

The Great Seal of the State of Ohio is a large, faint watermark in the background. It features a central sun with rays, a landscape with a river and hills, and a sheaf of wheat. The words "GREAT SEAL OF THE STATE OF OHIO" are written around the perimeter of the seal.

# **The Health Insurance Portability and Accountability Act (HIPAA)**

## **Guide to the HIPAA Privacy Rule**

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45 CFR cites:

GUIDE TO THE HIPAA PRIVACY RULE  
[45 CFR Parts 160 and 164]

1. **DEFINITIONS** [see 160.103, 160.202, 160.302, 164.501 for other definitions]:

160.103

- 1.1. **Covered Entity (CE)** means a health plan, a health care clearinghouse, or a health care provider that transmits any health information in electronic form relating to any covered transaction.
  - 1.1.1. **Health plan** means an individual plan or group plan that provides, or pays the cost of, medical care. [NOTE: includes the Medicaid and Medicare programs]
  - 1.1.2. **Health care clearinghouse** means an entity that processes health information received in a nonstandard format into a standard format, or processes health information received in a standard format into a nonstandard format for another entity.
  - 1.1.3. **Health care provider** means a provider of medical or health services and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business.

164.501

- 1.2. **Protected Health Information (PHI)** means individually identifiable information relating to the past, present or future physical or mental health or condition of an individual, provision of health care to an individual, or the past, present or future payment for health care provided to an individual.

164.502(g)

- 1.3. **Personal Representative** means a person who has authority under applicable law to make decisions related to health care on behalf of an adult or an emancipated minor, or the parent, guardian, or other person acting in *loco parentis* who is authorized under law to make health care decisions on behalf of an unemancipated minor, except where the minor is authorized by law to consent, on his/her own or via court approval, to a health care service, or where the parent, guardian or other person acting in *loco parentis* has assented to an agreement of confidentiality between the provider and the minor.

164.501	<p>1.4. <b>Treatment, Payment and Health Care Operations (TPO)</b> includes all of the following:</p> <p>1.4.1. <b>Treatment</b> means the provision, coordination or management of health care and related services, consultation between providers relating to an individual or referral of an individual to another provider for health care.</p> <p>1.4.2. <b>Payment</b> means activities undertaken to obtain or provide reimbursement for health care, including determinations of eligibility or coverage, billing, collections activities, medical necessity determinations and utilization review.</p> <p>1.4.3. <b>Health care operations</b> includes functions such as: quality assessment and improvement activities, reviewing competence or qualifications of health care professionals, conducting or arranging for medical review, legal services and auditing functions, business planning and development, and general business and administrative activities.</p>
164.501	<p>1.5. <b>Covered Functions</b> means those functions of a CE, the performance of which make the entity a health plan, a health care clearinghouse or a health care provider.</p>
164.504(a)	<p>1.6. <b>Hybrid Entity</b> means a single legal entity that is a CE whose covered functions are not its primary functions.</p>
164.501	<p>1.7. <b>Designated Record Set</b> means a group of records maintained by or for a CE that is: the medical and billing records relating to an individual maintained by or for a health care provider; the enrollment, payment, claims adjudication and case or medical management systems maintained by or for a health plan; or used, in whole or part, by of for a CE to make decisions about individuals.</p>
160.103	<p>1.8. <b>Business Associate (BA)</b> means a person or entity who, on behalf of the CE, and other than in the capacity of a workforce member: performs or assists in the performance of a function or activity that involves the use or disclosure of PHI; or provides legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial services.</p>
160.103	<p>1.9. <b>Workforce</b> means employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a CE, is under the direct control of such entity, whether or not they are paid by the entity.</p>

164.501	1.10. <b>Health Oversight Agency</b> means a governmental agency or authority, or a person or entity acting under a grant of authority from or a contract with such public agency, including the employees or agents of the public agency, its contractors and those to whom it has granted authority, that is authorized by law to oversee the public or private health care system or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights for which health information is relevant.
164.501	1.11. <b>Public Health Authority</b> means a governmental agency or authority, or a person or entity acting under a grant of authority from or a contract with such public agency, including the employees or agents of the public agency, its contractors and those to whom it has granted authority, that is responsible for public health matters as part of its official mandate.
164.501	1.12. <b>Indirect Treatment Relationship</b> means a relationship between an individual and a health care provider in which the health care provider delivers health care to the individual based on the orders of another health care provider and the health care provider typically provides services or products, or reports the diagnosis or results associated with the health care, directly to another health care provider, who provides the services or products or reports to the individual.
164.501	1.13. <b>Research</b> means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
164.501	1.14. <b>Law Enforcement Official</b> means a public employee from any branch of government who is empowered by law to investigate a potential violation of the law or to prosecute, or otherwise conduct a criminal, civil, or administrative proceeding arising from an alleged violation of law.

160.201-  
160.205

2. **GENERAL RULES:**

- 2.1. HIPAA privacy regulations **preempt state law** except where:
- 2.1.1. State law is determined by the Secretary of HHS to be necessary to prevent fraud and abuse related to the provision of or payment for health care, to ensure appropriate regulation of insurance and health plans, for state reporting on health care and delivery systems, or to serve a compelling need relating to public health, safety or welfare that outweighs the intrusion into privacy;
  - 2.1.2. State law has as its principal purpose the regulation of controlled substances;
  - 2.1.3. State law relates to privacy of health information and is more stringent than the regulations - i.e. state law meets one or more of the following criteria: prohibits or restricts a use/disclosure that would be permitted under the regulations, except where the disclosure required by the Secretary of HHS for determining a CE's compliance with the regulations, or where disclosure is to the individual who is the subject of the health information; allows the individual greater rights to access or amend his/her records (however, the regulations may not be construed to preempt any state law to the extent that it authorizes or prohibits disclosure of PHI about a minor to a parent, guardian, or person acting *in loco parentis*); requires more information be provided to the individual about the use/disclosure of his/her records; narrows the scope or duration of, increases the privacy protections afforded by, or reduces the coercive effect of the circumstances surrounding the consent or authorization; requires more record keeping relating to uses/disclosures, or; otherwise provides greater privacy protections;
  - 2.1.4. State law provides for reporting of disease or injury, child abuse, birth or death, or for the conduct of public health surveillance, investigation or intervention, or;
  - 2.1.5. State law requires a health plan to report or provide access to information for management, financial, programmatic or licensure or certification audit.
- 2.2. Except as permitted or required under the privacy regulations, CEs may not use or disclose PHI without consent or authorization. CE generally is required to allow individual access to his/her PHI, and to permit Secretary of HHS access to PHI for compliance/enforcement purposes.

164.502

	<p>2.2.1. <b>Consent:</b> Allows a provider to use/disclose PHI only for treatment, payment and health care operations; written in general terms; references the CE's Notice of Privacy Practices/Privacy Notice; no specific termination</p> <p>2.2.2. <b>Authorization:</b> Allows use/disclosure of PHI for purposes beyond TPO; written in specific terms; must specify termination date/event/condition</p> <p>2.2.3. <b>Exceptions:</b> Regulations provide exceptions for such uses/disclosures as public health, oversight, law enforcement, legal process, safety, and research activities, etc. [¶ 9.]</p>
164.502(b)	2.3. CE must make reasonable efforts to provide or request only the <b>minimum PHI necessary</b> to accomplish the intended purpose of the use, disclosure or request.
164.502(f)	2.4. Protection for PHI of <b>deceased persons</b> is the same as if still living.
164.520	2.5. CE is required to provide individuals with a <b>Notice of Privacy Practices/Privacy Notice</b> that gives sufficient notice of the uses/disclosures that CE may make of PHI, and of the individual's rights and the CE's duties relating to PHI. Inmates and correctional facilities are exempted from this right/obligation.
164.528	2.6. CE is required to <b>account</b> to individual for most uses/disclosures of PHI made over a period of up to six years.
164.530	2.7. Regulations impose <b>administrative requirements</b> upon CE, including development of policies, training of workforce, and documentation.

<p><b>164.502(a)(1)</b></p>	<p><b>3. USES AND DISCLOSURES:</b></p> <p><b>3.1. Permitted Uses and Disclosures:</b> CE is permitted to use/disclose PHI:</p> <ul style="list-style-type: none"> <li>3.1.1. To the individual;</li> <li>3.1.2. Pursuant to a consent, for TPO [164.506/¶ 5.];</li> <li>3.1.3. Without consent, if consent not required under 164.506(a) [¶ 5.1.1.] and has not been requested under 164.506(a)(4) [5.1.2.], for TPO, except with respect to psychotherapy notes [¶7.1]</li> <li>3.1.4. Pursuant to an authorization [164.508/¶ 7.];</li> <li>3.1.5. Pursuant to an agreement, or as otherwise permitted by 164.510 [¶ 6.];</li> <li>3.1.6. As otherwise permitted pursuant to 164.502, 164.512, 164.514(e),(f),(g) [¶¶ 3., 9.].</li> </ul>
<p><b>164.502(a)(2)</b></p>	<p><b>3.2. Required Disclosures:</b> CE is required to disclose PHI:</p> <ul style="list-style-type: none"> <li>3.2.1. To individual pursuant to 164.524, 164.528 [¶¶ 8.1., 11.2.];</li> <li>3.2.2. When required by the Secretary of HHS to investigate or determine CE's compliance with the regulations, [¶ 12.4];</li> <li>3.2.3. When required by law, [¶¶ 9.3.through 9.6.]</li> </ul>
<p><b>164.502(j)</b></p>	<p><b>3.3. Disclosures by Whistleblowers and Workforce Member Crime Victims:</b></p> <ul style="list-style-type: none"> <li>3.3.1. CE has not violated use/disclosure restrictions if a member of its workforce or a BA discloses PHI provided that: <ul style="list-style-type: none"> <li>3.3.1.1. The workforce member or BA believes in good faith that the CE has engaged in conduct that is unlawful or otherwise violates professional or clinical standards or the care, services, or conditions provided by the CE potentially endangers one or more patients, workers or the public; and</li> <li>3.3.1.2. The disclosure is to: <ul style="list-style-type: none"> <li>3.3.1.2.1. A public health authority, health oversight agency, or healthcare accreditation organization authorized to investigate or oversee the conduct at issue, or</li> </ul> </li> </ul> </li> </ul>

164.514(e)

- 3.3.1.2.2. An attorney retained by the workforce member or BA for the purpose of determining legal options of the workforce member or BA with regard to the conduct.
- 3.3.2. CE has not violated use/disclosure restrictions if a member of the workforce who is the victim of a criminal act discloses PHI to a law enforcement officer, provided that:
  - 3.3.2.1. PHI disclosed is about the suspected perpetrator of the criminal act; and PHI disclosed is limited to the information listed in 164.512(f)(2)(i) [see ¶ 9.6.2.1.]
- 3.4. **Uses and Disclosures of PHI for Marketing:**
  - 3.4.1. CE may not use or disclose PHI for marketing without an authorization pursuant to 164.508 [¶ 7.] except:
    - 3.4.1.1. When CE uses or discloses PHI to make a marketing communication to an individual that occurs in a face to face encounter, concerns products or services of nominal value, or concerns the health related products or services of the CE or of a third party and the communication meets the applicable requirements of ¶3.4.2.
    - 3.4.1.2. CE may disclose PHI for purposes of such communications only to a BA that assists the CE with such communications.
  - 3.4.2. For a marketing communication to qualify under ¶3.4.1.1., the following conditions must be met:
    - 3.4.2.1. The communication must:
      - 3.4.2.1.1. Identify the CE as the party making the communication;
      - 3.4.2.1.2. If applicable, prominently state that the CE has received or will receive direct or indirect remuneration for making the communication; and
      - 3.4.2.1.3. Except when the communication is contained in a newsletter or similar general communication device that CE distributes to a broad cross section of people, contain instructions on how the individual may opt out of receiving future communications.
    - 3.4.2.2. If the CE uses/discloses PHI to target communication to individuals based on their health status or condition:

<p><b>164.514(f)</b></p>	<ul style="list-style-type: none"> <li>3.4.2.2.1. CE must make a determination prior to making the communication that the product or service being marketed may be beneficial to the health of the class being targeted; and</li> <li>3.4.2.2.2. The communication must explain why the individual has been targeted and how the product or service relates to his/her health.</li> <li>3.4.2.3. CE must make reasonable efforts to ensure that individuals who opt out of receiving communications pursuant to ¶ 3.4.2.1.3. are not sent such communications.</li> </ul> <p><b>3.5. Uses and Disclosures for Fundraising:</b></p> <ul style="list-style-type: none"> <li>3.5.1. CE may use or disclose to a BA or to an institutionally related foundation the following PHI for the purpose of raising funds for its own benefit without authorization pursuant to 164.508 [¶ 7.]: <ul style="list-style-type: none"> <li>3.5.1.1. Demographic information relating to individual; and</li> <li>3.5.1.2. Dates of health care provided to individual.</li> </ul> </li> <li>3.5.2. Requirements for use/disclosure for fundraising: <ul style="list-style-type: none"> <li>3.5.2.1. CE may not use/disclose PHI for fundraising purposes unless CE's privacy notice includes a statement required by 164.520(b)(1)(iii)(B) [see ¶ 4.2.3.2.]</li> <li>3.5.2.2. CE must include in any fundraising materials sent a description of how to opt out of receiving further communications.</li> <li>3.5.2.3. CE must make reasonable efforts to ensure that individuals who opt out of receiving communications are not sent such communications.</li> </ul> </li> </ul>
<p><b>164.514(g)</b></p>	<p><b>3.6. Uses and Disclosures for Underwriting and Related Purposes:</b> If a health plan receives PHI for the purpose of underwriting, premium rating, or other activities relating to the creation, renewal or replacement of a contract of health insurance or health benefits, and if such health insurance or health benefits are not placed with the health plan, such health plan may not use or disclose such PHI for any other purpose, except as required by law.</p>
<p><b>164.502(b)</b></p>	<p><b>3.7. Minimum Necessary:</b> When using or disclosing PHI or when requesting PHI from another CE, a CE must make reasonable efforts to limit PHI to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.</p>

164.502(b)(2)

164.514(d)(2)

- 3.7.1. **Minimum necessary standard does not apply to:**
  - 3.7.1.1. Disclosures to or requests by a health care provider for treatment; Uses or disclosures made to the individual, or pursuant to an authorization, except an authorization requested by the CE under 164.508(d),(e) or (f) [¶¶ 7.4., 7.5., 7.6.];
  - 3.7.1.2. Disclosures made to the Secretary of HHS re: compliance and enforcement;
  - 3.7.1.3. Uses/disclosures required by law under 164.512(a) [¶ 9.3.], and;
  - 3.7.1.4. Uses/disclosures required for compliance with applicable parts of the privacy regulations.
- 3.7.2. Implementing standard for **minimum necessary uses** of PHI:
  - 3.7.2.1. CE must identify those persons or classes of persons, as appropriate, in its workforce who need access to PHI to carry out their duties; and
  - 3.7.2.2. For each such person or class of persons, the category or categories of PHI to which access is needed and any conditions appropriate to such access.
  - 3.7.2.3. CE must make reasonable efforts to limit the access of such persons or classes identified above to PHI consistent with the categories described above.

