# Health Care Privacy Compliance Handbook, 3rd Edition
# 1. HIPAA Privacy and Security

By David B. Nelson, CHPC, CHRC, CIPP/G, CIPP/US, CISSP, and Janis E. Anfossi, JD, MPH, CHC, CHPC[1]

## Introduction

This chapter outlines what is probably the single *most important set of regulations* to affect the healthcare privacy professional. Most every discipline (whether accounting, journalism, insurance, or banking) has one or more statutes, and their implementing regulations, that form the basis for legal standards in that industry. The Health Insurance Portability and Accountability Act (HIPAA), with its standards for the access, disclosure, transmission, and retention of protected health information (PHI), created a national baseline for healthcare information privacy and security. Individual states can also develop health information statutes, but they can only add higher standards than HIPAA to their healthcare information privacy/security rules. They cannot go lower than the federal HIPAA rules. As our nation continues to move toward the expanded sharing of information through electronic healthcare records (locally, regionally, and nationally) and with the development of electronically stored databases, it is incumbent on all healthcare privacy professionals to understand the various federal and state health information regulations. A healthcare privacy professional must first grasp HIPAA as the core academic discipline.

This chapter of HCCA's *Health Care Privacy Compliance Handbook* reviews these basic HIPAA standards and definitions. It also incorporates the provisions of the Health Information Technology for Economic and Clinical Health (HITECH) Act,[2] enacted through the American Recovery and Reinvestment Act of 2009, as well as the modifications issued January 25, 2013, by the Department of Health & Human Services (HHS), commonly known as the Omnibus Rule.[3] Additionally, recent updates to HITECH and the 21st Century Cures Act of 2016[4] are addressed that cover new privacy/security standards for telehealth, as well as the expanded jurisdiction of the Food and Drug Administration (FDA) over medical mobile apps.

Some of the outstanding changes brought by those provisions require the healthcare industry to:

- Modify the individual authorization form, and other requirements, to facilitate research and disclosure of child immunization proof to schools, and to enable access to decedent information by family members or others
- Adopt the Enforcement Rule
- Adopt the additional HITECH Act enhancements to the Enforcement Rule not previously adopted in the interim final rule of October 30, 2009, such as the provisions addressing enforcement of noncompliance with HIPAA rules due to willful neglect
- Adopt and implement the Breach Notification Rule
- Prohibit most health plans from using or disclosing genetic information for underwriting purposes
- Require medical mobile app manufacturers to report to and be overseen by the FDA

- Implement certified software platforms for use in telemedicine/telehealth and expand the use and Medicare reimbursement for those modalities

Other recommendations have also been made and incorporated into this text.

## Contents and Organization

Those new to privacy should note that the Code of Federal Regulations holds the HIPAA Rules, but the *Federal Register* contains the comments on regulations. Rules are the letter of the law, and the intent is in the *Federal Register*. The latter is very informative in gleaning "intent" and is written conversationally with examples. The HIPAA Privacy Rule in its original form resides at 65 Fed. Reg. 82,461 (December 28, 2000) .

Traditionally HIPAA has been taught, presented, and/or explained by reading down through the Code of Federal Regulations point by point. This can be tedious, as there are nearly one thousand lines to digest in subsets that can run six layers deep, which do not necessarily connect logically in the same order. This chapter pulls together privacy concepts and discusses implementation from a practical perspective by integrating topics. If it does not seem to apply to your situation, or appears to skip important pieces, go to the *Federal Register* to read the comments that HHS made on the proposed and adopted regulation.

This chapter is divided into the following segments for ease of understanding:

- **Section One:** HIPAA the Act
- **Section Two:** Organization
- **Section Three:** Use and Disclosure of Information and Authorization
- **Section Four:** Individual's Rights, CE/BA Duties and Penalties
- **Section Five:** Interaction with the HIPAA Security Rule
- **Section Six:** HITECH and the HIPAA Omnibus Rule
- **Section Seven:** Health Information Exchanges and Interoperability
- **Section Eight:** Mobile Medical Apps and Telehealth
- **Section Nine:** Federal Exceptions to HIPAA During Local or National Disasters

This chapter does not incorporate state or local laws and/or cross-references to other legal mandates and the relationship to HIPAA. However, the privacy professional should know that conflicts may exist between state and federal mandates, so documentation of how privacy or security or breach reporting will be administered is critical.

