disclosed to the sponsor in the course of the study.

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Final Rule Implications for Research - Summary

- > Most changes are beneficial to researchers and research subjects
 - Informed consent/authorization forms will be shorter
 - Explanations for future research uses will be clearer
 - Expanded opportunities for secondary research and research involving decedents' PHI
 - HIPAA Privacy Rule and Common Rule requirements aligned more closely
- > Currently unclear whether the restrictions related to "sale of PHI" will have an appreciable impact on the availability of limited data sets for research purposes

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III. MARKETING

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Communications Funded by Pharmaceutical Companies

Old Rule:

- > HIPAA Privacy Rule allowed covered entities like pharmacies and health plans to send communications discussing a particular drug/biologic without patient authorization, *even where the covered entity was paid by a third party for sending the communication.*
 - Communications concerning treatment options were classified as non-marketing.
- > California adopted a more restrictive standard by classifying all health care provider or health plan communications funded by a third party as "marketing" communications requiring prior patient authorization.

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Subsidized Communication Programs

New rule as of September 23, 2013:

- > Authorization required for all communications where the covered entity receives financial remuneration for making the communications from a third party whose product or service is being marketed.
- > **Exceptions:**
 - Communications about currently prescribed drugs/biologics
 - Communications made in face-to-face settings

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Exception for Currently Prescribed Products

- > Authorization not required for refill reminders and other communications **about a drug or biologic that is currently being prescribed for the individual, provided any financial remuneration received by the covered entity in exchange for making the communication is reasonably related to the covered entity's cost of making the communication.**
 - Allows a third party to cover the covered entity's cost of drafting, printing, and mailing the communications.
 - Profit by covered entity not permitted.
- > "Currently being prescribed" not defined.

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Face-to-Face Exception

- > Communications made face-to-face by a covered entity to an individual are permitted without authorization.
- > Covers both verbal and written communications.
- > Does not apply to communications over the phone, by email, or by postal mail.

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IV. QUESTIONS

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