3.7.3. Implementing standard for **minimum necessary disclosures** of PHI:

- 3.7.3.1. For any type of disclosure that it makes on a routine and recurring basis, a CE must implement policies and procedures (which may be standard protocols) that limit the PHI disclosed to the amount reasonably necessary to achieve the purpose of the disclosure. For all other disclosures, a CE must: develop criteria designed to limit the PHI disclosed to the information reasonably necessary to accomplish the purpose for which disclosure is sought, and; review requests for disclosure on an individual basis in accordance with such criteria.
- 3.7.3.2. CE may rely, if such reliance is reasonable under the circumstances, on a requested disclosure as the minimum necessary for the stated purpose when:
  - 3.7.3.2.1. Making disclosures to public officials that are permitted under 164.512 [¶ 9.], if the public official represents that the information requested is the minimum necessary for the stated purpose(s);
  - 3.7.3.2.2. The information is requested by another CE;
  - 3.7.3.2.3. The information is requested by a professional who is a member of its workforce or is a business associate of the CE for the purpose of providing professional services to the CE, if the professional represents that the information requested is the minimum necessary for the stated purpose(s); or
  - 3.7.3.2.4. Documentation or representations that comply with the applicable requirements of 164.512(i) [¶ 9.8.] have been provided by a person requesting the information for research purposes.

164.514(d)(4)

3.7.4. Implementing standard for **minimum necessary requests** for PHI:

3.7.4.1. CE must limit any request for PHI to that which is reasonably necessary to accomplish the purpose for which the request is made, when requesting such information from other CEs;

3.7.4.2. For a request that is made on a routine and recurring basis, CE must implement policies and procedures (which may be standard protocols) that limit the PHI requested to the amount reasonably necessary to accomplish the purpose for which the request is made;

3.7.4.3. For all other requests, CE must review the request on an individual basis to determine that the PHI sought is limited to the information reasonably necessary to accomplish the purpose for which the request is made.

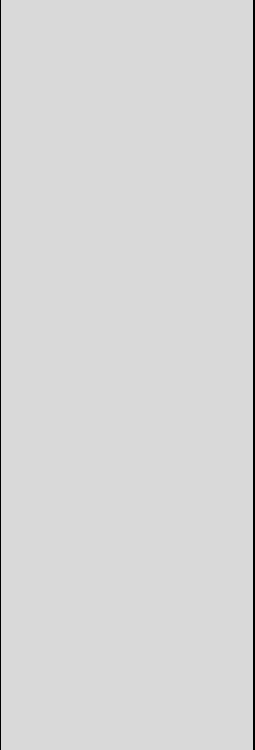
164.514(d)(5)

3.7.5. Requests for the **entire record**: For all uses, disclosures, or requests to which the requirements of ¶ 3.7. apply, a CE may not use, disclose or request an entire medical record, except when the entire medical record is specifically justified as the amount that is reasonably necessary to accomplish the purpose of the use, disclosure, or request.

164.502(f)

3.8. **PHI of Deceased Individuals**: CE must comply with requirements of the privacy regulations with respect to PHI of deceased individuals.

- 3.9. **Personal Representatives:** Except as provided in ¶¶ 3.9.2. and 3.9.4., CE must treat a personal representative as the individual.
  - 3.9.1. **Adults and emancipated minors:** If under applicable law, a person has authority to act on behalf of an adult or emancipated minor in making health care decisions, CE must treat the person as a personal representative with respect to PHI relevant to such representation.
  - 3.9.2. **Unemancipated minors:** If under applicable law, a parent, guardian, or other person acting in *loco parentis* , has authority to act on behalf of an unemancipated minor in making health care decisions, CE must treat the person as a personal representative with respect to PHI relevant to such representation, except that person may not be a personal representative and the minor may act as an individual with respect to PHI pertaining to health care if:
    - 3.9.2.1. Minor consents to such health care services, and no other consent is required by law (regardless of whether another person's consent has been obtained), and the minor has not requested that an other person to be treated as the personal representative;
    - 3.9.2.2. Minor may lawfully obtain health care service without consent of parent, guardian, or other person acting *in loco parentis* and consent (by the minor, or court, or another legally authorized person) has been obtained;
    - 3.9.2.3. Parent, guardian, or other person acting *in loco parentis* assents to an agreement of confidentiality between health care provider and the minor.

- 
- 3.9.3. **Deceased individuals:** If under applicable law, an executor, administrator, or other person has authority to act on behalf of a deceased individual or his/her estate, CE must treat the person as a personal representative with respect to PHI relevant to such representation.
  - 3.9.4. Abuse, neglect, and endangerment situations: Notwithstanding a state law or any requirement of ¶ 3.9.4 to the contrary, CE may elect not to treat a person as a personal representative of an individual if:
    - 3.9.4.1. CE has reasonable belief that individual has been or may be subjected to domestic violence, abuse or neglect by such person, or treating such person as the personal representative could endanger the individual, and
    - 3.9.4.2. CE, in exercise of professional judgment, decides it is not in the best interest of the individual to treat the person as the personal representative.

164.514(a)

164.514(b)

3.10. **De-identification of PHI:**

3.10.1. Health information that does not identify an individual and with respect to which there is no reasonable basis to believe that such information can be used to identify an individual is not individually identifiable health information.

3.10.2. Requirements for de-identification of PHI: CE may determine that health information is not individually identifiable health information only if:

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

3.10.2.1.1. Applies these principles and methods and 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

3.10.2.1.2. Documents the methods and results of the analysis that justify such determination;

**or**

3.10.2.2. The following identifiers of the individual or of relatives, employers, or household members of the individual, are removed, and the CE does not have actual knowledge that the information could be used alone, or in combination with other information to identify an individual who is the subject of the information:

- 3.10.2.2.1.Names;
- 3.10.2.2.2.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: (i) the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (ii) the initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000;
- 3.10.2.2.3.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;
- 3.10.2.2.4.Telephone numbers;
- 3.10.2.2.5.Fax numbers;
- 3.10.2.2.6.Electronic mail addresses;
- 3.10.2.2.7.Social security numbers;
- 3.10.2.2.8.Medical record numbers;
- 3.10.2.2.9.Health plan beneficiary numbers;
- 3.10.2.2.10.Account numbers;
- 3.10.2.2.11.Certificate/license numbers;
- 3.10.2.2.12.Vehicle identifiers and serial numbers, including license plate numbers;
- 3.10.2.2.13.Device identifiers and serial numbers;
- 3.10.2.2.14.Web Universal Resource Locators (URLs);
- 3.10.2.2.15.Internet Protocol (IP) address numbers;
- 3.10.2.2.16.Biometric identifiers, including finger and voice prints;
- 3.10.2.2.17.Full face photographic images and any comparable images; and
- 3.10.2.2.18.Any other unique identifying number, characteristic, or code; and

164.514(c)

- 3.10.3. **Re-identification:** CE may assign a code or other means of record identification to allow information de-identified under this section to be re-identified by the CE, provided that:
  - 3.10.3.1. 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
  - 3.10.3.2. CE does not use or disclose the code or other means of record identification for any other purpose, and does not disclose the mechanism for re-identification.

164.520

164.520(a)

4. **NOTICE OF PRIVACY PRACTICES/PRIVACY NOTICE:**

- 4.1. **Notice to Individuals Required:** An individual has a right to adequate notice of: the uses and disclosures of PHI that may be made by the CE, and; of the individual's rights and the CE's duties with respect to PHI except:
- 4.1.1. An inmate has no right to notice and these notice provisions do not apply to a correctional institution.
  - 4.1.2. An individual enrolled in a Group Health Plan (GHP) has a right to notice:
    - 4.1.2.1. From the GHP if the individual does not receive health benefits under the GHP through an insurance contract with a health insurance issuer or HMO; or
    - 4.1.2.2. From a health insurance issuer or HMO with respect to the GHP through which such individual receives his/her health benefits.
  - 4.1.3. A GHP that provides health benefits solely through an insurance contract with a health insurance issuer or HMO and that creates or receives PHI or information on whether an individual is participating in the GHP, or is enrolled or has disenrolled from a health insurance issuer or HMO offered by the plan must:
    - 4.1.3.1. Maintain a notice; and
    - 4.1.3.2. Provide notice to any person upon request.
  - 4.1.4. A GHP that provides health benefits solely through an insurance contract with a health insurance issuer or HMO and does not create or receive PHI other than summary health information or information on whether an individual is participating in the GHP or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan is not required to maintain or provide the notice.

164.520(b)(1)

- 4.2. **Content of Notice:** Notice must be written in plain language and contain the following elements:
- 4.2.1. The following **statement must be displayed** as a header or otherwise prominently: “THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.”
- 4.2.2. **Uses and Disclosures:** notice must contain:
- 4.2.2.1. A description, including at least one example, of the types of uses and disclosures the CE is permitted to make for purposes of TPO;
- 4.2.2.2. A description of each of the other purposes the CE is permitted or required to use or disclose PHI without an individual’s consent or authorization;
- 4.2.2.3. Descriptions of uses and disclosures must reflect more stringent law, if applicable;
- 4.2.2.4. Descriptions must contain sufficient detail to place an individual on notice of the uses and disclosures permitted or required;
- 4.2.2.5. A statement that other uses or disclosures will be made only with the individual’s written authorization and the individual may revoke such authorization as provided by 164.508(b)(5) [¶ 7.2.6.];
- 4.2.3. **Separate Statement for Certain Uses or Disclosures Required:** If CE intends to engage in any of the following activities, the description of uses/disclosures for TPO must include a statement, as applicable, that:
- 4.2.3.1. CE may contact individual for appointment reminders, information about treatment alternatives or other health benefits that may be of interest to the individual;
- 4.2.3.2. CE may contact individual to raise funds for the CE; or
- 4.2.3.3. A GHP, or a health insurance issuer or HMO with respect to a GHP, may disclose PHI to the sponsor of the plan.

- 4.2.4. **Individual Rights:** Must include a statement of the individual's rights with respect to the PHI and a brief description of how to exercise those rights, as follows:
- 4.2.4.1. Right to request restriction on certain uses/disclosures pursuant to 164.522(a) [¶ 8.2.1.], and statement CE not required to agree to restriction;
  - 4.2.4.2. Right to receive confidential communications of PHI pursuant to 164.522(b) [¶ 8.2.2.];
  - 4.2.4.3. Right to inspect and copy PHI pursuant to 164.524 [¶ 8.1.1.];
  - 4.2.4.4. Right to amend PHI pursuant to 164.526 [¶ 8.3.];
  - 4.2.4.5. Right to receive accounting of disclosures pursuant to 164.528 [¶ 11.2.]; and
  - 4.2.4.6. Right to obtain paper copy of the notice upon request.
- 4.2.5. **CE's Duties:** Notice must contain:
- 4.2.5.1. Statement that CE is required by law to maintain privacy of PHI and to provide individuals with notice of its legal duties and privacy policies with respect to PHI;
  - 4.2.5.2. Statement that CE is required to abide by the terms of the notice currently in effect; and
  - 4.2.5.3. For a CE to apply a change in a privacy practice described in the notice affecting PHI created or received prior to issuing a revised notice, a statement that the CE reserves the right to change terms of its notice and to make new notice provisions effective for all PHI that it maintains, and a description of how it will provide individuals with the revised notice.
- 4.2.6. **Complaints:** Notice must contain a statement that individuals may complain to the CE and to the Secretary of HHS about privacy rights violations, describe how the individual may file a complaint with the CE, and a statement that the individual will not be retaliated against for filing a complaint.
- 4.2.7. **Contact:** Notice must contain name, or title, and telephone number of person or office to contact for further information [¶ 11.3.1.2.];
- 4.2.8. **Effective date:** Notice must contain the date on which notice is first effective, which may not be earlier than date printed or published.

164.520(b)(2)	4.2.9. <b>Optional Elements for Notice:</b> If CE elects to limit the uses/disclosures that it is permitted to make under the regulations, the CE may describe its more limited uses/disclosures in its notice, but may not include a limitation affecting its right to make a use/disclosure required by law or permitted under 164.512(j)(1)(i) [¶ 9.7.]. In order for a CE to apply a change to its more limited uses/disclosures to PHI received prior to issuance of a new notice, the notice must include the statement permitting the CE to revise the notice as set forth in ¶ 4.2.5.3.
164.520(b)(3)	4.2.10. <b>Revisions to Notice:</b> CE must promptly revise and distribute its notice whenever there is a material change to the uses/disclosures, the individual's rights, the CE's legal duties, or other privacy practices stated in the notice. Except when required by law, a material change to any term may not be implemented prior to the effective date of the notice reflecting the change[¶4.2.8].
164.520(c)	4.3. <b>Provision of Notice:</b> CE must make the notice available on request to any person and to individuals specified hereunder, as applicable.
164.520(c)(1)	4.3.1. <b>Health plans (not including group health plans described in ¶4.1.3):</b> 4.3.1.1. Must provide notice: 4.3.1.1.1. No later than the compliance date for the health plan, to individuals then covered by the plan; 4.3.1.1.2. Thereafter, at the time of enrollment, to individuals who are new enrollees; and 4.3.1.1.3. Within sixty (60) days of a material revision of the notice to individuals then covered by the plan. 4.3.1.2. No less frequently than once every three years, the health plan must notify individuals then covered by the plan of the availability of the notice and how to obtain the notice. 4.3.1.3. Health plan satisfies ¶ 4.3.1.1. by providing notice to the named insured of policy under which coverage is provided to the named insured and dependent(s). 4.3.1.4. If health plan has more than one notice, ¶ 4.3.1.1. is met by providing the notice relevant to the insured.