## Section One: HIPAA the Act

HIPAA was passed by Congress and signed into law in 1996. HIPAA has three predominant purposes:

1. To make health insurance portable under the Employee Retirement Income Security Act of 1974 (ERISA)[5]
2. To move healthcare onto a nationally standardized electronic billing platform
3. To prevent fraud, waste, and abuse (administrative simplification)

Only by knowing what Congress *intended,* though, can the privacy professional attach importance in relation to all HIPAA mandates.

### Intent

It is the purpose of this subtitle to improve the Medicare program under Title XVIII of the Social Security Act, the Medicaid program under title XIX of such Act, and the efficiency and effectiveness of the healthcare system, by encouraging the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information.[6]

Between 1% and 1.5% of all private insurance dollars, and between 10% and 15% of public insurance dollars are lost to fraud, waste, or abuse of the healthcare system. No one knows exactly how much money is lost, but it is clear that this contributes to the rising cost of healthcare.

The intent of HIPAA, to improve healthcare programs and the delivery of services through the two largest health plans in the United States, is accomplished by improved data flows. Improved data will lead to better outcomes by increasing accuracy if done consistently, using national standards for formats, specific transactions, and an agreed-upon vocabulary.

At the same time, the improved data flows support a rapid way to review, cross-reference, and data mine for fraudulent behavior. It's easier to spot 991 dental services performed by one provider on a single day, or the use of a higher-paying billing code that requires three surgical packs when only one pack was used.

The standards and implementation specifications ensure that participatory entities are speaking the same language in the same electronic way. The specifics of data flow are outlined in the transaction and code set standards,[7] which include unique identifiers.

### Intent Barriers

Congress, knowing they wanted to improve the healthcare industry via the HIPAA vehicle, predicted accurately that the goals could not be accomplished unless privacy and security provisions were integral elements. Many states had no privacy rights or individual access rights to healthcare records. The lack of individual access and the intent to move to national standards contributed to a sense of foreboding in the privacy sector and by individuals, so the Privacy and Security rules were promulgated to make healthcare interstate commerce equal, thus creating a national healthcare privacy and security baseline or "floor."

Congress did not predict in 1996 how the internet would affect healthcare, though, and according to Dr. David Brailer, "HIPAA was never intended for the digital age."[8] Privacy professionals will face this issue as the regulations continue to evolve and catch up with the changing environment.

## Section Two: Organization

To determine what HIPAA requires of an organization and its business partners, an entity must determine *if* they are a covered entity, what *kind* of covered entity, what *data* is covered, what do they *use* the data for, where do they *disclose* the data, who do they *receive* data from, and what are all the *purposes* of the data. Organizationally, these decisions and documentation lead to a framework that guides development of policies and procedures to support HIPAA compliance.

First it is necessary to determine if an entity is subject to HIPAA. To accomplish this, an understanding of several definitions is required. An entity must meet the definition of at least one of the three types of covered entities

(CEs). But other definitions must be considered, as they clarify relationships.

## Definitions

**Applicability.** (a) Except as otherwise provided, the standards, requirements, and implementation specifications adopted under this subchapter apply to the following entities:

1. A health plan.
2. A healthcare clearinghouse.
3. A healthcare provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

(b) Where provided, the standards, requirements, and implementation specifications adopted under this subchapter apply to a business associate.[9]

**Health Plan.** Means an individual or group plan that provides, or pays the cost of, medical care (as defined in section 2791(a)(2) of the Public Health Service (PHS) Act[10] ). More specifically, from 45 C.F.R. § 160.103 :

