

Using and Disclosing Information with Individual Permission

I. Written Authorization:

A. General Rule: A covered entity *must* obtain an individual's written authorization for uses and disclosures of protected health information (PHI), unless the use or disclosure is required or otherwise permitted by the privacy rule.¹ 45 C.F.R. § 164.508.

1. Uses and disclosures "otherwise permitted" by the rule and, therefore, not requiring an authorization:
 - a. uses and disclosures for treatment, payment, and health care operations made pursuant to § 164.506
 - b. uses and disclosures pursuant to § 164.512 (national priority uses and disclosures, such as uses and disclosures required by state law, for health care oversight activities, for law enforcement purposes, and to avert a serious threat to health or safety).When no provision of the privacy rule applies to require or permit a use or disclosure, then the individual's written authorization is required to make the use or disclosure.
2. An authorization *permits*, but does not require, the covered entity to use or disclose PHI. § 164.502(a)(1)(iv).
3. A "voluntary consent" document does not constitute a valid permission to use or disclose PHI for a purpose that requires an authorization under the rule. A voluntary consent document is a document that a covered entity is permitted, but not required, to use to obtain individual permission to use or disclose PHI for treatment, payment, or health care operations. (See outline, "Using and Disclosing Information for Treatment, Payment, and Health Care Operations," Section I, B, for more on "voluntary consent.")
4. The individual's authorization must be *voluntary* and *informed*. That means the authorization process must provide individuals with the opportunity to know and understand the circumstances surrounding a requested authorization.

B. Voluntary: The privacy rule contains two provisions that are intended to prevent covered entities from coercing individuals into signing an authorization that is not necessary for their health care. 67 Fed. Reg. at 14,797 (March 27, 2002). These provisions concern the conditioning and revocation of authorizations.

¹ The term "privacy rule" in this outline refers to the final rule published in Volume 67, Number 157 of the Federal Register on August 14, 2002.

1. Conditioning of authorizations (§ 164.508(b)(4)): A covered entity may *not* condition the provision of treatment, payment, enrollment in a health plan, or eligibility for benefits on the individual's provision of an authorization, except:
 - a. A *covered health care provider* may condition the provision of research-related treatment on provision of an authorization for the use or disclosure of PHI for such research.
 - b. A *health plan*, in certain circumstances, may condition health plan enrollment or eligibility for benefits on the provision of an authorization requested by the health plan prior to the individual's enrollment in the health plan.²
 - c. A *covered entity* may condition the provision of health care that is solely for the purpose of creating PHI for disclosure to a third party on an authorization for such disclosure.
 - Example: John's employer requires periodic drug testing for his continued employment. A health care provider can condition the administration of the drug test on John's authorization to disclose the drug test to his employer, as the test is administered solely for the purpose of disclosing the results to a third party (and not for treatment purposes).
 - Example: Jane is applying for life insurance and the application requires that Jane receive and report the results of a physical exam to the life insurance company. A health care provider can condition the conducting of the exam on Jane's authorization to disclose the exam results to the life insurance company, as the exam is provided solely for the purpose of creating PHI for disclosure to a third party.
2. Revocation (§ 164.508(b)(5)): An individual may revoke an authorization *at any time* by putting the revocation in writing, except:
 - a. To the extent that the covered entity has taken action in reliance on the authorization, or
 - b. The authorization was obtained as a condition of obtaining insurance coverage and other law provides the insurer with the right to contest the policy or a claim under the policy.

² The circumstances that permit a health plan to condition enrollment and eligibility on an authorization are (1) the authorization sought is for the health plan's eligibility or enrollment determinations relating to the individual or for its underwriting of risk rating determinations, and (2) the authorization is not for the use or disclosure of "psychotherapy notes."