164.520(c)(2)

4.3.2. **Providers with a direct treatment relationship with individual** must:

- 4.3.2.1. Provide notice no later than the first service delivery, including electronically delivered services, after the compliance date;
- 4.3.2.2. If provider maintains a physical delivery site:
  - 4.3.2.2.1. Have notice available at delivery site for individuals to request to take with them;
  - 4.3.2.2.2. Post notice in a clear and prominent location where it is reasonable to expect individuals seeking service to be able to read it; and
- 4.3.2.3. Upon revision of the notice, make it available upon request on or after the effective date and promptly comply with ¶ 4.3.2.2., if applicable.

164.520(c)(3)

4.3.3. Requirements Specific to **Electronic Notice**:

- 4.3.3.1. CE that maintains a web site providing information about the CE's customer services or benefits must prominently post its notice on the web site and make it available electronically through the web site.
- 4.3.3.2. CE may provide notice to an individual by email if the individual agrees to electronic notice and such agreement has not been withdrawn. If CE knows that email transmission has failed, a paper copy of notice must be provided to the individual. Provision of electronic notice is timely when it complies with ¶¶ 4.3.1. or 4.3.2.
- 4.3.3.3. If first service delivery to individual is electronic, provider must provide notice automatically and contemporaneously in response to individual's first request for service.
- 4.3.3.4. Individual who receives electronic notice retains right to obtain paper copy upon request.

164.520(d)

- 4.4. **Joint notice by separate CEs:** CEs that participate in an organized health care arrangement [¶ 10.1.5.] may provide joint notice provided that:
  - 4.4.1. CEs involved agree to abide by the terms of the notice as part of participation in the organized health care arrangement;
  - 4.4.2. Joint notice meets the requirements of ¶ 4.2. , except that statements may reflect that notice covers more than one entity; and
    - 4.4.2.1. Describes with reasonable specificity the CEs, or class of entities, to which the joint notice applies;
    - 4.4.2.2. Describes with reasonable specificity the service delivery sites, or classes of service delivery sites, to which the joint notice applies;
    - 4.4.2.3. If applicable, states that the participating CEs will share PHI with each other, as necessary, to carry out TPO
  - 4.4.3. Participating CEs must provide notice to individuals in accordance with applicable specifications in ¶ 4.3. Provision of the joint notice to an individual by any one of the participating CEs will satisfy the provisions of ¶ 4.3. with respect to all other participating CEs.
  
- 4.5. **Documentation:** CE must document compliance with notice requirements by retaining copies of notices issued as required by 164.530(j). [¶11.3.10.]

164.506

164.506(a)

5. **CONSENT:**

- 5.1. **Consent Requirement:** Generally, a provider must obtain consent to use/disclose PHI for TPO purposes.
- 5.1.1. Covered health care provider must obtain individual's consent prior to using or disclosing PHI to carry out TPO, except:
- 5.1.1.1. Covered health care provider may use/disclose PHI for TPO without consent if:
- 5.1.1.1.1. Covered health care provider has an indirect treatment relationship with the individual; or
- 5.1.1.1.2. Covered health care provider created or received PHI in course of providing health care to inmate.
- 5.1.1.2. Covered health care provider may use/disclose PHI for TPO without prior consent in the following situations. If unable to obtain consent, provider must document attempts to obtain consent and reason not obtained:
- 5.1.1.2.1. In emergency treatment situations if provider attempts to obtain consent as soon as reasonably practicable after delivery of treatment;
- 5.1.1.2.2. If provider required by law to treat the individual and provider attempts, unsuccessfully, to obtain consent; or
- 5.1.1.2.3. Provider attempts to obtain consent, but is unable to do so because of substantial barriers to communication, and provider determines, in exercise of professional judgment, that individual's consent is clearly inferred from the circumstances.
- 5.1.2. If CE is not required to obtain consent, it may obtain consent for CE's own use/disclosure of PHI to carry out TPO, provided the consent meets the requirements of ¶ 5.
- 5.1.3. Except pursuant to joint consent under ¶ 5.6., a consent obtained by a CE is not effective to permit another CE to use/disclose PHI.

**164.506(b)**

- 5.2. **General Rules for Implementation:**
- 5.2.1. Covered health care provider may condition treatment on attaining individual's consent.
  - 5.2.2. Health plan may condition enrollment on attaining individual's consent sought in conjunction with enrollment.
  - 5.2.3. Consents for uses and disclosures of PHI may be combined with other types of written legal permission from the individual, including research authorization relating to PHI created for research that includes treatment of the individual (but not the privacy notice required by 164.520/¶ 4.) if consent:
    - 5.2.3.1. Is visually and organizationally separate;
    - 5.2.3.2. Is separately signed and dated.
  - 5.2.4. Individual may revoke consent at any time, in writing, except to the extent that CE has acted in reliance thereon.
  - 5.2.5. CE must document and retain signed consent for six years from last effective date (¶ 11.3.10).

**164.506(c)**

- 5.3. **Content requirements:** Consent must be in plain language and:
- 5.3.1. Inform the individual that the PHI may be used and disclosed to carry out TPO;
  - 5.3.2. Refer to the privacy notice for additional information about the uses and disclosures and state that the individual has the right to review the notice prior to signing the consent (¶4);
  - 5.3.3. If CE reserved the right to change its privacy practices in its notice (¶4.2.5.3), indicate that terms of the notice may change and must describe how the individual may obtain a revised notice;
  - 5.3.4. State that the individual has a right to request restrictions on uses and disclosures of PHI for TPO, that the CE is not required to agree to an individual's request but, if CE agrees to restriction, CE is bound by it (¶8.2.1);
  - 5.3.5. State that the individual has the right to revoke the consent in writing, to the extent CE has not already acted in reliance upon it;
  - 5.3.6. Be signed by the individual and dated.

**164.506(d)**

- 5.4. There is **no consent** if writing lacks a required element under ¶ 5.3. or has been revoked in accordance with ¶ 5.2.4.

164.506(e)

- 5.5. **Resolving Conflicting Consents and Authorizations:**
- 5.5.1. When the terms of a CE's consent conflict (are inconsistent) with the terms of another written legal permission from the individual for the CE to use or disclose PHI, the CE must adhere to the more restrictive document.
- 5.5.2. CE may resolve the conflict between consent and other written legal documents by:
- 5.5.2.1. Obtaining a new consent, or;
- 5.5.2.2. Communicating orally or in writing with the individual to determine his/her preference in resolving the conflict; CE must document the individual's preference, and act in accordance with it.

164.506(f)

- 5.6. **Joint Consent:**
- 5.6.1. CEs participating in an organized health care arrangement [¶ 10.1.5.] and having a joint privacy notice under 164.520(d)/¶ 4.4., may use a joint consent.
- 5.6.2. Joint Consent Requirements: a joint consent must:
- 5.6.2.1. Identify CEs, or class of CEs, to which joint consent applies, and
- 5.6.2.2. Meet requirements of ¶ 5., though statements may be modified to reflect that consent covers multiple CEs
- 5.6.3. If individual revokes joint consent, CE that receives the revocation must inform other CEs covered by the joint consent as soon as practicable.

164.510	<p>6. <b>USES/DISCLOSURES REQUIRING OPPORTUNITY TO AGREE OR TO OBJECT:</b> CE may use/disclose PHI without written consent or authorization in the following situations provided the individual is informed in advance and has the opportunity to agree to or to prohibit or restrict the disclosure in accordance with the requirements of ¶ 6. CE may orally inform the individual of and obtain oral agreement or objection to a use/disclosure under ¶ 6.:</p>
164.510(a)(1)	<p>6.1. <b>Facility Directories:</b> Except when an objection is expressed pursuant to ¶¶ 6.1.2. or 6.1.3., provider may:</p> <p>6.1.1. Use the following PHI to maintain a directory for its facility, and disclose the information to clergy, and (except religious affiliation) to persons who ask for the individual by name:</p> <p>6.1.1.1. Individual's name;</p> <p>6.1.1.2. Individual's location within the facility;</p> <p>6.1.1.3. Individual's condition, in general terms, that does not communicate specific medical information, and</p> <p>6.1.1.4. Individual's religious affiliation.</p>
164.510(a)(2)	<p>6.1.2. Opportunity to object: Provider must inform an individual of the PHI it may include in the directory and the persons to whom the PHI may be released and provide the individual with the opportunity to prohibit or restrict some or all of such uses/disclosures as permitted in ¶6.1.</p>
164.510(a)(3)	<p>6.1.3. Emergency circumstances: If, due to individual's incapacity or an emergency treatment circumstance, the provider cannot, practicably provide the individual an opportunity to object to the use/disclosure of directory PHI, the provider may use or disclose some or all of the directory PHI if disclosure is:</p> <p>6.1.3.1. Consistent with individual's prior expressed preference, if any, that is known to the provider; and</p> <p>6.1.3.2. In the best interest of the individual, as determined by the provider, exercising professional judgment.</p> <p>6.1.3.3. Provider must inform the individual and provide the individual an opportunity to object to uses or disclosures when it becomes practicable to do so.</p>

<b>164.510(b)</b>	6.2. <b>Uses/Disclosures to Those Involved in Individual's Care, or for Notification Purposes:</b>
<b>164.510(b)(1)</b>	6.2.1. Permitted uses/disclosures: <ul style="list-style-type: none"> <li data-bbox="776 296 1521 527">6.2.1.1. CE may, in accordance with ¶¶ 6.2.2. and 6.2.3., disclose to a family member, other relative, close personal friend of the individual, or any other person identified by individual, the PHI directly relevant to such person's involvement with or payment related to the individual's health care;</li> <li data-bbox="776 527 1521 787">6.2.1.2. CE may, in accordance with ¶¶ 6.2.2., 6.2.3., and 6.2.4., use/disclose PHI to notify or assist (including identifying and locating) in the notification of a family member, personal representative, or another person responsible for care of the individual, of the individual's location, general condition, or death.</li> </ul>
<b>164.510(b)(2)</b>	6.2.2. If individual is present or available (prior to use/disclosure), and has capacity to make health care decisions, CE may use/disclose PHI if it: <ul style="list-style-type: none"> <li data-bbox="776 905 1328 936">6.2.2.1. Obtains individual's agreement;</li> <li data-bbox="776 936 1521 1003">6.2.2.2. Provides individual with opportunity to object and individual does not object; or</li> <li data-bbox="776 1003 1521 1102">6.2.2.3. CE, in exercise of professional judgment, reasonably infers from the circumstances that the individual does not object.</li> </ul>
<b>164.510(b)(3)</b>	6.2.3. If individual is not present, or opportunity to agree or object cannot practicably be provided due to incapacity or emergency circumstance, CE may, in exercise of professional judgment, determine whether disclosure is in the best interests of individual, and, if so, disclose only PHI that is directly relevant to person's involvement with individual's health care, including picking up filled prescriptions, x-rays, medical supplies, or other similar forms of PHI.
<b>164.510(b)(4)</b>	6.2.4. CE may use/disclose PHI to public or private entity authorized by law or by its charter to assist in disaster relief efforts, for purpose of coordinating with such entities the uses or disclosures permitted by ¶ 6.2.1.2. The requirements of ¶¶ 6.2.2. and 6.2.3. apply to such uses/disclosures to extent that CE, in exercise of professional judgment, determines that the requirements do not interfere with the ability to respond to the emergency circumstances.

164.508

164.508(a)(1)

164.508(a)(2)

164.508(b)

**7. AUTHORIZATION:**

7.1. **Authorization Requirement:** Except as otherwise permitted or required under the privacy regulations, CE may not use or disclose PHI without a valid authorization, and may only use/disclose PHI consistent with such authorization.

7.1.1. Psychotherapy notes: CE must obtain authorization for any use/disclosure of psychotherapy notes, except:

7.1.1.1. For the following TPO, consistent with consent requirements in ¶ 5:

7.1.1.1.1. Use by originator of notes for treatment;

7.1.1.1.2. Use/disclosure by CE for conducting counseling training programs; or

7.1.1.1.3. Use/disclosure by CE to defend a legal action or other proceeding brought by the individual; and

7.1.1.2. Use/disclosure: to Secretary of HHS regarding compliance; as required by law; for health oversight activities with respect to the oversight of the originator of notes; to coroners and medical examiners, or; to avert serious threat to health or safety.

7.2. **General Requirements for Authorization:**

7.2.1. Must contain elements specified in ¶ 7.3., and as applicable, ¶¶ 7.4 - 7.6.;

7.2.2. May contain additional elements or information, provided they are not inconsistent with required elements;

7.2.3. Authorizations with following defects are not valid:

7.2.3.1. Expired date, or expiration event known by CE to have occurred;

7.2.3.2. Missing required element or missing or incompletely filled out required element;

7.2.3.3. Known by CE to have been revoked;

7.2.3.4. Compound authorization that violates ¶ 7.2.4.;

7.2.3.5. Authorization is known by CE to contain false material information.

164.508(b)(3)

7.2.4. **Compound authorizations:** Authorization may not be combined with any other document, including any other written legal permission from the individual, except as follows:

7.2.4.1. Authorization for use/disclosure of PHI created for research that includes treatment of the individual may be combined with consent to participate in research, consent for use/disclosure of PHI for TPO, and/or the privacy notice. [see ¶ 7.6.2.]

7.2.4.2. Authorization for use/disclosure of psychotherapy notes may only be combined with another authorization for use or disclosure of psychotherapy notes.