> (1) *Health plan* includes the following, singly or in combination:
>
> i. A group health plan, as defined in this section.
>
> ii. A health insurance issuer, as defined in this section.
>
> iii. An HMO [health maintenance organization], as defined in this section.
>
> iv. Part A or Part B of the Medicare program.[11]
>
> v. The Medicaid program.[12]
>
> vi. The Voluntary Prescription Drug Benefit Program (under Part D of the Medicare program).[13]
>
> vii. An issuer of a Medicare supplemental policy (under Part E of the Medicare program).[14]
>
> viii. An issuer of a long-term care policy, excluding a nursing home fixed indemnity policy.
>
> ix. An employee welfare benefit plan or any other arrangement that is established or maintained for the purpose of offering or providing health benefits to the employees of two or more employers.
>
> x. The healthcare program for uniformed services under title 10 of the United States Code (U.S.C.).[15]
>
> xi. The veteran's healthcare program under 38 U.S.C. Chapter 17 .[16]

xii. The Indian Health Service program under the Indian Health Care Improvement Act.[17]

xiii. The Federal Employees Health Benefits Program.[18]

xiv. An approved state child health plan under title XXI of the Social Security Act, providing benefits for child health assistance that meet the requirements of section 2103 of the act.[19]

xv. The Medicare Advantage program under Part C of the Medicare program.[20]

xvi. A high-risk pool that is a mechanism established under state law to provide health insurance coverage or comparable coverage to eligible individuals.

xvii. Any other individual or group plan, or combination of individual or group plans, that provides or pays for the cost of medical care (as defined in section 2791(a)(2) of the PHS Act).[21]

(2) *Health plan* excludes:

i. Any policy, plan, or program to the extent that it provides, or pays for the cost of, excepted benefits that are listed in section 2791(c)(1) of the PHS Act;[22] and

ii. A government-funded program (other than one listed in paragraph (1)(i)-(xvi) of this definition):

A. Whose principal purpose is other than providing, or paying the cost of, healthcare; or

B. Whose principal activity is:

1. The direct provision of healthcare to persons; or

2. The making of grants to fund the direct provision of healthcare to persons.

**Note:** Health plan exclusions set aside Medicaid enrollment as a traditional welfare program, a government-funded program whose principle purpose is *not* providing or paying for healthcare. It should be noted that if the same government program performs enrollment (either directly or through a centralized process), but then provides or pays the cost of healthcare, the exclusion provision would not apply. Documentation of what constitutes the "principal" activity guides the business relationship.

**Healthcare Clearinghouse.** Means a public or private entity, including a billing service, repricing company, community health management information system or community health information system, and value-added networks and switches, that does either of the following functions:

(1) Processes or facilitates the processing of health information received from another entity in a nonstandard

format or containing nonstandard data content into standard data elements or a standard transaction.

(2) Receives a standard transaction from another entity and processes or facilitates the processing of health information into nonstandard format or nonstandard data content for the receiving entity.[23]

**Healthcare Provider.** Means a "provider of services" (as defined in section 1861(u) of the Social Security Act[24] ), a provider of "medical or health services" (as defined in section 1861(s) of the Social Security Act[25] ), and any other person or organization who furnishes, bills, or is paid for healthcare in the normal course of business.[26] (The definition of healthcare provider is a two-step process: First an entity must meet the definition and second must transmit a defined transaction.)

As noted above, HIPAA regulations apply to a healthcare provider "who transmits any health information in electronic form in connection with a transaction." And so, one more definition is needed:

**Transaction.** Means the transmission of information between two parties to carry out financial or administrative activities related to healthcare. It includes the following types of information transmissions:

(1) Healthcare claims or equivalent encounter information.

(2) Healthcare payment and remittance advice.

(3) Coordination of benefits.

(4) Healthcare claim status.

(5) Enrollment and disenrollment in a health plan.

(6) Eligibility for a health plan.

(7) Health plan premium payments.

(8) Referral certification and authorization.

(9) First report of injury.

(10) Health claims attachments.

(11) Healthcare electronic funds transfers (EFT) and remittance advice.

(12) Other transactions that the Secretary may prescribe by regulation.[27]

The provider definition is very broad and includes nontraditional services such as acupuncture or case management, so a general rule of thumb usually works: If it looks like some kind of healthcare, it probably meets the definition. To obtain the named specific providers, the privacy professional must go to the Social Security Act. This is a long list. The definition of "medical and other health services" referenced above includes 17 specified services with dozens of subsets and clarifications, while the definition of "provider of services" includes "hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program…"

Furthermore, HIPAA defined "transactions" in general terms, so to be qualified as a covered provider under HIPAA, it is not required that the provider meet the transaction and code set criteria (e.g., content, terminology, transmission criteria) to be "transmitting." It only needs to be transmitting any of the categories of information

listed above.

