HIPAA Viewpoint

Clinical Trial Recruitment Under HIPAA

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The effects of the recently finalized privacy standards promulgated by the Department of Health and Human Services (''HHS'')[1] under the Health Insurance Portability and Accountability Act of 1996 (''HIPAA''),[2] will be felt at the earliest stages of preparing for a clinical trial. Beginning April 14, 2003, the date by which compliance with these privacy standards (the ''Privacy Rule'') is required, researchers will face new data access limitations and administrative requirements related to the process of identifying and recruiting participants.

The HIPAA Privacy Rule: General Principles

The Privacy Rule imposes new restrictions on the use and disclosure of individually identifiable health information, known as ''protected health information,'' by most health care providers, health plans, and health care clearinghouses. These ''covered entities'' may use and disclose protected health information: (1) for treatment, payment, and health care operations;[3] (2) with an individual's written authorization for marketing and other purposes unrelated to treatment, payment, and health care operations;[4] and (3) without authorization for certain enumerated purposes, if specified conditions are met.[5] To use and disclose protected health information for research, a covered entity generally must obtain individual authorization or documentation of waiver of authorization by an institutional review board (''IRB'') or specially constituted privacy board.[6] The authorization requirement is separate from and in addition to the informed consent requirement of the Common Rule (if applicable), and waiver of authorization must be determined independently from a decision by the IRB to waive informed consent.[7] In addition, the Privacy Rule does not preempt state laws that are more protective of the privacy of individuals' health information.[8]

Uses and Disclosures for Clinical Trial Recruitment

In the Aug. 14, 2002, final Privacy Rule, HHS clarified, at least partially, the rules regarding clinical trial recruitment under HIPAA. Recruitment, according to the Rule's preamble, is not a health care ''marketing'' activity which requires individuals' prior written authorization, nor is it a ''health care operation'' of the covered entity.[9] Under the Rule, a health care provider may discuss a clinical trial opportunity with a patient without prior written authorization, as a permitted disclosure of protected health information to the patient.[10] However, in order to disclose a patient's protected health information to a third party for recruitment purposes, the provider must obtain the patient's written authorization or a waiver of authorization.[11]

The Privacy Rule treats clinical trial recruitment as a two-step process: (1) the use and disclosure of protected health information for identification of prospective trial participants and (2) the disclosure of health information to these individuals as part of a discussion about the clinical trial opportunity. In clarifying that providers may *discuss* clinical trial opportunities with their patients (and, presumably, that health plans may do the same with their members), HHS addressed the conditions under which a covered entity may review, analyze, or otherwise use protected health information in its possession to *identify* prospective study enrollees. This area, however, is not well developed and would benefit from additional guidance from HHS.

Identification of Prospective Participants

The Privacy Rule provides two principal mechanisms through which a researcher may obtain access to protected health information for the purpose of identifying prospective research participants: (1) reviews preparatory to research; and (2) partial IRB or Privacy Board waivers.

Reviews Preparatory to Research. A covered entity may use or disclose to external investigators protected health information as part of a ''review preparatory to research,'' if the covered entity obtains representations from the person(s) conducting the review that:

[1] 65 Fed. Reg. 82,462 (Dec. 28, 2000) (codified at 45 C.F.R. part 160 & part 164, subpart E), as modified by 67 Fed. Reg. 53,182 (Aug. 14, 2002) (to be codified at 45 C.F.R. part 160 & part 164, subpart E).

[2] Pub. L. No. 104-191 (1996).

[3] *See* 45 C.F.R. §§ 164.502(a)(1)(ii), -.506.

[4] *See* 45 C.F.R. §§ 164.502(a)(1)(iv), -.508.

[5] *See* 45 C.F.R. §§ 164.502(a)(1)(v), -.512.

[6] *See* 45 C.F.R. § 164.512(i). Privacy boards—an invention of the Privacy Rule—function similarly to IRBs although their role is limited to waiving the authorizations required by the Privacy Rule to use and disclose protected health information for research purposes; they do not have authority under the Common Rule to approve research protocols. Any entity, including a research investigator, may establish a privacy board. *See* Department of Health and Human Services, HIPAA Privacy Rule Guidance (July 6, 2001) (available at http://aspe.hhs.gov/admnsimp/final/pvcguide1.htm).

[7] *See* 65 Fed. Reg. at 82,538 (stating that where the Privacy Rule and the Common Rule apply, both must be followed).

[8] *See* 45 C.F.R. §§ 160.201-.203.

[9] *See* 67 Fed. Reg. at 53,230-31.

[10] *See id.*

[11] *See id.*

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(1) the use or disclosure is solely to review protected health information as necessary to prepare a research protocol or for similar purposes preparatory to research;

(2) no protected health information will be copied or removed from the premises during the course of the review; and

(3) the protected health information to be reviewed is necessary for the research purposes.[12]

HHS has stated that such ''preparatory'' reviews are permitted to facilitate the development of research hypotheses and to aid in the recruitment of research participants.[13] Thus, in the hospital setting, members of the hospital workforce may review hospital records for clinical trial screening purposes consistent with the conditions set forth above. Similarly, a hospital or other covered entity may permit external investigators, such as researchers from contract research organizations or pharmaceutical companies, to review its patient records subject to these representations. Although no protected health information may be copied or removed from the premises, the reviewer may ''flag'' or otherwise mark records of interest so that these individuals may be contacted by the covered entity, consistent with the requirements discussed below.

The Privacy Rule does not specifically require that reviewers' representations be made in writing, but it is reasonable to expect that covered entities will require signed, written assurances to document their compliance with the Rule. Although not required by the Rule, some covered entities are requiring researchers to use standard representation or ''certification'' forms that have been pre-approved by an IRB.