7.2.4.3. Authorizations other than for use or disclosure of psychotherapy notes may be combined with any other such authorization, provided that the CE has not conditioned the provision of treatment, payment, enrollment in health plan, or eligibility for benefits on obtaining the authorization.

164.508(b)(4)

7.2.5. CE may not condition provision of treatment, payment, enrollment in health plan, or eligibility for benefits on provision of authorization except:

7.2.5.1. Provider may condition provision of research-related treatment;

7.2.5.2. Health plan may condition eligibility for benefits and enrollment in the health plan if authorization sought for its underwriting or risk-rating determinations and is not for use or disclosure of psychotherapy notes;

7.2.5.3. Health plan may condition payment of a claim for specified benefits if disclosure is sought from another CE, is necessary to determine payment, and authorization is not for use or disclosure of psychotherapy notes;

7.2.5.4. CE may condition the provision of health care for the sole purpose of creating PHI for disclosure to a third party upon authorization for disclosure to the third party.

164.508(b)(5)

164.508(b)(6)

164.508(c)

7.2.6. **Revocation:** An individual may revoke an authorization at any time, in writing, except to the extent that CE has taken action in reliance thereon, or if authorization was obtained as a condition of obtaining insurance coverage and other law provides insurer right to contest claim under the policy.

7.2.7. **Documentation:** CE must document and retain signed authorizations for period of six years from last effective date. [¶ 11.3.10.]

7.3. **Core Elements and Requirements:**

7.3.1. Description of the information to be used or disclosed, with sufficient specificity;

7.3.2. Name of the person(s) or class of persons authorized to use or disclose the PHI;

7.3.3. Name of the person(s) or class of persons to whom the CE is authorized to make the use or disclosure;

7.3.4. Expiration date or an expiration event that relates to the individual or the purpose of the use/disclosure;

7.3.5. Statement of the individual's right to revoke authorization in writing and exceptions thereto, with description of how to revoke;

7.3.6. Statement that information used or disclosed may be subject to re-disclosure by the recipient and may no longer be protected by this rule;

7.3.7. Signature of individual and date;

7.3.8. If signed by personal representative, a description of the representative's authority to act for the individual;

7.3.9. Must be written in plain language.

164.508(d)

- 7.4. **Additional elements required if CE seeks authorization for its own use or disclosure:** If the authorization is sought by CE for its own uses/disclosures of PHI that it maintains, authorization must include following elements in addition to those specified in ¶ 7.3.:
- 7.4.1. For any authorization to which the prohibition of ¶ 7.2.5. applies, a statement that treatment, payment, enrollment in health plan, or eligibility for benefits will not be conditioned by the CE on the individual's grant of authorization;
  - 7.4.2. Description of each purpose of the requested use or disclosure;
  - 7.4.3. State that the individual may inspect or copy the PHI to be used or disclosed as provided in 164.524 [see ¶ 8.1.];
  - 7.4.4. State that the individual may refuse to sign the authorization;
  - 7.4.5. State any remuneration to CE resulting from use or disclosure, if applicable.
  - 7.4.6. CE must provide individual with copy of the signed authorization.

164.508(e)

- 7.5. **Additional elements required if CE seeks authorization for disclosures to it by another CE:** If authorization is sought by CE for another CE to disclose PHI for TPO, the CE requesting the authorization must include the following elements in addition to those specified in ¶ 7.3.:
- 7.5.1. Description of each purpose of the requested disclosure;
  - 7.5.2. For any authorization to which the prohibition of ¶ 7.2.5. applies, a statement that treatment, payment, enrollment in health plan, or eligibility for benefits will not be conditioned on the individual's grant of authorization;
  - 7.5.3. Statement that individual may refuse to sign the authorization.
  - 7.5.4. CE must provide individual with copy of the signed authorization.

164.508(f)

- 7.6. **Authorizations for Use or Disclosure of PHI Created for Research that Includes Treatment of the Individual:**
- 7.6.1. Required Elements: Except as permitted under 164.512(i) [¶ 9.8.], CE that creates PHI for purpose, in whole or part, of research that includes treatment of individual must obtain authorization for use/disclosure of the PHI. Such authorization must meet requirements of ¶¶ 7.3. and 7.4., and contain:
- 7.6.1.1. Description of extent to which PHI will be used or disclosed for TPO;
  - 7.6.1.2. Description of any PHI that will not be used or disclosed for purposes permitted under 164.510 and 164.512 [¶¶ 6. and 9.], though CE may not limit its use/disclosures required by law or as necessary to avert serious, imminent threat to health and safety;
  - 7.6.1.3. If consent obtained or to be obtained, or privacy notice given or to be given, the authorization must refer to the consent [164.506/¶ 5.] or privacy notice [(164.520/¶ 4.)], and state that statements made pursuant to ¶ 7. are binding.
- 7.6.2. Optional Procedure: Authorization under ¶ 7.6. may be included in the same document as:
- 7.6.2.1. Consent to participate in research;
  - 7.6.2.2. Consent to use/disclose PHI for TPO [164.506/¶ 5.]; or
  - 7.6.2.3. Notice of privacy practices. [164.520/¶ 4.]

164.524  
164.524(a)(1)

164.524(a)(2)

## 8. INDIVIDUAL'S RIGHTS RELATED TO PHI:

### 8.1. Access of Individuals to PHI:

8.1.1. **Right of access:** An individual has a right of access to inspect and obtain a copy of PHI about the individual in a designated record set, for as long as the PHI is maintained in the designated record set, except for:

8.1.1.1. Psychotherapy notes;

8.1.1.2. Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding; and

8.1.1.3. PHI maintained by a CE that is: subject to the Clinical Laboratory Improvements Amendments of 1988 (CLIA), to the extent the provision of access to the individual would be prohibited by law; or exempt from CLIA.

8.1.2. **Denial of right of access without right of review:** A CE may deny an individual access without providing the individual an opportunity for review, in the following circumstances:

8.1.2.1. The PHI is excepted from the right of access [¶ 8.1.1.];

8.1.2.2. CE that is a correctional institution or a covered health care provider acting under the direction of the correctional institution may deny, in whole or in part, an inmate's request to obtain a copy of PHI, if obtaining such copy would jeopardize the health, safety, security, custody, or rehabilitation of the individual or of other inmates, or the safety of any officer, employee, or other person at the correctional institution or responsible for the transporting of the inmate;

164.524(a)(3)

- 8.1.2.3. An individual's access to PHI created or obtained by a covered health care provider in the course of research that includes treatment may be suspended while the research is in progress if the individual agreed to the denial of access when consenting to participate in the research, and the provider informed the individual that right of access will be reinstated upon completion of the research;
  - 8.1.2.4. An individual's access to PHI contained in records subject to the Privacy Act (5 U.S.C. 552a) may be denied in accordance with the requirements of the Act;
  - 8.1.2.5. The PHI was obtained from someone other than a health care provider under a promise of confidentiality and the access requested would be reasonably likely to reveal the source of the information.
- 8.1.3. **Denial of right of access with right of review.** CE may deny an individual access, provided that the individual is given a right to have such denials reviewed, in the following circumstances:
- 8.1.3.1. A licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to endanger the life or physical safety of the individual or another person;
  - 8.1.3.2. The PHI makes reference to another person (not a health care provider) and a licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to cause substantial harm to such other person, or;
  - 8.1.3.3. The request for access is made by the individual's personal representative and a The PHI makes reference to another person (not a health care provider) and a licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to cause substantial harm to the individual or another person.

164.524(a)(4);  
164.524(d)(4)

164.524(b)

8.1.3.4. If access is denied based on one of the grounds set forth in ¶¶ 8.1.3.1. to 8.1.3.3., the individual has the right to have the denial reviewed by a licensed health care professional, designated by the covered entity to act as a reviewing official, who did not participate in the original decision to deny. The covered entity must promptly refer a request for review to the reviewing official, who must then determine, within a reasonable period of time, whether or not to deny the access requested based on the grounds set forth above. The covered entity must promptly provide written notice to the individual of the reviewing official's determination, and must provide or deny access in accordance with the determination.

8.1.4. **Requests for access; timely action:**

8.1.4.1. CE must permit an individual to request access to inspect or to obtain a copy of the PHI about the individual that is maintained in a designated record set. CE may require individuals to make requests for access in writing, provided that it informs individuals of such a requirement.

8.1.4.2. CE must act on a request for access no later than 30 days after receipt of the request as follows:

8.1.4.2.1. If CE grants the request, in whole or in part, it must inform the individual of the acceptance of the request and provide the access requested, as set forth in ¶ 8.1.5.;

8.1.4.2.2. If the CE denies the request, in whole or in part, it must provide the individual with a written denial, as set forth in ¶ 8.1.6.

164.524(c)

- 8.1.4.3. If the request for access is for PHI that is not maintained or accessible to the CE on-site, the CE must act on the request no later than 60 days from the receipt of the request.
- 8.1.4.4. If the CE is unable to act on the request within the appropriate time limit (30 or 60 days, as applicable), the CE may extend the time for such actions by no more than 30 days, provided that the CE, within the appropriate time limit, as applicable, provides the individual with a written statement of the reasons for the delay and the date by which the CE will complete its action on the request. The CE may have only one such extension of time for action on a request for access.
- 8.1.5. **Provision of access:**
  - 8.1.5.1. CE must provide the access requested by individuals, including inspection or obtaining a copy, or both, of the PHI about them in designated record sets. If the same PHI that is the subject of a request for access is maintained in more than one designated record set or at more than one location, the CE need only produce the PHI once in response to a request for access.
  - 8.1.5.2. CE must provide the individual with access to the PHI in the form or format requested by the individual, if it is readily producible in such form or format; or, if not, in a readable hard copy form or such other form or format as agreed to by the CE and the individual.

- 8.1.5.3. CE may provide the individual with a summary of the PHI requested, in lieu of providing access to the PHI or may provide an explanation of the PHI to which access has been provided, if:
  - 8.1.5.3.1. The individual agrees in advance to such a summary or explanation; and
  - 8.1.5.3.2. The individual agrees in advance to the fees imposed, if any, by the CE for such summary or explanation.
- 8.1.5.4. CE must provide the access as requested by the individual in a timely manner, including arranging with the individual for a convenient time and place to inspect or obtain a copy of the PHI, or mailing the copy of the PHI at the individual's request.
- 8.1.5.5. If the individual requests a copy of the PHI or agrees to a summary or explanation of such information, the CE may impose a reasonable, cost-based fee, provided that the fee includes only the cost of:
  - 8.1.5.5.1. Copying, including the cost of supplies and labor;
  - 8.1.5.5.2. Postage; and
  - 8.1.5.5.3. Preparing an explanation or summary of the PHI, if agreed to by the individual.

164.524(d)

8.1.6. **Denial of access:**

- 8.1.6.1. CE must provide a timely, written denial to the individual. The denial must be in plain language and must contain:
  - 8.1.6.1.1. The basis for the denial;
  - 8.1.6.1.2. If applicable, a statement of the individual's right to have the denial reviewed, including a description of how the individual may exercise such right; and
  - 8.1.6.1.3. A description of how the individual may complain to the covered entity (pursuant to the complaint procedures set forth in ¶ 11.3.4. or to the Secretary of HHS pursuant to ¶ 12.2. The description must include the name, or title, and telephone number of the contact person or office designated in ¶ 11.3.1.2..
- 8.1.6.2. CE must, to the extent possible, give the individual access to any other PHI requested, after excluding the PHI as to which the CE has a ground to deny access.
- 8.1.6.3. If the CE does not maintain the PHI that is the subject of the individual's request for access, and the CE knows where the requested information is maintained, the CE must inform the individual where to direct the request for access.

164.524(e)

- 8.1.7. **Documentation:** CE must document the following and retain the documentation for six years from the date of its creation:
  - 8.1.7.1. The designated record sets that are subject to access by individuals; and
  - 8.1.7.2. The titles of the persons or offices responsible for receiving and processing requests for access by individuals.

164.522  
164.522(a)

- 8.2. **Rights to Request Privacy Protection for PHI:**
- 8.2.1. Right of an individual to request **restriction of uses and disclosures:**
- 8.2.1.1. CE must permit individual to request that CE restrict uses/disclosures for TPO and disclosures pursuant to ¶ 6.2.;
- 8.2.1.1.1. CE is not required to agree to the restriction;
- 8.2.1.1.2. If CE agrees to the restriction, it must not use or disclose the PHI in violation of the restriction except, if individual who made request is in need of emergency treatment and the restricted PHI is needed to provide that treatment, CE may use the restricted PHI or disclose it to a health care provider to provide such treatment;
- 8.2.1.1.3. Upon disclosure pursuant to ¶ 8.2.1.1.2., CE must request that such health care provider not further use or disclose the PHI;
- 8.2.1.1.4. An agreed upon restriction is not effective to prevent uses or disclosures permitted or required under 164.502(a)(2)(i), 164.510(a) or 164.512 [¶¶ 3.2.1.; 6.1; 9. ].
- 8.2.1.2. Terminating a restriction: CE may terminate its agreement to a restriction if:
- 8.2.1.2.1. The individual agrees to or requests the termination in writing;
- 8.2.1.2.2. The individual orally agrees to the termination, and agreement is documented; or
- 8.2.1.2.3. CE informs the individual that it is terminating its agreement to the restriction, except that termination is only effective as to PHI created or received after such notice.
- 8.2.1.3. Documentation: CE that agrees to a restriction must document the restriction in accordance with ¶ 11.3.10.

8.2.2. **Confidential communications:**

8.2.2.1. Requirements:

8.2.2.1.1. **Provider** must permit individuals to request (and must accommodate reasonable requests) to receive communications of PHI from the provider by alternative means or at alternative locations.

8.2.2.1.2. A **health plan** must permit individuals to request (and must accommodate reasonable requests) to receive communications of PHI from the health plan by alternative means or at alternative locations if the individual clearly states that disclosure of the information could endanger the individual

8.2.2.2. Conditions on providing confidential communications:

8.2.2.2.1. CE may require the individual to make a request for a communication to be made by alternative means or to an alternative location in writing;

8.2.2.2.2. CE may condition the provision of a reasonable accommodation on information as to how payment, if any, will be handled, when appropriate, and specification of an alternate address or method of contact;

8.2.2.2.3. A **provider** may not require an explanation from the individual as to the basis for the request as a condition of providing communications on a confidential basis;

8.2.2.2.4. A **health plan** may require that a request contain a statement that disclosure of the information to which the request pertains could endanger the individual.

