Myth Busters

HealthInfoLaw.org

November 2013

MYTH: A "limited data set" is the same as "de-identified data" under HIPAA.

FACT: A limited data set is a separate legal concept under the Privacy Rule and is considered identifiable data. It is not the same as de-identified data.

A limited data set is a form of Protected Health Information (PHI) that a covered entity is permitted to use and disclose for research, public health or health care operations, without obtaining patient authorization. If for research, the covered entity disclosing the PHI in a limited data set and the recipient (which can be another covered entity or a non-covered entity) must enter into a data use agreement that governs and protects how the information will be utilized. De-identified data, by contrast, is not considered PHI at all and thus not protected by the Privacy Rule. Covered entities may use and disclose de-identified data without restriction.

Specifically, a limited data set refers to PHI that has had the following 16 unique identifiers removed:

- Names
- Postal address information, other than town or city, state, and ZIP Code
- Telephone numbers
- Fax numbers
- Email addresses
- Social Security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers/serial numbers
- Device identifiers/serial numbers
- Web URLs
- IP address numbers
- Biometric identifiers
- Full-face photographic images and any comparable images.

These unique identifiers apply to information about the individual and the individual's relatives, employers or household members. By comparison, de-identified data requires the removal of all 16 unique identifiers listed above, plus geographic information smaller than a state (i.e. no county, city or town info) and all elements of dates (except year) directly related to an individual.

The required data use agreement for research using a limited data set addresses how the recipient may use, disclose, and ultimately return or destroy the data. The agreement must include the following:

- Specific permitted uses/disclosures of the limited data set
- Identify who is permitted to receive and use the limited data set
- Several additional privacy stipulations

If a covered entity that is the recipient of a limited data set for research violates the data use agreement with the disclosing covered entity, then the recipient covered entity is deemed to have violated the Privacy Rule. Likewise, if the disclosing covered entity is aware of any activity by the recipient that would violate the data use agreement, the disclosing covered entity must take the steps to correct the inappropriate activity. If unsuccessful, HHS must be notified.

For More Information:

- <u>Learn</u> about state and federal laws related to privacy.
- <u>Read</u> our overview of HIPAA and related resources.

Follow us on Twitter at <u>@HealthInfoLaw</u>

The website content and products published at <u>www.HealthInfoLaw.com</u> are intended to convey general information only and do not constitute legal counsel or advice. Use of site resources or documents does not create an attorney-client relationship.