**Documentation**

Once an entity has determined they are a CE, they should document (in a policy) what type of CE they have determined applies to them. The standards, implementation specifications, and organizational requirements for a provider are different than a health plan or clearinghouse. Only by documenting the determination can the privacy professional create the baseline compliance tools to develop an appropriate privacy program, including auditing or monitoring daily activities.

## Other HIPAA Entity Designations

Some business arrangements do not clearly fall into the three covered entity definitions but are intimately related to HIPAA-covered functions. To account for this, HHS included some definitions for complex business relationships.

**Hybrid Entity.** Means a single legal entity:

(1) That is a covered entity;

(2) Whose business activities include both covered and noncovered functions; and

(3) That designates healthcare components in accordance with paragraph §164.105(a)(2)(iii)(D).[28]

An example might be a university that runs a community clinic. The clinic information could easily be covered by HIPAA, yet the educational records are not. The entity can self-declare itself a hybrid CE and then document which parts perform covered functions and which ones do not.

**Documentation**

Another element to be documented for the hybrid designation is whether or not PHI or individually identifiable health information flows out of the covered division into a noncovered division for a support activity, such as work done by the general counsel or auditing department. These divisions—while still part of the same legal entity—may, like a business associate discussed below, perform functions on behalf of the covered division. They are part of the same legal entity, so any data that flows from the covered division to the noncovered division must meet the disclosure provisions, such as the minimum necessary standard. While not constituting a business associate relationship because they are part of the same workforce, the hybrid entity's covered division must get "assurances" that meet the specifications at 45 C.F.R. § 164.314(a) .

**Business Associates.** The business associate (BA) is probably the most familiar arrangement that an external party would participate in with a HIPAA CE. However, the privacy professional should note that the BA describes a particular type of relationship and should not be used if the relationship does not meet the definition. Additionally, BAs are directly liable for compliance with certain HIPAA Privacy and Security rules requirements.

> Business associate: (1) Except as provided in paragraph (4) of this definition, business associate means, with respect to a covered entity, a person who:
>
> i. On behalf of such covered entity or of an organized healthcare arrangement (as defined in this section) in which the covered entity participates, but other than in the capacity of a member of the workforce of such covered

entity or arrangement, creates, receives, maintains, or transmits protected health information for a function or activity regulated by this subchapter, including claims processing or administration, data analysis, processing, or administration, utilization review, quality assurance, patient safety activities listed at 42 C.F.R. § 3.20 , billing, benefit management, practice management, and repricing; or:

ii. Provides, other than in the capacity of a member of the workforce of such covered entity, legal, actuarial, accounting, consulting, data aggregation (as defined in § 164.501 of this subchapter), management, administrative, accreditation, or financial services to or for such covered entity, or to or for an organized healthcare arrangement in which the covered entity participates, where the provision of the service involves the disclosure of protected health information from such covered entity or arrangement, or from another business associate of such covered entity or arrangement, to the person.

(2) A covered entity may be a business associate of another covered entity.

(3) Business associate includes:

i. A Health Information Organization, E-prescribing Gateway, or other person that provides data transmission services with respect to protected health information to a covered entity and that requires access on a routine basis to such protected health information.

ii. A person that offers a personal health record to one or more individuals on behalf of a covered entity.

iii. A subcontractor that creates, receives, maintains, or transmits protected health information on behalf of the business associate.

(4) Business associate does not include:

i. A healthcare provider, with respect to disclosures by a covered entity to the healthcare provider concerning the treatment of the individual.

ii. A plan sponsor, with respect to disclosures by a group health plan (or by a health insurance issuer or HMO with respect to a group health plan) to the plan sponsor, to the extent that the requirements of [ 45 C.F.R. § 164.504(f) ] of this subchapter apply and are met.

iii. A government agency, with respect to determining eligibility for, or enrollment in, a government health plan that provides public benefits and is administered by another government agency, or collecting protected health information for such purposes, to the extent such activities are authorized by law.

iv. A covered entity participating in an organized healthcare arrangement that

> performs a function or activity as described by paragraph (1)(i) of this definition for or on behalf of such organized healthcare arrangement, or that provides a service as described in paragraph (1)(ii) of this definition to or for such organized healthcare arrangement by virtue of such activities or services.[29]

**Note:** To ensure that HIPAA CEs extend the privacy and security standards to contractors (downhill data flow), the concept of the BA was added to the HIPAA Security and Privacy rules. A mandate is placed on the CE to either get "assurances" for privacy and security standards from their business partners or to include BA language in a contract.