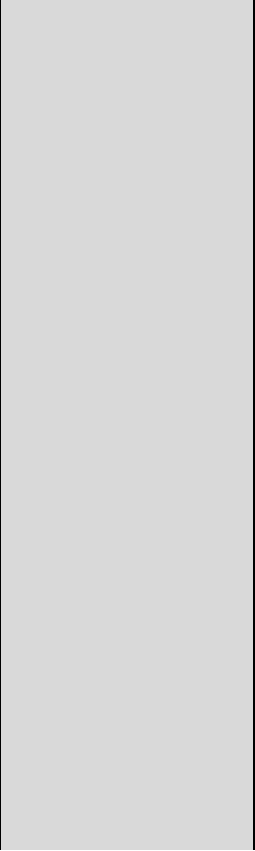
164.526	8.3. <b>Amendment of PHI:</b>
164.526(a)(1)	8.3.1. <b>Right to amend and denial of amendment:</b>
164.526(a)(2)	8.3.1.1. Individual has the right to have CE amend PHI or other information in the designated record set for as long as CE maintains the record sets. 8.3.1.2. CE may deny amendment request if it determines that the PHI or other record: 8.3.1.2.1. Was not created by the CE, unless the individual provides reasonable basis to believe that originator of PHI is no longer available to act on request; 8.3.1.2.2. Is not part of the designated record set; 8.3.1.2.3. Would not be available for inspection under ¶ 8.1.; or 8.3.1.2.4. Is accurate and complete.
164.526(b)	8.3.2. <b>Request for amendment and timely action:</b> 8.3.2.1. CE must permit an individual to request that the CE amend PHI maintained in the designated record set. CE may require request to be in writing and to provide reason/support for request, provided there is advance notice of these requirements. 8.3.2.2. CE must act on request within 60 days of receipt, as follows: 8.3.2.2.1. If CE grants the request, in whole or in part, it must follow the requirements of ¶¶ 8.3.3.1. and 8.3.3.2. If it denies the request, in whole or in part, it must follow the requirements of ¶ 8.3.4. 8.3.2.2.2. If CE needs more time to comply, it may obtain <b>one</b> extension for up to thirty days, provided that the CE notifies the individual in writing within the first 60 days of the reasons for delay and of the date by which action will be taken.

164.526(c)

- 8.3.3. **Accepting the amendment:** If the CE accepts the requested amendment, in whole or part, it must:
- 8.3.3.1. Make the amendment by, at a minimum, identifying the affected records and appending or otherwise providing a link to the location of the amendment;
  - 8.3.3.2. Timely inform the individual that the amendment is accepted and obtain his/her identification of and agreement to have the CE notify relevant persons with which amendment needs to be shared pursuant to ¶ 8.3.3.3.;
  - 8.3.3.3. Make reasonable efforts to inform and timely provide amendment to:
    - 8.3.3.3.1. Persons identified by the individual as having received PHI and needing the amendment; and
    - 8.3.3.3.2. Persons, including business associates, that the CE knows to have PHI that is the subject of the amendment and that may have relied, or could foreseeably rely on such information to the detriment of the individual.

164.526(d)

- 8.3.4. **Denying the amendment:** If the CE denies the requested amendment, in whole or part, it must:
- 8.3.4.1. Provide the individual with a timely, written denial in plain language and containing:
    - 8.3.4.1.1. The basis for the denial, in accordance with ¶ 8.3.1.2.;
    - 8.3.4.1.2. Notice of individual's right to submit a written statement disagreeing with the denial, and information on how to file such statement;
    - 8.3.4.1.3. Statement that, if individual does not submit a statement of disagreement, individual may request that CE provide individual's request and the denial with any future disclosures of the PHI that is subject of the request; and
    - 8.3.4.1.4. Description of how individual may complain to CE pursuant to procedures described in ¶ 11.3.4. (including name or title, and telephone number of contact person or office), or to the Secretary of HHS.

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- 8.3.4.2. Statement of disagreement: CE must permit the individual to submit to the CE a written statement disagreeing with the denial and the basis for disagreement. CE may reasonably limit the length of the statement.
  - 8.3.4.3. Rebuttal statement: CE may prepare a written rebuttal to the statement of disagreement. Whenever a rebuttal is prepared, CE must provide a copy to the individual.
  - 8.3.4.4. Record keeping: CE must, as appropriate, identify the record or PHI that is subject to the disputed amendment and append or otherwise link the request for amendment, the denial, any statement of disagreement, and any rebuttal to the designated record set.
  - 8.3.4.5. Future disclosures:
    - 8.3.4.5.1. If a statement of disagreement has been submitted, the CE must include the material appended in accordance with ¶ 8.3.4.4. or, at the election of the CE, an accurate summary of such information, with any subsequent disclosure of the PHI to which the disagreement relates.

8.3.4.5.2. If a statement of disagreement has not been submitted, the CE must include the request for amendment and the denial, or an accurate summary of such information, with any subsequent disclosure of PHI only if the individual has requested such action in accordance with ¶ 8.3.4.1.3.

8.3.4.5.3. When a subsequent disclosure is being made using a standard transaction under Part 162 of the regulations that does not permit additional material to be included, the CE must separately transmit the material required by ¶¶ 8.3.4.5.1. or 8.3.4.5.2., as applicable, to the recipient of the standard transaction.

8.3.5. A CE that is informed by another CE of an amendment to an individual's PHI pursuant to ¶ 8.3.3.3. must amend the PHI in designated record sets as provided in ¶ 8.3.3.1.

8.3.6. **Documentation:** CE must document the titles of the persons or offices responsible for receiving and processing requests for amendments and maintain documentation as required by ¶ 11.3.10.

164.512

164.512(d)

9. **USES AND DISCLOSURES OF PHI FOR WHICH CONSENT, AUTHORIZATION, OR OPPORTUNITY TO AGREE OR OBJECT IS NOT REQUIRED:** When CE is required hereunder to inform the individual of, or when individual may agree to, a use or disclosure permitted under this ¶ 9., CE's information and the individual's agreement may be given orally.
- 9.1. **Uses and Disclosures for Health Oversight Activities:**
- 9.1.1. Permitted disclosures: CE may disclose PHI to a health oversight agency for oversight activities authorized by law; including audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary actions; civil, administrative, or criminal proceedings or actions; or other activities necessary for appropriate oversight of:
- 9.1.1.1. The health care system;
- 9.1.1.2. Government benefit programs for which health information is relevant to beneficiary eligibility;
- 9.1.1.3. Entities subject to government regulatory programs for which health information is necessary for determining compliance with program standards; or
- 9.1.1.4. Entities subject to civil rights laws for which health information is necessary for determining compliance.
- 9.1.2. Exception to health oversight activities: For purpose of disclosures permitted pursuant to ¶ 9.1.1., a health oversight activity does not include an investigation or other activity in which the individual is the subject of the investigation or activity and the investigation or other activity does not arise out of and is not directly related to:
- 9.1.2.1. The receipt of health care;
- 9.1.2.2. A claim for public benefits related to health; or
- 9.1.2.3. Qualification for, or receipt of, public benefits or services when a patient's health is integral to the claim for public benefits or services.

164.512(b)

- 9.1.3. Joint activities or investigations: Notwithstanding ¶ 9.1.2., if a health oversight activity or investigation is conducted in conjunction with an oversight activity or investigation relating to a claim for public benefits not related to health, the joint activity or investigation is considered a health oversight activity for purposes of ¶ 9.1.
- 9.1.4. Permitted uses: If a CE is also a health oversight agency, the CE may use PHI for health oversight activities as outlined in ¶ 9.1.

9.2. **Uses and Disclosures for Public Health Activities:**

- 9.2.1. Permitted disclosures: CE may disclose PHI for public health activities and purposes to:
  - 9.2.1.1. A public health authority authorized by law to collect or receive 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;
  - 9.2.1.2. A public health authority or other government authority authorized by law to receive reports of child abuse or neglect;
  - 9.2.1.3. A person subject to the jurisdiction of the FDA to:
    - 9.2.1.3.1. Report adverse events (or similar reports with respect to food or dietary supplements), product defects or problems (including use and labeling problems), or biological product deviations if disclosure is made to the person required or directed to report such information to the FDA;
    - 9.2.1.3.2. Track products if disclosure is to a person required or directed by FDA to track product;
    - 9.2.1.3.3. Enable product recalls, repairs, or replacement (including locating and notifying persons of recalls, repairs, or problems); or
    - 9.2.1.3.4. Conduct post-marketing surveillance for FDA;

164.512(a)

- 9.2.1.4. 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 CE 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
- 9.2.1.5. An employer, about an individual who is a member of the employer's workforce if:
  - 9.2.1.5.1. The CE is a covered health care provider who is a member of the workforce of such employer or who provides a health care service to the individual at the request of the employer to conduct an evaluation relating to medical surveillance of the workplace; or evaluate whether the individual has a work-related illness or injury;
  - 9.2.1.5.2. The PHI that is disclosed consists of findings concerning a work-related illness or injury or a workplace-related medical surveillance;
  - 9.2.1.5.3. The employer needs such findings in order to comply with federal or state law to record such illness or injury or to carry out responsibilities for workplace medical surveillance; and
  - 9.2.1.5.4. The provider provides written notice (directly or posted) to the individual that PHI relating to the medical surveillance of the workplace and work-related illness and injuries is disclosed to the employer.
- 9.2.2. Permitted uses: If the CE is also a public health authority, the CE is permitted to use protected health information in all cases in which it is permitted to disclose such information for public health.

9.3. **Uses/Disclosures Required by Law:** CE may use or disclose PHI to the extent such use/disclosure is required by law and the use/disclosure complies with and is limited to the relevant requirements of such law. CE must meet the requirements described in ¶¶ 9.4 through 9.6 for uses/disclosures required by law.

9.4. **Uses/Disclosures Relating to Abuse and Neglect:**

- 9.4.1. Permitted disclosures: Except for reports of child abuse or neglect covered under ¶ 9.2.1.2., CE may disclose PHI about an individual whom CE believes to be a victim of abuse, neglect, or domestic violence to a governmental authority authorized to receive such reports:
  - 9.4.1.1. To extent the disclosure is required by law, and is limited to relevant requirements of that law;
  - 9.4.1.2. If the individual agrees; or
  - 9.4.1.3. To the extent the disclosure is expressly authorized by statute or regulation, and the CE believes, in the exercise of professional judgment that the disclosure is necessary to prevent serious physical harm to the individual or others, or, if the individual cannot agree due to incapacity, law enforcement or other public official authorized to receive the report represents that disclosure is not intended for use against the victim and that the law enforcement activity would be materially and adversely affected by waiting for the consent.
- 9.4.2. Informing the individual: CE that makes a disclosure permitted under ¶ 9.4.1 must promptly inform the individual that the report has been or will be made unless:
  - 9.4.2.1. CE, in the exercise of professional judgment, believes that informing the individual would place the individual at risk of serious harm; or
  - 9.4.2.2. CE would be informing a personal representative whom the CE reasonably believes is responsible for the abuse, neglect, or other injury, and CE reasonably believes, in exercise of professional judgment, that informing such person would not be in the individual's best interests.

9.5. **Uses/Disclosures for Judicial and Administrative Proceedings:**

9.5.1. CE may disclose PHI in the course of any judicial or administrative proceeding:

9.5.1.1. In response to an order of a court or administrative tribunal, but only the PHI expressly authorized for release by such order; or

9.5.1.2. In response to a subpoena, discovery request or other lawful process not accompanied by a court or administrative order if:

9.5.1.2.1. CE receives satisfactory assurance, as described in ¶ 9.5.1.3, from the party seeking the PHI that reasonable efforts have been made to give the individual notice of the request; or

9.5.1.2.2. CE receives satisfactory assurance, as described in ¶ 9.5.1.4., from the party seeking the PHI that reasonable efforts have been made to secure a qualified protective order compliant with ¶ 9.5.1.5.

9.5.1.3. Satisfactory assurance that individual has been given notice may be met by provision of a written statement and accompanying documentation demonstrating that:

9.5.1.3.1. Party requesting the PHI has made a good faith attempt to provide written notice to the individual;

9.5.1.3.2. Notice includes sufficient information about the litigation or proceeding to permit the individual to raise an objection in the tribunal; and

9.5.1.3.3. The time to raise objections has lapsed and either no objection was filed or objections have been resolved in a manner consistent with disclosure.

164.512(f)

164.512(f)(1)

9.5.1.4. Satisfactory assurance that reasonable efforts have been made to secure a qualified protective order may be met by provision of a written statement and accompanying documentation demonstrating that the parties to the dispute have agreed to a qualified protective order and presented it to the tribunal, or the party seeking the PHI has requested a qualified protective order from the tribunal.

9.5.1.5. A *qualified protective order* means an order that prohibits the use or disclosure of PHI for any purpose beyond the litigation at hand, and requires that the PHI, and all copies, be returned to the CE or destroyed when the litigation is over.

9.5.1.6. Notwithstanding ¶ 9.5.1.2., a CE may disclose PHI without the described assurances if the CE makes reasonable efforts to contact the individual as described in ¶ 9.5.1.3. or if it makes reasonable efforts to obtain a qualified protective order as described in ¶ 9.5.1.4.

9.5.2. Nothing in this section is meant to supersede or limit disclosures allowed by other sections.

9.6. **Uses/Disclosures for Law Enforcement Purposes:** CE may disclose PHI to law enforcement official for a law enforcement purpose if the conditions of ¶ 9.6 are met, as applicable.

