De-identified Data & Limited Data Set

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Agenda

- HIPAA is a “TEAM SPORT” and everyone has a role in protecting protected health information (PHI).
- What is De-identified Data?
- What is a Limited Data Set?
- HIPAA Obligations for De-identified Data
- HIPAA Obligations for Limited Data Set
What is De-identified Data?

- De-identified data is not considered PHI
- No obligations to the Privacy/Security/Breach Notification Rules
- May use and disclose de-identified data without restriction
- Two methods to de-identify data: Expert Determination & Safe Harbor
  [https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html](https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html)
Expert Determination & Safe Harbor

HIPAA Privacy Rule De-identification Methods

- **Expert Determination** § 164.514(b)(1)
  - Apply statistical or scientific principles
  - Very small risk that anticipated recipient could identify individual

- **Safe Harbor** § 164.514(b)(2)
  - Removal of 18 types of identifiers
  - No actual knowledge residual information can identify individual
What is De-identified Data?

- Removal of all 18 unique identifiers
  - Name
  - All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census: (1) the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people and (2) the initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
  - All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
  - Telephone numbers
  - Fax numbers
  - Email addresses
  - Social Security numbers
  - Medical record numbers
What is De-identified Data?

- Removal of all 18 unique identifiers (Expert Determination & Safe Harbor)
  - 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
  - Any other unique identifying number, characteristic, or code; and
    - The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.
What is a Limited Data Set?

- Limited Data Set is a form of Protected Health Information (PHI)
- Obligations to the Privacy/Security/Breach Notification Rules
- 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.
What is a Limited Data Set?

- Removal of 16 unique identifiers
  - 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.
- Any other unique identifying number, characteristic, or code; and
  - The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.
HIPAA Obligations for Limited Data Set

- With another Covered Entity
  - Data Use Agreement

- With a non-Covered Entity
  - Business Associate Agreement
  - Data Use Agreement
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