The BA relationship is defined where a separate legal entity uses or discloses PHI on behalf of the CE. Usually, the BA relationship looks like claims processing, data analysis, billing, benefit management, quality assurance, quality improvement, practice management, legal, actuarial, accounting, accreditation, or other administrative services. This is not an exhaustive list of functions, and the relationship should be reviewed from the standpoint of the information handled: If it is individually identifiable information going outside of your legal boundary, you are halfway to the BA relationship.

In general, if the other entity is:

- Part of the same legal entity (hybrid)—get assurances—it is not a BA, as per 45 C.F.R. § 164.314(a) .
- Not part of the same legal entity and is using/disclosing on the CEs behalf, it is BA.
- A BA, it should specifically spell out the permitted uses and disclosures.
- Taking action that a state/federal or federal/federal mandate would define as "illegal" for the CE, that action is still illegal for the BA to perform (e.g., other party's research, sharing or giving of PHI to BA).
- Not part of the same legal entity, *neither* using nor disclosing *on the CE's behalf* but providing services, a service contract with privacy/security clauses will meet the 45 C.F.R. § 164.314(a) provision of "assurances."

**Note:** A perceived weakness of BA contract enforcement was addressed later by the language in the HITECH Act. The BA is now responsible for its own violations of an administration simplification provision.[30] The mandate on a CE to establish assurances or institute the BA language still exists, but the legal liability for violations, and possible penalties, flow directly via the contract tool to the entity that violates the rule.

There is still much debate on how to perform due diligence to detect if a BA is abiding by the provisions of administration simplification. However, one key provision privacy professionals should be aware of is the requirement that a BA pass down identical requirements to any subcontractor they use.

The author's opinion is that the BA language/contract/amendments have probably been overused. In the maturation of the industry, the early stages were fraught with inserting BA language in everything. This was not unreasonable to reduce perceived risk, as the industry had no clear idea of how penalties would work. Everyone was overcautious and leapt into BA language "just in case." Legal debates over whose BA language should be used and which party constituted a BA were widespread. Many institutions still do not fully grasp the intent of the mandate for BA contracts.

**Organized Health Care Arrangement.** Means:

(1) A clinically integrated care setting in which individuals typically receive healthcare from more than one healthcare provider;

(2) An organized system of healthcare in which more than one covered entity participates and in which the participating covered entities:

i. Hold themselves out to the public as participating in a joint arrangement; and

ii. Participate in joint activities that include at least one of the following:

A. Utilization review, in which healthcare decisions by participating covered entities are reviewed by other participating covered entities or by a third party on their behalf;

B. Quality assessment and improvement activities, in which treatment provided by participating covered entities is assessed by other participating covered entities or by a third party on their behalf; or

C. Payment activities, if the financial risk for delivering healthcare is shared, in part or in whole, by participating covered entities through the joint arrangement and if protected health information created or received by a covered entity is reviewed by other participating covered entities or by a third party on their behalf for the purpose of administering the sharing of financial risk.

(3) A group health plan and a health insurance issuer or HMO with respect to such group health plan, but only with respect to protected health information created or received by such health insurance issuer or HMO that relates to individuals who are or who have been participants or beneficiaries in such group health plan;

(4) A group health plan and one or more other group health plans each of which are maintained by the same plan sponsor; or

(5) The group health plans described in paragraph (4) of this definition and health insurance issuers or HMOs with respect to such group health plans, but only with respect to protected health information created or received by such health insurance issuers or HMOs that relates to individuals who are or have been participants or beneficiaries in any of such group health plans.[31]

**Note:** Typically, an organized healthcare arrangement (OHCA) is a clinically integrated care setting where individuals receive healthcare from more than one healthcare provider. The definition also applies when more than one CE participates in care but hold themselves out to the public as participating in a joint arrangement. To be an OHCA, the entities must also participate in joint activities and do one of the following: utilization review, quality assessment and improvement activities, or payment activities.

