Definition of Protected Health Information (PHI) (45 C.F.R. 160.103)

Protected health information means individually identifiable health information:
(1) Except as provided in paragraph (2) of this definition, that is:
   (i) Transmitted by electronic media;
   (ii) Maintained in electronic media; or
   (iii) Transmitted or maintained in any other form or medium.
(2) Protected health information excludes individually identifiable health information:
   (i) In education records covered by the Family Educational Rights and Privacy Act, as amended, 20
       U.S.C. 1232g;
   (ii) In records described at 20 U.S.C. 1232g(a)(4)(B)(iv);
   (iii) In employment records held by a covered entity in its role as employer; and
   (iv) Regarding a person who has been deceased for more than 50 years.

Individually identifiable health information is information that is a subset of health information, including demographic information collected from an individual, and:
(1) Is created or received by a health care provider, health plan, employer, or health care
    clearinghouse; and
(2) Relates to the past, present, or future physical or mental health or condition of an individual; the
    provision of health care to an individual; or the past, present, or future payment for the provision
    of health care to an individual; and
    (i) That identifies the individual; or
    (ii) With respect to which there is a reasonable basis to believe the information can be used to
        identify the individual.

Health information means any information, including genetic information, whether oral or recorded in
any form or medium, that:
(1) Is created or received by a health care provider, health plan, public health authority, employer, life
    insurer, school or university, or health care clearinghouse; and
(2) Relates to the past, present, or future physical or mental health or condition of an individual; the
    provision of health care to an individual; or the past, present, or future payment for the provision
    of health care to an individual.

Individual means the person who is the subject of protected health information.
Definitions of Covered Entity, Hybrid Entity, and Public Health Authority (45 C.F.R. 160.103, 164.103, and 164.501)

Covered entity means:
   (1) A health plan.
   (2) A health care clearinghouse.
   (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

Hybrid entity means a single legal entity:
   (1) That is a covered entity;
   (2) Whose business activities include both covered and non-covered functions; and
   (3) That designates health care components in accordance with paragraph § 164.105(a)(2)(iii)(D).

Health care component means a component or combination of components of a hybrid entity designated by the hybrid entity in accordance with § 164.105(a)(2)(iii)(D).

Public health authority means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

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1 For more information about hybrid entities, please see the HIPAA hybrid entity rules, 45 C.F.R. 164.105(a) and (c). The Network for Public Health Law has a hybrid entity toolkit that local health departments may find useful, at https://www.networkforphl.org/resources/topics__resources/health_information_and_data_sharing/hipaa_hybrid_toolkit/.
§ 164.512 Uses and disclosures for which an authorization or opportunity to agree or object is not required. A covered entity may use or disclose protected health information without the written authorization of the individual, as described in § 164.508, or the opportunity for the individual to agree or object as described in § 164.510, in the situations covered by this section, subject to the applicable requirements of this section. When the covered entity is required by this section to inform the individual of, or when the individual may agree to, a use or disclosure permitted by this section, the covered entity's information and the individual's agreement may be given orally.

(b) Standard: Uses and disclosures for public health activities –

(1) Permitted uses and disclosures. A covered entity may use or disclose protected health information for the public health activities and purposes described in this paragraph to:

(i) A public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions; or, at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority;

(ii) A public health authority or other appropriate government authority authorized by law to receive reports of child abuse or neglect;

(iii) A person subject to the jurisdiction of the Food and Drug Administration (FDA) with respect to an FDA-regulated product or activity for which that person has responsibility, for the purpose of activities related to the quality, safety or effectiveness of such FDA-regulated product or activity. Such purposes include:

(A) To collect or report adverse events (or similar activities with respect to food or dietary supplements), product defects or problems (including problems with the use or labeling of a product), or biological product deviations;
(B) To track FDA-regulated products;
(C) To enable product recalls, repairs, or replacement, or lookback (including locating and notifying individuals who have received products that have been recalled, withdrawn, or are the subject of lookback); or
(D) To conduct post marketing surveillance;

(iv) A person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading a disease or condition, if the covered entity or public health authority is authorized by law to notify such person as necessary in the conduct of a public health intervention or investigation; or
(v) An employer, about an individual who is a member of the workforce of the employer, if:
(A) The covered entity is a covered health care provider who provides health care to
the individual at the request of the employer:
   (1) To conduct an evaluation relating to medical surveillance of the workplace; or
   (2) To evaluate whether the individual has a work-related illness or injury;
(B) The protected health information that is disclosed consists of findings concerning a work-
related illness or injury or a workplace-related medical surveillance;
(C) The employer needs such findings in order to comply with its obligations, under 29 CFR parts
1904 through 1928, 30 CFR parts 50 through 90, or under state law having a similar purpose, to
record such illness or injury or to carry out responsibilities for workplace medical surveillance;
and
(D) The covered health care provider provides written notice to the individual that
protected
health information relating to the medical surveillance of the workplace and work-related
illnesses and injuries is disclosed to the employer:
   (1) By giving a copy of the notice to the individual at the time the health care is provided; or
   (2) If the health care is provided on the work site of the employer, by posting the notice in a
prominent place at the location where the health care is provided.

(vi) A school, about an individual who is a student or prospective student of the school, if:
(A) The protected health information that is disclosed is limited to proof of immunization;
(B) The school is required by State or other law to have such proof of immunization prior to
admitting the individual; and
(C) The covered entity obtains and documents the agreement to the disclosure from either:
   (1) A parent, guardian, or other person acting in loco parentis of the individual, if
   the individual is an unemancipated minor; or
   (2) The individual, if the individual is an adult or emancipated minor.

(2) Permitted uses. If the covered entity also is a public health authority, the covered entity is
permitted to use protected health information in all cases in which it is permitted to disclose such
information for public health activities under paragraph (b)(1) of this section.
§ 164.514 Other requirements relating to uses and disclosures of protected health information.

(a) Standard: De-identification of protected health information. 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 is not individually identifiable health information.

(b) Implementation specifications: Requirements for de-identification of protected health information. A covered entity may determine that health information is not individually identifiable health information only if:

1. A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:
   (i) 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
   (ii) Documents the methods and results of the analysis that justify such determination; or

2. (i) The following identifiers of the individual or of relatives, employers, or household members of the individual, are removed:
   (A) Names;
   (B) 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.
   (C) 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;
   (D) Telephone numbers;
   (E) Fax numbers;
   (F) Electronic mail addresses;
   (G) Social security numbers;
   (H) Medical record numbers;
   (I) Health plan beneficiary numbers;

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2 For more information about de-identification of PHI, please see the guidance document from the U.S. Department of Health and Human Services, Guidance Regarding Methods for De-Identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (November 2012). A copy of this document was provided as part of the on-line materials for the UNC School of Government’s 2019 Health Directors’ Legal Conference.
(J) Account numbers;
(K) Certificate/license numbers;
(L) Vehicle identifiers and serial numbers, including license plate numbers;
(M) Device identifiers and serial numbers;
(N) Web Universal Resource Locators (URLs);
(O) Internet Protocol (IP) address numbers;
(P) Biometric identifiers, including finger and voice prints;
(Q) Full face photographic images and any comparable images; and
(R) Any other unique identifying number, characteristic, or code, except as permitted
by paragraph (c) of this section; and

(ii) 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.