

## Accounting for disclosures checklist

**INSTRUCTIONS:** The following is the text of 164.528 (f) (containing the requirements for accounting for disclosures of protected health information) and Accounting of Disclosures of Protected Health Information (changes effective October 15, 2002).

Check off each element if disclosing PHI for these purposes or trying to determine if you need to use an authorization.

### § 164.528 Accounting of disclosures of protected health information.

#### (a) Standard: right to an accounting of disclosures of protected health information.

1.  An individual has a right to receive an accounting of disclosures of protected health information made by a covered entity in the six years prior to the date on which the accounting is requested, except for disclosures:
  - i.  To carry out treatment, payment and health care operations as provided in § 164.502;
  - ii.  To individuals of protected health information about them as provided in § 164.502;
  - iii.  For the facility's directory or to persons involved in the individual's care or other notification purposes as provided in § 164.510;
  - iv.  For national security or intelligence purposes as provided in § 164.512(k)(2);
  - v.  To correctional institutions or law enforcement officials as provided in § 164.512(k)(5); or
  - vi.  That occurred prior to the compliance date for the covered entity.
2. 
  - i.  The covered entity must temporarily suspend an individual's right to receive an accounting of disclosures to a health oversight agency or law enforcement official, as provided in § 164.512(d) or (f), respectively, 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.
  - ii.  If the agency or official statement in paragraph (a)(2)(i) of this section is made orally, the covered entity must:
    - A.  Document the statement, including the identity of the agency or official making the statement;
    - B.  Temporarily suspend the individual's right to an accounting of disclosures subject to the statement; and
    - C.  Limit the temporary suspension to no longer than 30 days from the date of the oral statement, unless a written statement pursuant to paragraph (a)(2)(i) of this section is submitted during that time.
  - iii.  An individual may request an accounting of disclosures for a period of time less than six years from the date of the request.

**(b) Implementation specifications: content of the accounting.** The covered entity must provide the individual with a written accounting that meets the following requirements.

1.  Except as otherwise provided by paragraph (a) of this section, the accounting must include disclosures of protected health information that occurred during the six years

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(or such shorter time period at the request of the individual as provided in paragraph (a)(3) of this section) prior to the date of the request for an accounting, including disclosures to or by business associates of the covered entity.

2.  The accounting must include for each disclosure:
  - i.  The date of the disclosure;
  - ii.  The name of the entity or person who received the protected health information and, if known, the address of such entity or person;
  - iii.  A brief description of the protected health information disclosed; and
  - iv.  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:
    - A.  A copy of the individual's written authorization pursuant to § [164.508](#); or
    - B.  A copy of a written request for a disclosure under §§ [164.502\(a\)\(2\)\(ii\)](#) or [164.512](#), if any.
3. If, during the period covered by the accounting, the covered entity has made multiple disclosures of protected health information to the same person or entity for a single purpose under §§ [164.502\(a\)\(2\)\(ii\)](#) or [164.512](#), or pursuant to a single authorization under § [164.508](#), the accounting may, with respect to such multiple disclosures, provide:
  - i.  The information required by paragraph (b)(2) of this section for the first disclosure during the accounting period;
  - ii.  The frequency, periodicity, or number of the disclosures made during the accounting period; and
  - iii.  The date of the last such disclosure during the accounting period.

### **(c) Implementation specifications: provision of the accounting.**

1.  The covered entity must act on the individual's request for an accounting, no later than 60 days after receipt of such a request, as follows.
  - i.  The covered entity must provide the individual with the accounting requested; or
  - ii.  If the covered entity is unable to provide the accounting within the time required by paragraph (c)(1) of this section, the covered entity may extend the time to provide the accounting by no more than 30 days, provided that:
    - A.  The covered entity, within the time limit set by paragraph (c)(1) of this section, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will provide the accounting; and
    - B.  The covered entity may have only one such extension of time for action on a request for an accounting.
2.  The covered entity must provide the first accounting to an individual in any 12 month period without charge. The covered entity 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 covered entity 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.