9.6.1. **Permitted disclosures pursuant to process and as otherwise required by law:**

9.6.1.1. As required by law, including laws requiring reporting of certain types of wounds and injuries, except laws subject to ¶ 9.2.1.2. (re: reporting child abuse and neglect) and ¶ 9.4.1.1.; or

9.6.1.2. In compliance with and as limited by relevant requirements of:

9.6.1.2.1. A court order, or a court ordered warrant, subpoena or summons issued by a judicial officer;

9.6.1.2.2. A grand jury subpoena; or

9.6.1.2.3. An administrative request, provided that the information is relevant to the law enforcement inquiry, the request is limited to the extent practicable, and de-identified information could not reasonably be used.

164.512(f)(2)

9.6.2. **Permitted disclosure of limited information for identification and location purposes:** Except for disclosures required by law as permitted under ¶ 9.6.1., CE may disclose PHI in response to a law enforcement official's request to assist in identifying or locating a suspect, fugitive, material witness or missing person:

9.6.2.1. CE may disclose only the following information:

- 9.6.2.1.1. Name and address;
- 9.6.2.1.2. Date and place of birth;
- 9.6.2.1.3. Social security number;
- 9.6.2.1.4. ABO blood type and rh factor;
- 9.6.2.1.5. Type of injury;
- 9.6.2.1.6. Date and time of treatment;
- 9.6.2.1.7. Date and time of death;
- 9.6.2.1.8. Distinguishing physical characteristics, including height, weight, gender, race, hair and eye color, presence or absence of facial hair, scars, and tattoos.

9.6.2.2. Except as permitted under ¶ 9.6.2.1., CE may not disclose for identification or location purposes any PHI relating to DNA or DNA analysis, dental records, typing, samples or analysis of body fluids or tissues.

164.512(f)(3)

9.6.3. **Victims of Crime:** Except for disclosures permitted under ¶ 9.6.1., CE may disclose PHI in response to a law enforcement official's request relating to an individual who is or is suspected of being a victim of a crime, other than disclosures subject to ¶¶ 9.2. and 9.4., if:

9.6.3.1. Individual agrees; or

9.6.3.2. CE is unable to obtain individual's agreement because of incapacity or other emergency provided that:

9.6.3.2.1. The law enforcement official needs the information to determine if someone else committed a crime, and the PHI will not be used against the victim;

9.6.3.2.2. Immediate law enforcement activity that depends on disclosure of the PHI would be materially and adversely affected by waiting; and

9.6.3.2.3. CE, exercising professional judgment, believes disclosure is in the best interest of the victim.

164.512(f)(4)	9.6.4. <b>Decedents:</b> CE may disclose decedent’s PHI to law enforcement in order to alert law enforcement of the death if the CE suspects the death resulted from criminal conduct.
164.512(f)(5)	9.6.5. <b>Crime on Premises:</b> CE may disclose PHI to law enforcement if the CE in good faith believes the PHI constitutes evidence of a crime committed on the premises of the CE.
164.512(f)(6)	9.6.6. <b>Reporting Crime in Emergencies:</b> A covered provider, providing off-site emergency medical care may report PHI as necessary to alert law enforcement to the commission and nature of the crime; location of the crime and of crime victim(s); and the identity, description and location of the perpetrator. If CE believes that the emergency is the result of abuse, neglect or domestic violence, disclosure is subject to ¶ 9.4.
164.512(k)(5)	<p>9.6.7. <b>Correctional institutions and other law enforcement custodial situations:</b> CE may disclose PHI to a correctional institution or to law enforcement official with custody of the individual when a correctional institution or law enforcement official represent that the PHI is necessary to provide care to the individual, or for the health and safety of the individual, other inmates, correctional employees, transport employees, law enforcement personnel at the location, and for the safety, security and good order of the institution.</p> <p>9.6.7.1. CE that is a correctional institution may use PHI for any purpose for which the PHI may be disclosed.</p> <p>9.6.7.2. An individual is no longer an inmate once released on parole, probation, supervised release or is otherwise no longer in lawful custody.</p>

- 9.7. **Uses and Disclosures to Avert a Serious Threat to Health or Safety:**
- 9.7.1. CE may, consistent with applicable law and standards of ethical conduct, use or disclose PHI if the CE in good faith believes the use or disclosure is:
    - 9.7.1.1. Necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public and is to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat; or
    - 9.7.1.2. Necessary for law enforcement authorities to identify or apprehend an individual:
      - 9.7.1.2.1. Because of a statement by an individual admitting participation in a violent crime that the CE reasonably believes may have caused serious physical harm to the victim, or
      - 9.7.1.2.2. Where it appears from all circumstances that the individual has escaped from a correctional institution or from lawful custody.
  - 9.7.2. Use/disclosure not permitted: A use or disclosure pursuant to ¶ 9.7.1.2.1. may not be made if the information described therein is learned by the CE in the course of treatment to affect the propensity to commit the criminal conduct that is the basis for the disclosure, or counseling or therapy; or through a request by the individual to initiate or to be referred for the treatment, counseling, or therapy.
  - 9.7.3. Limit on information to be disclosed: A disclosure made pursuant to ¶ 9.7.1.2.1. shall contain only the statement described therein and the PHI described under ¶ 9.6.2.1. (disclosures for law enforcement for identification and location purposes).
  - 9.7.4. A CE is presumed to have acted in good faith if its belief is based upon the CE's actual knowledge or reliance on a credible representation by a person with apparent knowledge or authority.

164.512(i)  
164.512(i)(1)

- 9.8. **Uses and Disclosures for Research Purposes:**
- 9.8.1. CE may use/disclose PHI for research, regardless of source of funding, provided that:
- 9.8.1.1. CE obtains documentation that an alteration or waiver of the authorization required under 164.508 [¶ 7.] has been approved by either:
- 9.8.1.1.1. An Institutional Review Board (IRB) established under cited sections of the CFR, or
- 9.8.1.1.2. A Privacy Board that: (i) has members with varying backgrounds and appropriate professional competency to review the effect of the research protocol on privacy rights and related interests; (ii) includes at least one member who is not affiliated with the CE or the entity conducting or sponsoring the research, and is not related to anyone affiliated with these entities, and; (iii) does not have any member participating in a review of a project in which s/he has a conflicting interest.
- 9.8.1.2. CE obtains from researcher representations that:
- 9.8.1.2.1. Use/disclosure is sought solely to review PHI to prepare a research protocol, or for a similar preparatory purpose;
- 9.8.1.2.2. No PHI will be removed from the CE, and;
- 9.8.1.2.3. PHI sought is necessary for research purposes.
- 9.8.1.3. For research on decedents' information, CE obtains from the researcher:
- 9.8.1.3.1. Representation that use/disclosure is sought solely for research on PHI of decedents;
- 9.8.1.3.2. Documentation of the death of individuals whose PHI is sought, upon request by the CE;
- 9.8.1.3.3. Representation that the PHI is necessary for research purposes.

**164.512(i)(2)**

- 9.8.2. Documentation supporting approval of alteration/waiver per 164.512(i)(1)(i) [¶ 9.8.1.1.] must include:
  - 9.8.2.1. Identification of approving board and date of approval;
  - 9.8.2.2. Statement that board determined that alteration/waiver satisfies the following criteria:
    - 9.8.2.2.1. Use/disclosure of PHI involves no more than minimal risk;
    - 9.8.2.2.2. Alteration/waiver will not adversely affect privacy rights and welfare of individuals;
    - 9.8.2.2.3. Research could not practicably be done without the alteration/waiver;
    - 9.8.2.2.4. Research could not practicably be done without PHI access;
    - 9.8.2.2.5. Privacy risks are reasonable in relation to benefits of research;
    - 9.8.2.2.6. Adequate plan exists to protect identifiers from improper use/disclosure
    - 9.8.2.2.7. Adequate plan exists to destroy identifiers unless there is justification for retention, and;
    - 9.8.2.2.8. Adequate written assurances given that PHI will not be used or disclosed other than as authorized for research project or otherwise under law.
  - 9.8.2.3. Description of the PHI determined to be necessary for the research project.
  - 9.8.2.4. Statement that the alteration/waiver was reviewed and approved as follows:
    - 9.8.2.4.1. IRB must follow requirements of the Common Rule, including normal and expedited procedures (see cites in 164.512(i)(2)(iv)(A));
    - 9.8.2.4.2. Privacy Board: normal review - must review at convened meetings where majority of members are present, including at least one member satisfying criteria of 164.512(i)(1)(i)(B)(2) [¶ 9.8.1.1.2.(ii)] (at least one member not affiliated with CE or conduct/sponsorship of project); alteration/waiver must be approved by majority of members present; or

164.512(g)

9.8.2.4.3. Privacy Board: expedited review - may be used only if research involves no more than minimal risk to privacy; review and approval may be carried out by Chair, or one or more members as designated by Chair.

9.8.2.5. Documentation must be signed by Chair of approving IRB or Privacy Board, or by member designated by Chair.

9.9. **Uses and Disclosures about Decedents:**

9.9.1. Coroners and Medical Examiners: CE may disclose PHI to a coroner or medical examiner to identify a deceased person, determine the cause of death, or perform other functions authorized by law. A CE may use PHI for these purposes if it functions as a coroner or medical examiner.

9.9.2. Funeral Directors: CE may disclose PHI to funeral directors, consistent with applicable law, as necessary to carry their duties. If necessary, PHI may be disclosed prior to, and in reasonable anticipation of, the individual's death.

164.512(h)

9.10. **Uses and Disclosures for Cadaveric Organ, Eye or Tissue Donation Purposes:** CE may use or disclose PHI to organ procurement organizations or other entities engaged in procurement, banking, or transplantation of cadaveric organs, eyes or tissue for the purpose of facilitating organ, eye or tissue donation or transplantation.

164.512(k)  
164.512(k)(1)

9.11. **Uses and Disclosures for Specialized Government Functions:**

9.11.1. **Military and veterans activities:**

- 9.11.1.1. CE may use/disclose PHI of armed forces personnel for activities deemed necessary by the appropriate military command authority to fulfill the military mission if notice has been published in the Federal Register that identifies the appropriate military command authorities and the purposes for which the PHI may be used or disclosed.
- 9.11.1.2. CE that is a component of the Department of Defense or Department of Transportation may disclose PHI of a member of the armed services to the Department of Veterans Affairs (DVA) upon his or her discharge or separation from the military for the purpose of a determination by DVA of the individual's eligibility for or entitlement to benefits.
- 9.11.1.3. CE that is a component of DVA may use and disclose PHI to other components of DVA that determine eligibility for or entitlement to, or that provide, benefits.
- 9.11.1.4. CE may use and disclose PHI of foreign military personnel to their appropriate foreign military authority for the same purposes for which uses and disclosures are permitted for U.S. armed services personnel.

164.512(k)(2)

- 9.11.2. **National security and intelligence activities:** CE may disclose PHI to authorized federal officials for the conduct of lawful intelligence, counterintelligence, and other activities authorized by the National Security Act (50 U.S.C. 401, *et seq.*) and implementing authority.

164.512(k)(3)

- 9.11.3. **Protective services for the President and others:** CE may disclose PHI to authorized federal officials for the provision of protective services:
  - 9.11.3.1. To the President and others designated under 18 U.S.C. 3056;
  - 9.11.3.2. To foreign heads of state or others designated under 22 U.S.C. 2709(a)(3); or
  - 9.11.3.3. For the conduct of investigations authorized by 18 U.S.C. 871 and 879.

164.512(k)(4)

- 9.11.4. **Medical suitability determinations:** CE that is a component of the Department of State may use PHI to make medical suitability determinations and may disclose results to officials in the Department of State who need access to it for the following purposes:
- 9.11.4.1. Required security clearance conducted pursuant to Executive Orders 10450 and 12698;
  - 9.11.4.2. As necessary to determine worldwide availability or availability for mandatory service abroad under sections 101(a)(4) and 504 of the Foreign Service Act; or
  - 9.11.4.3. For family to accompany a foreign service member abroad, consistent with sections 101(b)(5) and 904 of the Foreign Service Act.

164.512(k)(6)

- 9.11.5. **CEs that are government programs providing public benefits:**
- 9.11.5.1. Health plan that is a government program providing public benefits may disclose PHI relating to eligibility for or enrollment in the health plan to another agency administering a government program providing public benefits if the sharing of eligibility or enrollment information among such agencies or the maintenance of such information in a single or combined data system accessible to all such agencies is required or expressly authorized by statute or regulation.
  - 9.11.5.2. CE that is a government agency administering a government program providing public benefits may disclose PHI relating to the program to another CE that is a government program providing public benefits if the programs serve the same or similar populations and the disclosure of PHI is necessary to coordinate the covered functions of such programs or to improve administration and management relating to the covered functions.

164.512(l)

- 9.12. **Disclosures for Workers' Compensation:** CE may disclose PHI as authorized by and to the extent necessary to comply with laws relating to workers' compensation or other similar programs.

164.504(a)

10. ORGANIZATIONAL REQUIREMENTS:

10.1. Relevant Definitions:

- 10.1.1. **Common control** exists if entity has power to directly or indirectly direct or influence the actions or policies of another entity.
- 10.1.2. **Common ownership** exists if entity(ies) possess ownership or equity interest of 5% or more of another entity.
- 10.1.3. **Health care component** means:
  - 10.1.3.1. Component(s) of the CE that perform(s) covered functions; or
  - 10.1.3.2. Another component of the CE to the extent that: (i) it performs as if it would be a business associate, were it a separate legal entity, on behalf of a component of the CE that performs covered functions, and (ii) its activities involve use/disclosure of PHI that it creates or receives from or on behalf of the other component.
- 10.1.4. **Hybrid entity** means a single legal entity that is a covered entity whose covered functions are not its primary functions.
- 10.1.5. **Organized health care arrangement** means:
  - 10.1.5.1. A clinically integrated care setting in which individuals typically receive health care from more than one provider;
  - 10.1.5.2. An organized system of care in which multiple participating CEs:
    - 10.1.5.2.1. Hold themselves out to the public as a joint arrangement; and
    - 10.1.5.2.2. Participate in at least one of the following joint activities: (i) utilization review; (ii) quality assessment and improvement; or (iii) payment activities where there is shared financial risk;
  - 10.1.5.3. A group health plan and a health insurance issuer or HMO with respect to the plan, but only relating to PHI of participants or beneficiaries of the plan;
  - 10.1.5.4. Multiple group health plans maintained by the same plan sponsor; or
  - 10.1.5.5. Multiple group health plans maintained by the same plan sponsor and health insurance issuers or HMOs with respect to such plans, but only relating to PHI of participants or beneficiaries of the plan.