C. Informed (Contents): To help ensure that individuals give their authorization on an informed basis, the privacy rule sets out elements that must be included in any authorization. § 164.508(c). To be valid, an authorization to disclose PHI must contain the elements listed below. A valid authorization may contain elements or information in addition to the required elements, so long as the additional elements or information are consistent with the required elements. § 164.508(b)(1). Required elements are:

1. The name or other specific identification of the person(s), or classes of persons, authorized to make the requested use or disclosure.
2. The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure.
3. A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.
4. A description of each purpose of the requested use or disclosure.
 - a. The statement “at the request of the individual” is a sufficient description of purpose when an individual initiates the authorization and does not, or elects not to, provide a statement of purpose.
5. An expiration date or event that *relates* to the individual or the purpose of the use or disclosure.
 - a. An authorization that purports to expire on the date when the stock market reached a specified level would not be valid, as the expiration event would not relate to the individual or purpose of the use or disclosure.
 - b. The statement “end of research study” or similar language is sufficient if the authorization is for a use or disclosure of PHI for research.
 - c. The statement “none” or similar language is sufficient if the information is for the creation and maintenance of a research database or research repository.
6. Signature of the individual (the person who is the subject of the PHI) and date.
 - a. If the authorization is signed by a “personal representative” of the individual, a description of such representative’s authority to act for the individual must also be provided. According to the preamble to the final rule (August 14, 2002), the rule requires that covered entities verify and document a person’s authority to sign an authorization on an individual’s behalf.
 - Personal representative: Generally, if under state law a person has the authority to act on behalf of an individual, the covered entity

must treat such person as the “personal representative” of the individual. 164.502(g). With some exceptions, the personal representative must be treated as the individual, i.e., allowed to exercise the rights of the individual (see outline entitled, “Personal Representatives”).

7. A statement that notifies the individual of the right to revoke the authorization in writing that includes either:
 - a. The exceptions to the right to revoke and a description of how the individual may revoke the authorization, or
 - b. To the extent that the information referred to in “a.” is included in the Notice of Privacy Practices, a reference to the covered entity’s notice.
8. Either:
 - a. A statement that treatment, payment, enrollment, or eligibility for benefits may not be conditioned on obtaining the authorization (if such conditioning is prohibited by the privacy rule) (see part C, above), or
 - b. A statement about the consequences of refusing to sign the authorization (if conditioning is permitted by the privacy rule) (see part C, above)
9. A statement about the potential for PHI disclosed pursuant to the authorization to be subject to redisclosure by the recipient and no longer protected by the privacy rule. This statement is necessary because the recipient could not be a covered entity and, therefore, not subject to the privacy rule. While a general statement to this effect will suffice, a covered entity has the discretion to provide a more definitive statement where appropriate. For example, if a covered health care provider is requesting the authorization so that it may receive PHI for its own use from another health care provider, the covered health care provider may provide assurances that the information will remain subject to the privacy rule.

D. Other requirements (§ 164.508(b) and (c)):

1. Plain language. The authorization must be written in plain language.
2. Copy to individual. If a covered entity seeks an authorization from an individual for a use or disclosure of PHI, the covered entity must provide the individual with a copy of the signed authorization.
3. Consistency. When a covered entity obtains or receives a valid authorization for the use or disclosure of PHI, such use or disclosure must be consistent with such authorization. This means that covered entities are bound by the statements provided in the authorization, and use and disclosure for purposes inconsistent with the statements made in the authorization constitute a violation of the privacy rule.

4. Defective authorizations. An authorization is not valid if
 - a. The expiration date has passed or the expiration event is known by the covered entity to have occurred.
 - b. The authorization has not been filled out completely with respect to a required element.
 - c. The authorization is *known* by the covered entity to have been revoked.
 - d. The authorization violates the rule regarding the conditioning of authorizations (see C.1., above).
 - e. The authorization violates the rule regarding compound authorizations (see 5., below).
 - f. Any *material* information in the authorization is known by the covered entity to be false.

5. Compound authorizations. An authorization for use or disclosure of PHI may *not* be combined with any other document to create a compound authorization except as set forth in b., below.
 - a. Example: An authorization for use and disclosure of PHI may not be combined with a consent to receive treatment or a consent to assign payment of benefits to a provider. It cannot be combined with any other legal permission from the individual.