An OHCA could be a group health plan, a health insurance issuer, or HMO with respect to such a group health plan. But that classification qualifies only in terms of PHI created or received that relates to individuals who are or who have been participants or beneficiaries in such a group health plan.

An OHCA could be a group health plan and one or more other group health plans that are maintained by the same plan sponsor, but only where PHI is created or received by insurance issuers that relates to individuals who are or have been participants or beneficiaries in any of such group health plans.

**Affiliated Covered Entity.** Means: "Legally separate covered entities that are affiliated may designate themselves as a single covered entity for purposes of this part."[32]

**Note:** These are legally distinct entities that share common control or common ownership and choose to designate themselves as one affiliated CE for the purposes of complying with the HIPAA Privacy standard. Affiliated entities must meet the same requirements as a single CE, but this designation allows for things like the Notice of Privacy Practices and privacy policies and procedures to be held in common as long as they all agree to abide by them. The concept is similar to the long-standing qualified service organization for federally supported substance use disorder program subject to 42 C.F.R. Part 2 , the key being *separate legal entities.*

## HIPAA Covered Data

Once it is determined that an entity meets the HIPAA CE criteria and some of the relationships are defined, the entity must identify what information is covered, where it resides, and how it uses the information. It is important that a privacy program be based on information use and data flow so that the program can determine where an authorization is required or detect violations such as unauthorized disclosure.

### Definitions

The following definitions describe parts of a diagram (see graphic below), followed by other data definitions that affect the determination of HIPAA-covered data.

**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 healthcare provider, health plan, public health authority, employer, life insurer, school or university, or healthcare clearinghouse; and

(2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of healthcare to an individual; or the past, present, or future payment for the provision of healthcare to an individual.[33]

**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 healthcare provider, health plan, employer, or healthcare clearinghouse; and

(2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of healthcare to an individual; or the past, present, or future payment for the provision of healthcare 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.[34]

**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) ; and

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.[35]

**Electronic Protected Health Information.** Means information that comes within paragraphs (1)(i) or (1)(ii) of the definition of protected health information as specified in this section.[36]

**Note:** The following two definitions reside in the middle of the regulation and not in one of the sections reserved for definitions.

**De-identified Information.** This means information that does not identify an individual and which there is no reasonable basis to believe that the information can be used to identify an individual.

Health information is rendered 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;

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.[37]

**Limited Data Set.** A CE may use or disclose a limited data set if the CE enters into a data use agreement with the limited data use recipient and the following direct identifiers of the individual or of relatives, employers, or household members of the individual are removed:

- Names;
- Postal address information, other than town or city, state, and zip code;
- Telephone numbers;
- Fax numbers;
- Electronic mail addresses;