[164.501]

164.504(b)

- 10.1.6. **Plan administration functions** means administrative functions performed by the plan sponsor of a group health plan on behalf of that plan, and excludes functions performed by the sponsor in connection with any other benefit or plan of the sponsor.
  - 10.1.7. **Summary health information** means information that may be individually identifiable health information and
    - 10.1.7.1. That summarizes claims history, claims expenses, or types of claims relating to benefits under a group health plan; and
    - 10.1.7.2. Which has been de-identified pursuant to 164.514(b)(2)(i) [¶ 3.10.2.2.], except that geographic information need only be aggregated to the level of a five digit zip code.
- 10.2. **Health Care Component:** If a CE is a hybrid entity, except as specified in ¶ 10, the regulations apply only to the health care component of the entity.

- 10.3. **Hybrid Entities:**
- 10.3.1. Applicability of other provisions of the regulations to hybrid entities:
- 10.3.1.1. Reference to a CE refers to the health care component of the CE;
- 10.3.1.2. Reference to "health plan," "covered health care provider," or "health care clearinghouse" refers to health care component of CE if the component performs the functions of a health plan, covered health care provider or health care clearinghouse; and
- 10.3.1.3. Reference to "protected health information" refers to PHI that is created or received by or on behalf of the health care component of the CE.
- 10.3.2. Safeguard requirements: Hybrid entity must ensure that its health care components comply with applicable requirements of the regulations, including ensuring:
- 10.3.2.1. Health care component does not disclose PHI to another component of the CE, if such sharing would not be permitted if the two components were separate and distinct legal entities;
- 10.3.2.2. Component acting as a "business associate" does not use/disclose PHI it creates or receives from or on behalf of the other component other than as permitted in its "business associate" type functions, and
- 10.3.2.3. Workforce members who perform duties for both health care component(s) and other component(s) of CE must not use/disclose PHI created or received in the course of their work for the health care component in a way that is prohibited hereunder.
- 10.3.3. Responsibilities of hybrid entity:
- 10.3.3.1. Comply with compliance and enforcement requirements of Subpart C, Part 160 [¶ 12.];
- 10.3.3.2. Comply with implementation of policies and procedures required under 164.530(i) [¶ 11.3.9.]and safeguard provisions of 164.504(c)(2) [¶ 10.3.2.]; and
- 10.3.3.3. Designate components that are part of one or more health care components of the CE and document the designations as required under 164.530(j) [¶ 11.3.10.].

164.504(d)

- 10.4. **Affiliated Covered Entities:**
- 10.4.1. Legally separate CEs that are affiliated may designate themselves (including any health care component) as a single covered entity if all CEs so designated are under common ownership or control; such designation must be documented in accordance with 164.530(j) [¶ 11.3.10].
  - 10.4.2. Affiliated CE must ensure that its use and disclosure of PHI complies with applicable requirements of the regulations, and that if the affiliated CE combines functions of a health plan, a provider, or a health care clearinghouse, it complies with 164.504(g) [¶ 10.7.].

164.502(e);  
164.504(e)

- 10.5. **Disclosures to Business Associates (BAs):**
- 10.5.1. Standard for disclosures to BAs: CE may disclose PHI, or allow BA to create or receive PHI on CE's behalf, if CE obtains assurance that BA will safeguard the information; this standard does not apply with respect to:
    - 10.5.1.1. Disclosure by CE to a provider concerning the individual's treatment;
    - 10.5.1.2. Disclosure by group health plan, or health insurance issuer or HMO with respect to the plan, when requirements of ¶ 10.6. are met, or;
    - 10.5.1.3. Uses/disclosures by health plan that is a governmental program providing public benefits, regarding PHI collected or shared for determination of eligibility or enrollment, where such information is collected, or eligibility or enrollment is determined, by an agency other than the one administering the plan, and such activity is authorized by law.

164.502(e)(2);  
164.504(e)

- 10.5.2. CE must document assurances through a written agreement or other arrangement meeting the following requirements:
  - 10.5.2.1. Establish permitted and required uses/disclosures of PHI that are consistent with those authorized for the CE under the regulations, except that the contract/arrangement:
    - 10.5.2.1.1. May permit BA to use/disclose PHI for management and administration of the BA: (i) if disclosure is required by law, or (ii) BA obtains reasonable assurances that the PHI will be held confidentially and used/disclosed only as required by law or for the purpose of the disclosure and person notifies BA of any breach of confidentiality; and
    - 10.5.2.1.2. May permit BA to provide data aggregation services relating to the health care operations of the CE;
  - 10.5.2.2. Provide that the BA will:
    - 10.5.2.2.1. Not use/disclose PHI except as authorized or as required by law;
    - 10.5.2.2.2. Use safeguards to prevent unauthorized uses/disclosures;
    - 10.5.2.2.3. Report unauthorized uses/disclosures to CE;
    - 10.5.2.2.4. Pass on same obligations to subcontractors/agents;
    - 10.5.2.2.5. Make PHI available for access and/or amendment by individuals in accordance with the provisions of 164.524 and 164.526 [¶¶ 8.1. and 8.3.];
    - 10.5.2.2.6. Make information available for provision of accounting of uses/disclosures [¶ 11.2.];
    - 10.5.2.2.7. Make information available to the Secretary of HHS for purposes of determining CE's compliance with the regulations, and;
    - 10.5.2.2.8. Return or destroy all PHI at termination of the contract, or offer ongoing protection for PHI.
  - 10.5.2.3. Authorize termination of the contract by the CE upon material breach by the BA.

164.504(e)(1)	10.5.3. If CE knows of a pattern or practice of material non-compliance by the BA, and reasonable steps have not cured breach, CE must do one of the following:
164.504(e)(3)(i)	10.5.3.1. Terminate the contract, if feasible; or 10.5.3.2. Report the problem to the Secretary of HHS. 10.5.4. If CE and BA are both governmental entities, CE may comply with requirements of a BA agreement:
164.504(e)(3)(ii)	10.5.4.1. By entering into a Memorandum of Understanding covering the required terms; or 10.5.4.2. If other law contains requirements applicable to the BA that satisfy the objectives of the terms.
164.504(e)(3)(iii)	10.5.5. If a BA is required by law to perform a function or activity or to perform a specified service on behalf of a CE, the CE may disclose PHI to the extent necessary to comply with that mandate, as long as CE documents an attempt to obtain the enumerated BA assurances and the reasons such assurances could not be obtained.
164.504(f) 164.504(f)(1)	10.5.6. CE may omit requirement for termination provision in contract if it would be inconsistent with statutory obligations of CE or BA.  10.6. <b>Group Health Plans:</b> 10.6.1. Generally, in order for a group health plan to use or disclose PHI to the plan sponsor or to permit disclosure of PHI to the plan sponsor by a health insurance issuer or HMO for the plan, the group health plan must ensure that plan documents restrict uses and disclosures by the plan sponsor consistent with the requirements of the regulations, except when the use/disclosure: 10.6.1.1. Is made pursuant to the terms of an authorization pursuant to 164.508 [¶ 7.]; or 10.6.1.2. Involves summary health information disclosed to the plan sponsor in response to a request to use the information for the purposes of obtaining premium bids from health plans for providing coverage under the group health plan or modifying, amending or terminating the group health plan.

**164.504(f)(2)**

- 10.6.2. **Plan documents** of a group health plan must be amended to incorporate provisions to:
- 10.6.2.1. Establish permitted and required uses/disclosures of health information by the plan sponsor in keeping with the requirements of the regulations;
  - 10.6.2.2. Provide that the group health plan will not disclose PHI to the plan sponsor until receipt of a certification from the plan sponsor that the plan documents have been amended to incorporate the following provisions and that the plan sponsor agrees to:
    - 10.6.2.2.1. Only use or disclose the information as permitted or required by law;
    - 10.6.2.2.2. Ensure that any agents/subcontractors agree to the same restrictions and conditions relating to PHI;
    - 10.6.2.2.3. Not use/disclose PHI for employment related actions/decisions or in connection with other benefit or employee benefit plan of the plan sponsor;
    - 10.6.2.2.4. Report to the group health plan any unauthorized uses/disclosures of which it becomes aware;
    - 10.6.2.2.5. Make PHI available: for individual's access in accordance with 164.524 [¶ 8.1.], and for amendment in accordance with 164.526 [¶ 8.3.];
    - 10.6.2.2.6. Make necessary information available for accounting of disclosures in accordance with 164.528 [¶ 11.2.];
    - 10.6.2.2.7. Make internal practices and records relating to use/disclosure of PHI received from the group health plan available to Secretary of HHS for compliance review of group health plan;
    - 10.6.2.2.8. If feasible, return or destroy all PHI received once no longer needed, and if not feasible to return or destroy, ensure that further use/disclosure is limited to purposes making return/destruction not feasible;
    - 10.6.2.2.9. Ensure establishment of adequate separation pursuant to 164.504(f)(2)(iii) [¶ 10.6.2.3.].

164.504(f)(3)

- 10.6.2.3. Provide for adequate separation between the group health plan and the plan sponsor; plan documents must:
  - 10.6.2.3.1. Describe employees or classes of employees or persons under control of plan sponsor to be given access to PHI; must include all employees or persons who receive PHI relating to payment or other matters in the usual course of business;
  - 10.6.2.3.2. Restrict access and use of PHI to plan administration functions performed on behalf of the group health plan, and;
  - 10.6.2.3.3. Provide effective mechanism for resolving issues of noncompliance by such employees.
- 10.6.3. Uses and disclosures by **group health plans**:  
GHPs are:
  - 10.6.3.1. Permitted to disclose PHI to plan sponsor to carry out plan administration functions consistent with the provisions of 164.504(f)(2) [¶ 10.6.2.];
  - 10.6.3.2. Not to permit a health insurance issuer or HMO for the group health plan to disclose PHI to plan sponsor except as permitted hereunder;
  - 10.6.3.3. Not to disclose or permit health insurance issuer or HMO to disclose PHI to plan sponsor as otherwise permitted hereunder unless statement of such disclosure, as required by 164.520(b)(1)(iii)(C), is included in privacy notice [¶ 4.2.3.3.];
  - 10.6.3.4. Not to disclose PHI to plan sponsor for purpose of employment related actions/decisions or in connection with any other benefit or employee benefit plan of the plan sponsor.

164.504(g)

- 10.7. **Requirements for CE with Multiple Covered Functions:**  
CE that performs multiple covered functions that would make the entity any combination of a health plan, a provider or a health care clearinghouse:
- 10.7.1. Must comply with the standards, requirements, and implementation specifications of the regulations as applicable to the covered functions performed, and;
  - 10.7.2. May use or disclose PHI of individuals who receive the services of the health plan or provider, but not both, only for purposes related to the appropriate function being performed.

164.514(h)  
164.514(h)(1)

164.514(h)(2)

## 11. ADMINISTRATIVE REQUIREMENTS:

### 11.1. Verification Requirements:

11.1.1. Prior to any disclosure permitted under the regulations, CE must:

11.1.1.1. Except with respect to disclosures under ¶ 6., verify the identity of a person requesting PHI and the authority of such person to access the PHI if not known to the CE; and

11.1.1.2. Obtain any documentation, statements, or representations, whether oral or written, from the person requesting the PHI when it is a condition of the disclosure under the regulations.

11.1.2. Implementation requirements:

11.1.2.1. Conditions on disclosure: If a disclosure is conditioned under the regulations on particular documentation, statements, or representations from the person requesting the PHI, CE may rely, if reasonable under the circumstances, on documentation, statements or representations that, on their face, meet the applicable requirements.

11.1.2.1.1. The conditions in 164.512(f)(1)(ii)(C) [¶ 9.6.1.2.3.] may be satisfied by the administrative subpoena or similar process or by a separate written statement that, on its face, demonstrates that the applicable requirements have been met.

11.1.2.1.2. The documentation required by 164.512(i)(2) [¶ 9.8.2.] may be satisfied by one or more written statements, provided that each is appropriately dated and signed in accordance with the provisions 164.512(i)(2)(i)(v) [¶¶ 9.8.2.1 and 9.8.2.5].

- 11.1.2.2. Identity of public officials: CE may rely, if reasonable under the circumstances, on any of the following to verify identity when the disclosure of PHI is to a public official or a person acting on behalf of a public official:
  - 11.1.2.2.1. If the request is made in person, presentation of agency identification badge, other official credentials, or other proof of government status;
  - 11.1.2.2.2. If the request is in writing, on appropriate government letterhead;
  - 11.1.2.2.3. If the disclosure is to a person acting on behalf of a public official, a written statement on appropriate government letterhead that the person is acting with authority, or other evidence of agency, such as a contract for services, MOU, purchase order, that establishes that the person is acting on behalf of the public official;
- 11.1.2.3. Authority of public officials: CE may rely, if reasonable under the circumstances, on any of the following to verify authority when the disclosure of PHI is to a public official or a person acting on behalf of the public official:
  - 11.1.2.3.1. A written statement of legal authority under which the information is requested, or, if a written statement would be impractical, an oral statement of such authority;
  - 11.1.2.3.2. A request made by legal process, warrant, subpoena, order, or other legal process issued by a grand jury or a judicial or administrative tribunal is presumed to constitute legal authority.
- 11.1.2.4. Exercise of professional judgment: Verification requirements of ¶ 11.1 are met if CE relies on the exercise of professional judgment in making a use or disclosure in accordance with 164.510 [¶ 6.] or acts on a good faith belief in making a disclosure under 164.512(j) [¶ 9.7.].