 - b. Exceptions:
 - An authorization for the use and disclosure of PHI for a specific research study may be combined with any other type of written permission for the same research study, including a consent to participate in such research.
 - An authorization for the use or disclosure of psychotherapy notes may only be combined with another authorization for the use or disclosure of psychotherapy notes.
 - Example: an authorization for the use or disclosure of psychotherapy notes for multiple purposes—treatment and research—may be combined in a single document, but may not be combined with authorizations for use and disclosure of other PHI.
 - An authorization for the use and disclosure of PHI may be combined with any other such authorization (other than an authorization for a use or disclosure of psychotherapy notes; and except when a covered entity has conditioned the provision of treatment, payment, enrollment in the health plan, or eligibility for benefits on the provision of one of the authorizations).
 - Example/multiple purposes: An authorization for the disclosure of the individual's demographic information for both marketing and fundraising purposes.
 - Example/multiple entities: A crisis center, an inpatient alcoholism treatment program, and a provider of supportive

housing for persons with disabilities may want to work together to coordinate treatment and housing services for homeless individuals who initially seek help from the crisis center. The three agencies could develop a single authorization form, to be signed by clients who agree to have them coordinate these services, which authorizes each agency to disclose to and receive from the others PHI about the client that is needed for the purpose of enabling them to provide and coordinate that client's treatment and housing services.

6. Documentation.
 - a. Authorization: A covered entity must maintain the written authorization, or an electronic copy, as documentation.
 - b. Revocation: A covered entity must maintain the written revocation, or an electronic copy, as documentation.
 - c. Period of retention: Documentation must be retained for six years from the date of its creation or the date when it was last in effect, whichever is later. § 164.530(j)

E. Psychotherapy notes: When it comes to using and disclosing a special category of PHI—psychotherapy notes—many of the *exceptions* to the rule requiring individual authorization to use or disclose PHI do not apply. In other words, notwithstanding the many provisions of the privacy rule that permit or require the use or disclosure of PHI without individual authorization, a covered entity must obtain authorization for any use or disclosure of psychotherapy notes, except:

1. To carry out the covered entity's own very *limited* treatment, payment, or health care operations activities set forth in Section III of the outline entitled, "Using and Disclosing Information for Treatment, Payment, and Health Care Operations." Use and disclosure for any other TPO activities requires authorization.
2. When disclosure is required by the Secretary of US DHHS to investigate or determine whether the covered entity is in compliance with the privacy standards.
3. When use or disclosure is required by law.
4. When use or disclosure to a health oversight agency for oversight activities is authorized by law and the oversight activity pertains to the originator of the psychotherapy notes.
5. When use or disclosure to a coroner or medical examiner is necessary to carry out their duties with respect to a decedent.

6. When use or disclosure is necessary to avert a serious threat to health or safety. § 164.508(a)(2).

Note: Each of these exceptions, and their accompanying requirements, are discussed in more detail in the outline entitled, "Using and Disclosing Information Without Individual Permission Pursuant to Privacy Rule § 164.512."

II. Opportunity to agree or object

A. General rule: A covered entity may use or disclose PHI for facility directory purposes and for involving family members or friends in the individual's care, provided that the individual is informed in advance of the use or disclosure and has the opportunity to agree to, prohibit, or restrict the use or disclosure. § 164.510.

B. Use and disclosure for facility directories. § 164.510(a).

1. Except when the individual objects, a covered health care provider may:
 - a. Use the following PHI to maintain a directory of individuals in its facility:
 - The individual's name;
 - The individual's location in the provider's facility;
 - The individual's condition, described in general terms that do not communicate specific medical information about the individual (e.g., fair, critical, stable, etc.); and
 - The individual's religious affiliation.
 - b. Disclose for directory purposes
 - To members of the clergy, all of the above-described PHI.
 - To all other persons who ask for the individual by name, the individual's general condition and location in the facility.
2. Opportunity to object. Before using PHI for a facility directory, the covered health care provider must
 - a. inform the individual of the PHI that may be included in the directory and the persons to whom it may be disclosed, and
 - b. provide the individual the opportunity to restrict or prohibit some or all of the uses or disclosures.