**(d) Implementation specification: documentation.** A covered entity must document the following and retain the documentation as required by § [164.530\(j\)](#):

1.  The information required to be included in an accounting under paragraph (b) of this section for disclosures of protected health information that are subject to an accounting under paragraph (a) of this section;
2.  The written accounting that is provided to the individual under this section; and

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

### I. Section 164.528--Accounting of Disclosures of Protected Health Information

#### Final Modifications

Based on the general support in the public comment,  the Department adopts the modification to eliminate the accounting requirement for authorized disclosures. The authorization process itself adequately protects individual privacy by assuring that the individual's permission is given both knowingly and voluntarily. The Department agrees with the majority of commenters that felt accounting for authorized disclosures did not serve to add to the individual's knowledge about disclosures of protected health information. The Department does recognize the role of accounting requirements in the detection of altered or fraudulent authorizations. However, the Department considers the incidence of these types of abuses, and the likelihood of their detection through a request for an accounting, to be too remote to warrant the burden on all covered entities of including authorized disclosures in an accounting. As noted by some commenters, the covered entity must retain a copy of the authorization to document their disclosure of protected health information and that documentation would be available to help resolve an individual's complaint to either the covered entity or the Secretary.

In response to comment on this proposal, as well as on the proposals to permit incidental disclosures and disclosures of protected health information, other than direct identifiers, as part of a limited data set, the Department has added two additional exclusions to the accounting requirements.  Disclosures that are part of a limited data set and  disclosures that are merely incidental to another permissible use or disclosure will not require an accounting. The limited data set does not contain any protected health information that directly identifies the individual and the individual is further protected from identification by the required data use agreement. The Department believes that accounting for these disclosures would be too burdensome. Similarly, the Department believes that it is impracticable to account for incidental disclosures, which by their very nature, may be uncertain or unknown to the covered entity at the time they occur. Incidental disclosures are permitted as long as reasonable safeguards and minimum necessary standards have been observed for the underlying communication. Moreover, incidental disclosures may most often happen in the context of a communication that relates to treatment or health care operations. In that case, the underlying disclosure is not subject to an accounting and it would be arbitrary to require an accounting for a disclosure that was merely incidental to such a communication.

The Department disagrees with commenters' proposal to exempt all research disclosures made pursuant to a waiver of authorization from the accounting requirement. Individuals have a right to know what information about them has been disclosed without their authorization, and for what purpose(s). However, the Department agrees that the Rule's accounting requirements could have the undesired effect of causing covered entities to halt disclosures of protected health information for research. Therefore, the Department adopts commenters' proposal to revise the accounting requirement at Sec. 164.528 to permit covered entities to meet the requirement for research disclosures if they provide individuals with a list of all protocols for which the patient's protected health information may have been disclosed for research pursuant to a waiver of authorization under Sec. 164.512(i), as well as the

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researcher's name and contact information. The Department agrees with commenters that this option struck the appropriate balance between affirming individuals' right to know how information about them is disclosed, and ensuring that important research is not halted.

The Department considered and rejected a similar proposal by commenters when it adopted the Privacy Rule in December 2000. While recognizing the potential burden for research, the Department determined that the individual was entitled to the same level of specificity in an accounting for research disclosures as any other disclosure. At that time, however, the Department added the summary accounting procedures at Sec. 164.528(b)(3) to address the burden issues of researchers and others in accounting for multiple disclosures to the same entity. In response to the Department's most recent request for comments, researchers and others explained that the summary accounting procedures do not address the burden of having to account for disclosures for research permitted by Sec. 164.512(i). These research projects usually involve many records. It is the volume of records for each disclosure, not the repeated nature of the disclosures, that presents an administrative obstacle for research if each record must be individually tracked for the accounting. Similarly, the summary accounting procedures do not relieve the burden for covered entities that participate in many different studies on a routine basis. The Department, therefore, reconsidered the proposal to account for large research projects by providing a list of protocols in light of these comments.

Specifically, the Department adds a paragraph (4) to Sec. 164.528(b) to provide for simplified accounting for research disclosures as follows:

(1) The research disclosure must be pursuant to Sec. 164.512(i) and involve at least 50 records. Thus, the simplified accounting procedures may be used for research disclosures based on an IRB or Privacy Board waiver of individual authorization, the provision of access to the researcher to protected health information for purposes preparatory to research, or for research using only records of deceased individuals. The large number of records likely to be disclosed for these research purposes justifies the need for the simplified accounting procedures. The Department has determined that a research request for 50 or more records warrants use of these special procedures.

(2) For research protocols for which the individual's protected health information may have been disclosed during the accounting period, the accounting must include the name of the study or protocol, a description of the purpose of the study and the type of protected health information sought, and the timeframe of disclosures in response to the request.

(3) When requested by the individual, the covered entity must provide assistance in contacting those researchers to whom it is likely that the individual's protected health information was actually disclosed.