



DE-IDENTIFICATION OF HEALTH INFORMATION SUBJECT TO THE PRIVACY RULE (HIPAA)

9/28/2021

I. OVERVIEW

The Privacy Rule applies to all research activities that involve accessing, creating, recording, storing, or disclosing individually identifiable health information (PHI) related to human data or specimens. These include, for example: tissue samples, chart reviews, and/or data or specimens stored in databases or repositories. Research not meeting this criterion is not subject to the Privacy Rule.

The Privacy Rule is applicable to both living individuals and decedents. This includes both living individuals and decedents (for 50 years following death).

II. APPLICABILITY

45 CFR 160 and 164 set forth policies for the protection of subject privacy (HIPAA Privacy Rule). 45 CFR 164 section 514(a) sets the standard for de-identification of protected health information as health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual. Then it is not considered individually identifiable health information.

Section 514(b) outlines the implementation requirements for de-identification of protected health information. These two methods are discussed below.

III. DE-IDENTIFICATION PROCEDURES

A covered entity may determine that health information is not individually identifiable health information only if it is de-identified by one of two methods:

A. De-identification Certified by Statistician or Qualified Individual

A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:

- Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; AND
- Documents the methods and results of the analysis that justify such determination

B. De-identification by Removal of HIPAA Identifiers

1. All of the following identifiers of the individual or of relatives, employers, or household members of the individual, are removed:
 - Names
 - 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:
 - The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
 - The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.

According to the August 2002 Final Modifications to the Privacy Rule and utilizing the 2000 Census data, there are 17 restricted three-digit ZIP codes that correspond to populations of 20,000 or fewer persons and must be changed to 000 to be de-identified: 036, 059, 063, 102, 203,556, 692, 790, 821, 823, 830, 831, 878, 879, 884, 890, and 893

- 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
- Electronic mail addresses
- Social security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) address numbers
- Biometric identifiers, including finger and voice prints
- Full face photographic images and any comparable images
- Any other unique identifying number, characteristic, or code (see below)

In addition, the covered entity may 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.

IV. CODES

A covered entity may assign a code or other means of record identification to allow information de-identified under this section to be re-identified by the covered entity, provided that:

- The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual, AND
- The covered entity does not use or disclose the code or other means of record identification for any other purpose, and does not disclose the mechanism for reidentification.

Disclosure of a code or other means of record identification designed to enable coded or otherwise de-identified information to be re-identified constitutes disclosure of protected health information.

If de-identified information is re-identified, a covered entity may use or disclose such re-identified information only as permitted or required by the Privacy Rule.

Previous Version Dates:

4/18/2008, 3/1/2016