Both the notice to the individual and the individual's opt-out or restriction may be given orally.
3. Special circumstances. If it is not practicable to provide an opportunity to object because of the individual's *incapacity* or an *emergency* treatment circumstance, the provider may use or disclose *some or all* of the PHI for the facility's directory, if such disclosure is:

- a. Consistent with the individual's prior expressed preference, if any, that is *known* to the covered health care provider; and
- b. In the individual's *best interest* as determined by the covered provider, in the exercise of professional judgment.

The provider must inform the individual and provide an opportunity to object to uses or disclosures when it becomes practicable to do so.

4. Discussion about incapacitated patients and emergency treatment circumstances:
 - a. If a health care provider learns of an incapacitated patient's prior expression of preference not to be included in a facility's directory, the facility must not include the patient's information in the directory. If there is no known prior preference, then only the "best interest" portion of the rule governs the discretion of the health care provider.
 - b. Health care providers may decide to include some portions of the patient's information (such as name) but not other information (such as location in the facility) in order to protect patient interests.
 - c. US DHHS encourages health care providers to take into account the following factors when determining whether to include an incapacitated patient's information in a directory:
 - Whether disclosing that an individual is in the facility could reasonably cause harm or danger to the individual (e.g., if it appeared that an unconscious patient had been abused and disclosing the information could give the attacker sufficient information to seek out the person and repeat the abuse);
 - Whether disclosing a patient's location within a facility implicitly would give information about the patient's condition (e.g., whether a patient's room number revealed that he or she was in a psychiatric ward); and
 - Whether it was necessary or appropriate to give information about patient status to family or friends (e.g., if giving information to a family member about an unconscious patient could help a physician determine appropriate medications). 65 Fed. Reg. at 82521.

C. Use and disclosure for notifying family or friends, and for involving family or friends in care. § 164.510(b).

1. Subject to the individual's objection or the covered entity's determination that disclosure would not be in the best interest of the individual a covered entity may:
 - a. Disclose to a person involved with the health care of the individual (such as family member, other relative, close personal friend, or any other

person identified by the individual) PHI “directly relevant” to the person’s involvement with the individual’s care or payment related to the individual’s health care.

- Directly relevant: The privacy rule does not define the term “directly relevant” but the preamble to the privacy rule indicates that the covered entity should disclose “only the minimum information necessary for the friend or relative to provide the assistance or care he or she was providing.”
- Example # 1: Health care providers should not disclose to a friend or relative, who is simply driving a patient home from the hospital, extensive information about the patient’s surgery or past medical history when the friend or relative has no need for this information. 65 Fed. Reg. at 82523.
- Example # 2: A covered entity may disclose functional information to a person assisting in the patient’s care. It allows hospital staff to give information about a person’s mobility limitations to a friend driving the patient home from the hospital. This information is directly relevant to the assistance the friend is providing.

b. Use or disclose PHI to notify or assist in the notification of (including identifying or locating) a family member, a personal representative, or another person responsible for the individual’s care, of the individual’s location, general condition, or death.

- Example: A covered entity may notify a patient’s adult child that his father has suffered a stroke and to tell the person that the father is in the hospital’s intensive care unit.

2. Opportunity to agree or object.

a. Individual present: If the individual is present or available prior to a use or disclosure and has the capacity to make health care decisions, the covered entity may use or disclose PHI only if it:

- Obtains the individual’s agreement to disclose to the third parties involved in their care (may be oral);
 - Agreement at one point in time does not imply agreement to disclose indefinitely in the future. US DHHS encourages “the exercise of professional judgment in determining the scope of the person’s involvement in the individual’s care and the time period for which the individual is agreeing to the other person’s involvement. For example, if a friend simply picks up a patient from the hospital but has played no other role in the individual’s care, hospital staff should not call the friend to disclose lab test results a month after the initial encounter with the friend.” 65 Fed. Reg. 82523.
- Provides the individual with an opportunity to object to the disclosure and the individual does not express an objection; or