Partial IRB Waivers for Clinical Trial Recruitment. The second mechanism for identification of prospective research participants is an IRB or Privacy Board ''partial'' waiver of authorization. With written documentation of waiver, a covered entity may disclose protected health information to an external investigator for the limited purpose of identifying prospective research participants.[14] Although a waiver permits the investigator to screen the records outside of the covered entity's premises, the burden of obtaining a waiver is greater than that for a review preparatory to research. To grant a waiver, the IRB or privacy board must determine that:

(1) the use or disclosure of protected health information involves no more than minimal risk to the individuals' privacy, based on the presence of at least the following elements—

a) an adequate plan to protect identifiers from improper use and disclosure;

b) an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research; and

c) adequate written assurances by the reviewer that the protected health information will not be reused or disclosed to any third party (except in limited circumstances specified by the Privacy Rule);

(2) the proposed research could not practicably be conducted without the partial waiver; and

(3) the research could not practicably be conducted without access to and use of the protected health information.[15]

Minimum Necessary

Whether a records review is conducted as a review preparatory to research or under a partial IRB waiver, covered entities must limit the amount of protected health information to which a reviewer has access to the minimum necessary to identify the prospective research participants.[16] The Privacy Rule does permit a covered entity to rely (if such reliance is reasonable under the circumstances) on an investigator's representations or the written documentation of waiver as evidence that the information sought is the minimum necessary amount.[17] To document compliance with the reasonable reliance standard, hospitals and other covered entities may require external investigators, in particular, to describe the nature of the proposed protocol and to specify the scope of the information sought to be reviewed.

Accounting of Disclosures

Under the Privacy Rule, individuals have a right to an accounting of certain disclosures of their protected health information.[18] Disclosures for research-related purposes that are not made pursuant to an individual authorization must be included in this accounting. Thus, it appears that when disclosures are made for a ''review preparatory to research'' or pursuant to a partial waiver, covered entities must document in writing the disclosure of protected health information. For reviews of data involving fewer than 50 persons, the covered entity must document for each disclosure: (i) the date of the disclosure; (ii) the identity of the external reviewer and, if known, the reviewer's address; (iii) a brief description of the information disclosed; and (iv) a brief statement of the purpose of the disclosure (i.e., clinical trial recruitment).[19] For screening reviews involving the protected health information of 50 or more persons, the covered entity may elect instead to maintain a list of such reviews and to provide this list to individuals who request an accounting of disclosures of their protected health information. With respect to each clinical trial screening identified on the list, the covered entity must provide: (i) the name of the proposed protocol or study; (ii) a description of the proposed protocol or study, including its purpose and inclusion criteria; (iii) the date or period of time during which the disclosure(s) occurred or may have occurred; (iv) contact information for the person(s) who reviewed the data and the research sponsor, if any; and (v) a statement that protected health information about the individual may *or may not* have been disclosed for the research activity.[20] If the covered entity believes it is ''reasonably likely'' that an individual's protected health information actually was screened by an external investigator, upon request it must assist the individual in contacting the investigator and the research sponsor, if any.[21]

For covered entities, these accounting requirements can be extremely burdensome and are likely to serve as

[12] 45 C.F.R. § 164.512(i)(1)(ii).
[13] *See* 65 Fed. Reg. at 82,537.
[14] *See* 67 Fed. Reg. 14,776, 14,794 (March 27, 2002).
[15] 45 C.F.R. § 164.512(i)(2)(ii).
[16] *See* 45 C.F.R. §§ 164.502(b), -.514(d).
[17] *See* 45 C.F.R. § 164.514(d)(3)(iii)(D).
[18] *See* 45 C.F.R. § 164.528.
[19] *See* 45 C.F.R. § 164.528(b)(1)-(3).
[20] *See* 45 C.F.R. § 164.528(b)(4)(i).
[21] *See* 45 C.F.R. § 164.528(b)(4)(ii).

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a disincentive to making research-related disclosures. For researchers, the accounting requirement may lead to calls from individuals seeking access to information that they believe is in the researchers' possession. Investigators who screen patient records at hospitals or other covered entities with which they are not affiliated will need to prepare for such inquiries. Where the investigator does not retain any individually identifiable information from the review and thus cannot determine if an individual's information was, in fact, reviewed, these interactions are likely to be frustrating for both the investigator and the individual.

Contacting Prospective Participants

Once potential participants have been identified, they may be contacted only in accordance with the Privacy Rule's requirements. HHS's statements on this issue, along with the limitation on disclosures of protected health information for third parties' recruitment efforts, indicate that, without authorization or partial waiver of authorization, only a covered entity with a direct relationship with an individual may contact that individual about enrolling in a trial. Thus, a hospital workforce member may contact current or former hospital patients about participation in a clinical trial. Similarly, a physician may communicate with his or her current or former patients about a clinical trial opportunity but may *not* approach patients of another provider about the trial without a waiver of authorization. An external investigator may contact prospective research participants only if an IRB or Privacy Board-approved waiver of authorization specifically permits such contact;[22] otherwise, the investigator must rely on the hospital or physician to make the communication on his or her behalf.

Conclusion

Although HHS has stated on several occasions that it did not intend for the Privacy Rule to hamper important research activities, the Rule undoubtedly will complicate investigators' clinical trial recruitment efforts. The administrative burdens imposed on covered entities, particularly the requirement to account for disclosures of information as part of record reviews, are substantial and likely will be costly. Although additional guidance from HHS can help alleviate some of these concerns, covered entities, investigators, and research sponsors should prepare to address these new requirements.

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[22] *See* 67 Fed. Reg. at 14,794 (stating that an IRB or Privacy Board may waive authorization to permit the disclosure of protected health information to a researcher ''as necessary for the researcher to be able to contact and recruit individuals as potential research subjects'').