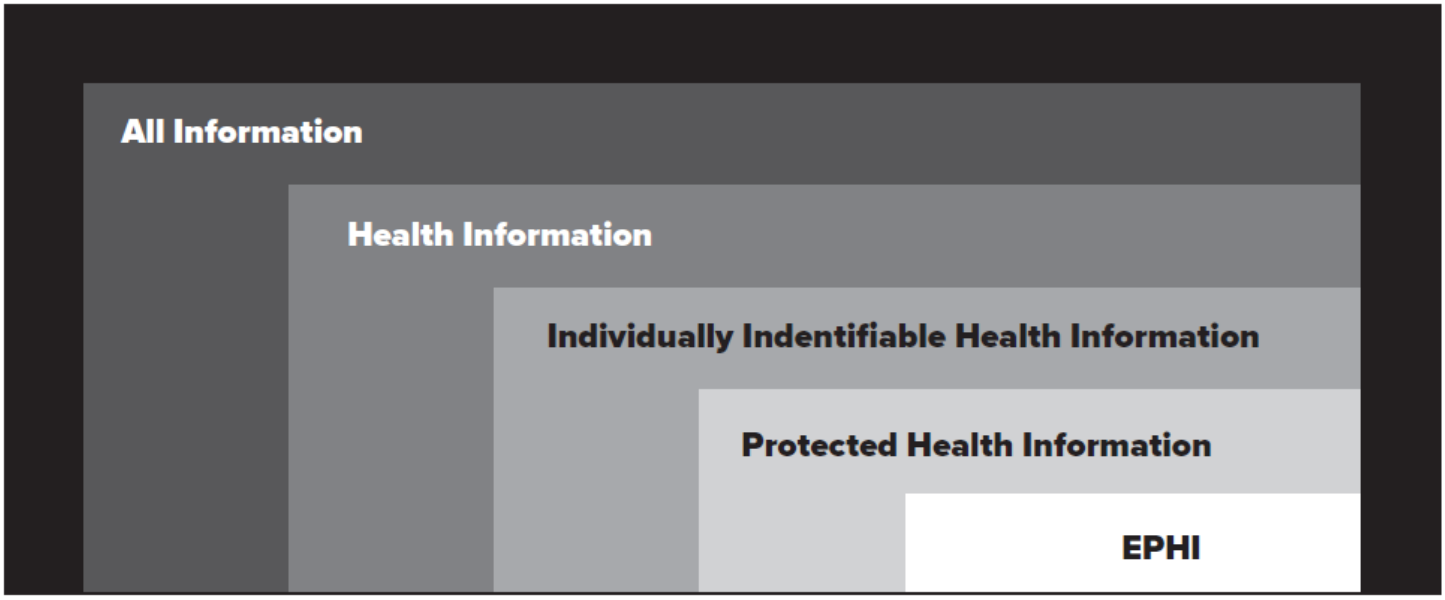
- Social Security numbers;
- Medical record numbers;
- Health plan beneficiary numbers;
- Account numbers;
- Certificate/license numbers;
- Vehicle identifiers and serial numbers, including license plate numbers;
- Device identifiers and serial numbers;
- Web Universal Resource Locators (URLs);
- Internet Protocol (IP) address numbers;
- Biometric identifiers, including finger and voice prints; and
- Full face photographic images and any comparable images.[38]

**Note:** One of the proposed uses of de-identified and limited data sets is to make them available for research purposes. However, combined with publicly available information, especially in small population centers, it may be possible to reidentify the individual. This is of concern for the privacy professional as, while using the data is permitted, it may not be foolproof from re-identification.

**Unsecured Protected Health Information.** Means protected health information that is not rendered unusable, unreadable, or indecipherable to unauthorized persons through the use of a technology or methodology specified by the Secretary in the guidance issued under section 13402(h)(2) of Public Law 111-5,[39] the American Recovery and Reinvestment Act of 2009.[40]

**Note:** To put HIPAA-covered information in context, think of the HIPAA rules as looking at increasingly smaller sets, or classifications, of information.

- All Information: Literally every piece of information your entity has in its possession or has access too.
- Health Information: Every piece of health and health-related information.
- Individually Identifiable Health Information: Health information that identifies an individual or can be used in combination with other information to identify an individual.
- Protected Health Information: Health information that is transmitted in one of the covered HIPAA transactions.
- Electronically Protected Health Information: This is a subset that is covered by some specialized standards in the HIPAA Security Rule.




In the lower right corner of the graphic is electronic protected health information (ePHI).

One thing to consider is that if the ePHI cannot be segmented from the universe of information, the entity may have to protect all information to the same degree as the HIPAA data—or provide greater protections if state or federal law demands it. Further, it is the author's opinion that electronic health records (EHRs) will not be able to provide segmentation by specific definitions or regulations for some time to come. The privacy professional should know what elements within an electronic record constitute: the legal record, the medical record, the designated record set, or any other mandated definition that creates a subset from the record. The latter is important in meeting some state's regulations.

Once information has been determined to be covered by HIPAA, the privacy professional must ferret out where the information resides and what the use of the information is. This identification process plays a part in doing the risk analysis. The risk analysis is required by the HIPAA Security Rule and should not be skipped by the privacy professional because the risk analysis is a "security thing."

**Note:** The Security Rule at 45 C.F.R. § 164.306(a)(3) says, "Protect against any reasonably anticipated uses or disclosures of such information that are not permitted or required under subpart E of this part." Subpart E is the Privacy Rule. To implement the Security Rule, the privacy professional must be able to communicate to the security professional exactly what the uses and disclosures will be, any mandates such as a required authorization, and a prediction regarding what security failures would look like so that an appropriate electronic detection mechanism may be used. In this way, the risk analysis can fulfill its intent by identifying all relevant risks, not just risks to the system or data.