- Reasonably infers from the circumstances, based on the exercise of professional judgment, that the individual does not object to the disclosure
 - Example # 1: A colleague or friend brings the individual to the emergency room for treatment of a seriously lacerated hand and waits with the individual. The physician can infer that the individual does not object to disclosures about the painkiller to be prescribed, the side effects, and the limitations on driving.
 - Example # 2: A patient *routinely* brings a spouse into the doctor's office when treatment is discussed. The physician can infer that the spouse is playing a *long-term role* in the patient's care, and the rule allows disclosure of PHI to the spouse consistent with his or her role in the patient's care, for example, discussion of treatment options.

- b. Individual not present: If the individual is *not present* (e.g., the friend of a patient seeks to pick up the patient's prescription at a pharmacy) or the opportunity to agree or object cannot practicably be provided because of the individual's *incapacity* or an *emergency* circumstance, the covered entity may, in the exercise of professional judgment, determine whether the disclosure is in the "best interests" of the individual and, if so, disclose only the PHI that is directly relevant to the person's involvement with the individual's health care.
 - Example: A covered entity may inform relatives or others involved in a patient's care, such as the person who accompanied the individual to the emergency room, that a patient has suffered a heart attack and to provide updates on the patient's progress and prognosis when the patient is incapacitated and unable to make decisions about such disclosures.
 - Best interests:
 - A covered entity may use professional judgment and its experience with common practice to make reasonable inferences of the individual's best interest in allowing a person to act on behalf of the individual to pick up filled prescriptions, medical supplies, X-rays, or other similar forms of PHI. Thus, a pharmacist may release a prescription to a patient's friend who is picking up the prescription for him or her.
 - When exercising professional judgment regarding the individual's best interests, covered entities must taking into account whether such a disclosure is likely to put the individual at risk of serious harm. For example, the exercise of professional judgment as to the patient's best interest would deny disclosure when the person seeking disclosure is suspected of abusing a victim of domestic violence and there is reason to believe that such a disclosure could cause the patient serious harm.

3. Disaster relief: A covered entity may use or disclose PHI to federal, state, or local government agencies engaged in disaster relief activities, as well as to private disaster relief or disaster assistance organizations (such as the Red Cross), that are authorized by law or by their charters to assist in disaster relief efforts, for the purpose of coordinating with such entities the notification of a family member, personal representative, or other person of the individual's location, general condition, or death (see activities set forth in C.1.b., above).
 - a. The opportunity to agree or object (when the individual is present) and the best interest test (when the individual is not present), see Number 2, above, do not apply to such uses and disclosures unless the covered entity determines that such requirements do not interfere with the ability to respond to the emergency.
 - b. Example: A covered entity may disclose PHI to disaster relief organizations so that these organizations can help family members, friends, or others to locate the individuals affected by a disaster and to inform them of the individual's general health condition.

III. Fundraising: Although fundraising for the benefit of a covered entity is considered a health care operation of the covered entity, and uses and disclosures for health care operations are generally permitted without individual permission, uses and disclosures for fundraising require either an opt out procedure or individual authorization.

- A. Opportunity to opt out.** A covered entity may use and disclose PHI to contact the individual without authorization only if the entity provides the individual with an opportunity to opt out of receiving such materials, and only under the following limitations and requirements. § 164.514(f).
1. Limitations: A covered entity may use, or disclose to a business associate or to an institutionally related foundation, the following *limited PHI* for the *limited purpose* of raising funds for its own benefit:
 - a. Demographic information relating to an individual; and
 - b. Dates of health care provided to an individual.
 2. Requirements:
 - a. The covered entity may not use or disclose PHI for fundraising purposes unless the covered entity's *privacy notice* states that the covered entity may contact the individual to raise funds for the covered entity.
 - b. The covered entity must include in any fundraising materials it sends to an individual a description of how the individual may *opt out* of receiving any further fundraising communications.
 - c. The covered entity must make reasonable efforts to ensure that individuals who decide to opt out of receiving *future fundraising* communications are not sent such communications.