164.528  
164.528(a)(1)

- 11.2. **Accounting of Disclosures of PHI:**
- 11.2.1. Right to an accounting of disclosures of PHI:
- 11.2.1.1. An individual has a right to receive an accounting of disclosures of PHI made by a covered entity in the six years prior to the date on which the accounting is requested, except for disclosures:
- 11.2.1.1.1. To carry out TPO as provided in ¶ 3.1.2.;
  - 11.2.1.1.2. To individuals of PHI about them as provided in ¶ 3.1.1.;
  - 11.2.1.1.3. For the facility's directory or to persons involved in the individual's care or other notification purposes as provided in ¶ 6.;
  - 11.2.1.1.4. For national security or intelligence purposes as provided in ¶ 9.11.2.;
  - 11.2.1.1.5. To correctional institutions or law enforcement officials as provided in ¶ 9.6.7.; or
  - 11.2.1.1.6. That occurred prior to the compliance date for the CE.

164.528(a)(2)

- 11.2.1.2. Suspension of right to accounting:
  - 11.2.1.2.1. CE must temporarily suspend an individual's right to receive an accounting of disclosures to a health oversight agency or law enforcement official, as provided for in ¶ 11.2.1.1., for the time specified by such agency or official, if such agency or official provides the covered entity with a written statement that such an accounting to the individual would be reasonably likely to impede the agency's activities and specifying the time for which such a suspension is required.
  - 11.2.1.2.2. If the agency or official statement is made orally, the covered entity must: (i) document the statement, including the identity of the agency or official making the statement; (ii) temporarily suspend the individual's right to an accounting of disclosures subject to the statement; and (iii) limit the temporary suspension to no longer than 30 days from the date of the oral statement, unless a written statement pursuant to ¶ 11.2.1.2.1. is submitted during that time.
- 11.2.1.3. An individual may request an accounting of disclosures for a period of time less than six years from the date of the request.

- 11.2.2. **Content of the Accounting:** CE must provide the individual with a written accounting that meets the following requirements:
  - 11.2.2.1. Except as otherwise provided above, the accounting must include disclosures of PHI that occurred during the six years (or such shorter time period at the request of the individual) prior to the date of the request for an accounting, including disclosures to or by business associates of the CE.
  - 11.2.2.2. The accounting must include for each disclosure:
    - 11.2.2.2.1. The date of the disclosure;
    - 11.2.2.2.2. The name of the entity or person who received the PHI and, if known, the address of such entity or person;
    - 11.2.2.2.3. A brief description of the PHI disclosed; and
    - 11.2.2.2.4. A brief statement of the purpose of the disclosure that reasonably informs the individual of the basis for the disclosure; or, in lieu of such statement: (i) a copy of the individual's written authorization; or (ii) a copy of a written request for a disclosure, if any.
  - 11.2.2.3. If, during the period covered by the accounting, the CE has made multiple disclosures of PHI to the same person or entity for a single purpose, or pursuant to a single authorization, the accounting may, with respect to such multiple disclosures, provide:
    - 11.2.2.3.1. The information required in ¶11.2.2.2 for the first disclosure during the accounting period;
    - 11.2.2.3.2. The frequency, periodicity, or number of the disclosures made during the accounting period; and
    - 11.2.2.3.3. The date of the last such disclosure during the accounting period.

164.528(c)

11.2.3. **Provision of the Accounting:**

11.2.3.1. CE must provide the individual with the accounting requested no later than 60 days after receipt of the request; or

11.2.3.2. If CE is unable to provide the accounting within 60 days after receipt of the request, the CE may extend the time to provide the accounting by no more than 30 days, provided that:

11.2.3.2.1. CE, within 60 days after receipt of the request, provides the individual with a written statement of the reasons for the delay and the date by which the CE will provide the accounting; and

11.2.3.2.2. CE may have only one such extension of time for action on a request for an accounting.

11.2.3.3. CE must provide the first accounting to an individual in any 12 month period without charge. CE may impose a reasonable, cost-based fee for each subsequent request for an accounting by the same individual within the 12 month period, provided that the CE informs the individual in advance of the fee and provides the individual with an opportunity to withdraw or modify the request for a subsequent accounting in order to avoid or reduce the fee.

164.528(d)

11.2.4. **Documentation:** CE must document the following and retain the documentation for six years from the date of its creation[¶11.3.10]:

11.2.4.1. The information required to be included in an accounting for disclosures of PHI that are subject to an accounting;

11.2.4.2. The written accounting that is provided to an individual; and

11.2.4.3. The titles of the persons or offices responsible for receiving and processing requests for an accounting by individuals.

164.530  
164.530(a)

164.530(b)

- 11.3. **Administrative Requirements:**
- 11.3.1. **Required Personnel Designations:** CE must designate, and document, according to ¶11.3.10, designations of:
    - 11.3.1.1. Privacy Official: Responsible for development and implementation of the CE's policies and procedures, and
    - 11.3.1.2. Contact person or office: Responsible for receiving complaints under this section and able to provide information relating to the Privacy Notice [¶4].
  - 11.3.2. **Required Training:** CE must train, and document the training of, all workforce members on policies and procedures relating to PHI as necessary and appropriate to their work functions, as follows:
    - 11.3.2.1. To all workforce members by the applicable compliance date for the CE;
    - 11.3.2.2. To each new member of the workforce within a reasonable time upon joining the CE's workforce;
    - 11.3.2.3. To each workforce member whose functions are affected by a material change in policies or procedures required under the privacy regulations, within a reasonable time after the material change becomes effective.

164.530(c)	11.3.3. <b>Safeguards to be in place:</b> CE must have in place appropriate administrative, technical and physical safeguards to reasonably safeguard PHI from intentional or unintentional unauthorized use or disclosure.
164.530(d)	11.3.4. <b>Complaint Process:</b> CE must provide a process for individuals to make complaints about the CE's policies and procedures required by the privacy regulations and/or the CE's compliance with those policies and procedures, and must document all complaints received and disposition of same, if any.
164.530(e)	11.3.5. <b>Sanctions to be in place:</b> CE must have, apply, and document application of appropriate sanctions against its workforce members who fail to comply with the CE's privacy policies and procedures or the requirements of the privacy regulations; NOTE: <u>This standard does not apply to workforce members' actions meeting the requirements of the sections relating to disclosures by whistleblowers and workforce member crime victims [164.502(j)/¶ 3.3.], or intimidating and retaliatory acts [164.530(g)(2)/¶ 11.3.7.2.].</u>
164.530(f)	11.3.6. <b>Mitigation of harmful effects:</b> CE must mitigate, to extent practicable, any harmful effects that are known to the CE of unauthorized uses/disclosures of PHI in violation of its policies and procedures or the requirements of the privacy regulations by CE or BA.
164.530(g)	11.3.7. <b>Intimidating or retaliatory acts prohibited:</b> CE may not intimidate, threaten, coerce, discriminate against or take other retaliatory action against: <ul style="list-style-type: none"> <li data-bbox="777 1209 1515 1314">11.3.7.1. Any individual for exercise of any right or participation in any process established by the privacy regulations; or</li> <li data-bbox="777 1314 1515 1671">11.3.7.2. Any individual or other person for: filing a complaint with the Secretary of HHS; testifying, assisting, or participating in investigation, compliance review, or proceeding/hearing under the regulations, or; engaging in reasonable opposition to any act or practice that the person in good faith believes to be unlawful under the regulations, as long as such opposition does not involve the disclosure of PHI in violation of privacy regulations.</li> </ul>
164.530(h)	11.3.8. <b>Waiver of Rights prohibited:</b> CE may not require individuals to waive any of their rights to file a complaint with the secretary of HHS or otherwise under these regulations as a condition of treatment, payment, enrollment, or eligibility for benefits.

164.530(i)

11.3.9. **Necessary Policies and Procedures:**

11.3.9.1. CE must design and implement policies and procedures relating to PHI to comply with requirements of the privacy regulations, taking into account the size and the types of activities that relate to PHI engaged in by the CE. (This standard is not to be construed to permit or excuse an action that violates any other standard, implementation, specification, or other requirement of the privacy regulations.)

11.3.9.2. **Changes to Policies and Procedures:**

11.3.9.2.1. CE must change its policies and procedures as necessary and appropriate to changes in the law/regulations. Whenever there is a change in law that necessitates a change to CE's policies and procedures, CE must promptly document and implement the revised policy or procedure; if the change materially affects the content of the Privacy Notice [¶ 4.2.], the CE must promptly make appropriate revisions to the notice in accordance with 164.520(b)(3) [¶ 4.2.10.].

11.3.9.2.2. When CE changes its privacy practices as stated in its Privacy Notice, and makes corresponding changes in policies and procedures, changes may be effective as to PHI created or received prior to the effective date of the policy/procedure changes and notice revision if its Privacy Notice includes a statement reserving the right to make changes in the CE's privacy practices. To implement change in privacy practice, and corresponding changes in policies/procedures, CE must ensure that revised policies and procedures comply with the regulations, document the revised policies and procedures, revise the Privacy Notice and make it available; changes to policies and procedures may not be implemented prior to the effective date of the revised notice.

	<p>11.3.9.2.3. If CE has not reserved right to change privacy practices, CE is bound by privacy practices as stated in Privacy Notice with regard to PHI created or received while notice is in effect; CE may change a privacy practice without having reserved the right to do so as long as the practice is in compliance with the regulations and is effective only with respect to PHI created or received after the effective date of the notice (§4.2.8).</p> <p>11.3.9.2.4. CE may change policies and procedures that do not materially affect the content of the Privacy Notice provided that the revised policies and procedures comply with the regulations and are properly documented.</p>
164.530(j)	<p>11.3.10. <b>Documentation Requirements:</b> CE must maintain the required policies and procedures in written or electronic form, and must maintain written or electronic copies of all communications, actions, activities, or designations that are required to be documented under the regulations, for a period of six years from the later of the date of creation or the last effective date.</p>
164.530(k)	<p>11.3.11. <b>Group Health Plans:</b> To the extent that a group health plan provides health benefits solely through an insurance contract with a health insurance issuer or HMO, and the plan does not create or receive PHI except for summary health information (defined in 164.504(a)/§ 10.1.7.) or information on the individual's participation in the plan, or enrollment and disenrollment from a health insurance issuer or HMO offered by the plan:</p> <p>11.3.11.1. The group health plan is not subject to the provisions requiring personnel designations, training, safeguards, complaint process, sanctions, mitigation, and policies and procedures, described in § 11.3; and</p> <p>11.3.11.2. The group health plan is subject to the documentation standard only with respect to plan documents amended in accordance with 164.504(f) [relating to sharing of information among or between a group health plan, the plan sponsor, a health insurance issuer, and/or an HMO, see § 10.6.]</p>

<p><b>160.304</b></p>	<p><b>12. COMPLIANCE AND ENFORCEMENT:</b></p> <p>12.1. <b>Principles for Achieving Compliance:</b></p> <p>12.1.1. Cooperation: Secretary of HHS will, to the extent practicable, seek cooperation of CEs in obtaining compliance with the regulations.</p> <p>12.1.2. Assistance: Secretary of HHS may provide technical assistance to CEs to help them comply voluntarily with the regulations.</p>
<p><b>160.306</b></p>	<p>12.2. <b>Complaints to the Secretary of HHS:</b></p> <p>12.2.1. Right to file complaint: A person who believes a CE is not complying with the regulations may file a complaint with the Secretary of HHS.</p> <p>12.2.2. Requirements for filing complaint:</p> <p>12.2.2.1. Complaint must be filed in writing, either on paper or electronically;</p> <p>12.2.2.2. Complaint must name entity that is the subject of the complaint and describe acts or omissions believed to be in violation of the regulations;</p> <p>12.2.2.3. Complaint must be filed within 180 days of when complainant knew or should have known of the act or omission, unless the time limit is waived by the Secretary of HHS for good cause shown.</p> <p>12.2.3. Investigation: Secretary of HHS may investigate complaints, which may include review of policies, procedures, or practices of the CE and of the circumstances regarding the alleged acts or omissions.</p>
<p><b>160.308</b></p>	<p>12.3. <b>Compliance Reviews:</b> Secretary of HHS may conduct compliance reviews to determine whether CEs are complying with applicable requirements of the regulations.</p>

- 12.4. **Responsibilities of CEs:**
- 12.4.1. Provide records and compliance reports: CE must keep such records and submit such compliance reports, in such time and manner and containing such information, as the Secretary of HHS may determine to be necessary to enable the Secretary to ascertain whether CE has complied and is complying with the regulations.
  - 12.4.2. Cooperate with complaint investigations and compliance reviews: CE must cooperate with the Secretary of HHS if the Secretary undertakes an investigation or compliance review of the policies, procedures or practices of a CE.
  - 12.4.3. Permit access to information:
    - 12.4.3.1. CE must permit access by the Secretary of HHS during normal business hours to its facilities, books, records, accounts, and other sources of information, including PHI, that are pertinent to ascertaining compliance with the regulations. If the Secretary determines that exigent circumstances exist, a CE must permit access at any time, without notice.
    - 12.4.3.2. If any of the information required of a CE hereunder is in the exclusive possession of another agency, institution, or person that fails or refuses to furnish the information, the CE must so certify, and set forth the efforts it undertook to obtain the information.
    - 12.4.3.3. PHI obtained by the Secretary of HHS in connection with an investigation or compliance review will not be disclosed by the Secretary, except if necessary for ascertaining or enforcing compliance with the applicable requirements of the regulations.

160.312

12.5. **Secretarial Action Regarding Complaints and Compliance Reviews:**

12.5.1. Resolution where noncompliance is indicated:

12.5.1.1. If an investigation or compliance review indicates a failure to comply, the Secretary of HHS will so inform the CE and, if the matter arose from a complaint, the complainant, in writing and attempt to resolve the matter by informal means whenever possible.

12.5.1.2. If the Secretary of HHS finds the CE is not in compliance and determines that the matter cannot be resolved informally, the Secretary may issue to the CE, and, if the matter arose from a complaint, the complainant, written findings documenting the noncompliance.

12.5.2. Resolution when no violation is found: If, after an investigation or compliance review, the Secretary of HHS determines that further action is not warranted, the Secretary will so inform the CE and, if the matter arose from a complaint, the complainant, in writing.

**NOT COVERED:** Transition Provisions [164.532]; Compliance Dates [164.534]

**Appendix  
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