- B. Authorization.** Any use or disclosure for fundraising purposes that does not meet the limitations and requirements of A, above, requires authorization. For example, covered entities must obtain the individual's authorization to use or disclose PHI to raise funds for any entity other than the covered entity.

IV. Authorizing use and disclosure for marketing.

- A. General rule:** Notwithstanding other provisions of the privacy rule that permit the use or disclosure of PHI without individual authorization, a covered entity must obtain an authorization for any use or disclosure of PHI for "marketing," with two exceptions. A written authorization is not required if the communication is in the form of

1. a face-to-face communication made by a covered entity to an individual, or
2. a promotional gift of nominal value provided by the covered entity. § 164.508(a)(3)

Explanation: The preamble to the final rule published on August 14, 2002, explains that face-to-face communications, number 1, above, are excluded from the requirement to obtain authorization, even if such communications fall within the definition of marketing, to prevent the marketing authorization requirements from interfering with the relationship and dialogue between health care providers and individuals.

- B. Authorization.** The authorization to use or disclose PHI for marketing must be in writing and comply with the authorization requirements set forth in Section I, above. § 164.508(a)(3).

1. If the marketing involves direct or indirect remuneration (payment or compensation) to the covered entity from a third party, the authorization must state that such remuneration is involved.

C. "Marketing" means:

1. To make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service, unless the communication is made:
 - a. To describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the covered entity making the communication, including communications about:

- the entities participating in a health care provider network or health plan network;
 - replacement of, or enhancements to, a health plan; and
 - health-related products or services available only to a health plan enrollee that add value to, but are not part of, a plan of benefits.
- b. For treatment of the individual
- c. For case management or care coordination for the individual. (Note that this activity that falls within the definition of “health care operations.”)
- d. To direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual.
2. An arrangement between a covered entity and any other entity whereby the covered entity discloses PHI to the other entity, in exchange for direct or indirect remuneration, for the other entity or its affiliate to make a communication about its own product or service that encourages recipients of the communication to purchase or use that product or service. § 164.501.

D. Explanation of definition of “marketing”

1. Exclusions: The purpose of the exclusions from the definition of marketing is to facilitate those communications that enhance the individual’s access to quality health care. Thus, the exclusions permit covered health care providers and health plans to communicate freely to their patients or enrollees about their own products, services, and benefits. The exceptions also exclude all communications that fall within the definition of “treatment.” For example, a doctor that writes a prescription or refers an individual to a specialist for follow-up is engaging in a treatment communication and is not “marketing” a service or product. Note, however, that there is not a blanket exception for all communications that fall within the definitions of “payment” and “health care operations.”
2. Business associates: With respect to the exclusions, a covered entity does not need an authorization for these types of communications and may make the communication itself or use a business associate to do so. Covered entities may not disclose PHI to third parties for “marketing” purposes, however, without authorization from the individual, even if the third party is acting as a business associate of the disclosing covered entity. A covered entity cannot use a business associate agreement to escape the definition of marketing. For example, a covered entity cannot sell PHI to another company for the marketing of that company’s products or services, under the guise of the company acting as a business associate of the covered entity for the purpose of recommending an alternative treatment or therapy to the individual. The

language in part two of the definition referring an arrangement between a covered entity and another entity was specifically added to make clear that business associate transactions of this nature are “marketing,” and the communications in this relationship can only occur if the covered entity obtains the individual’s written authorization in accordance with § 164.508.

- V. Transition provisions.** § 164.532(a) and (b). A covered entity may use or disclose PHI that it created or received prior to the applicable compliance date of the privacy rule (April 2003) pursuant to an authorization or other express legal permission obtained from an individual prior to the compliance date, provided that the authorization or other express legal permission specifically permits such use or disclosure and there is no agreed-to restriction in accordance with § 164.522(a) (which gives an individual the right to request the covered entity to restrict (1) uses and disclosures of PHI to carry out treatment, payment, and health care operations; and (2) disclosures for involvement in the individual’s care and notification purposes under § 164.510(b)).