

January 5, 2018

HHS Office for Civil Rights Releases Research-Related HIPAA Guidance Required by 21st Century Cures Act

In December 2017, the U.S. Department of Health and Human Services Office for Civil Rights (“HHS OCR”) released two sets of guidance mandated by the 21st Century Cures Act, which was enacted in 2016 (the “Act”). The guidance clarifies certain research-related provisions of the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (“HIPAA”). Generally, under HIPAA, “covered entities” must obtain an individual’s authorization to use or disclose protected health information (“PHI”) for purposes other than treatment, payment or health care operations (a so-called “TPO Purpose”) or certain other purposes that are exempted from the authorization requirement, such as disclosures for public health purposes.¹ Because research is not considered a TPO Purpose, covered entities generally must obtain an individual’s authorization before using and disclosing PHI for research purposes.² An additional provision under HIPAA relating to research is the “preparatory to research” provision, which permits researchers to use and disclose PHI for certain activities preparatory to research, such as preparing a research protocol or identifying potentially eligible research subjects. These activities may be carried out absent an individual’s authorization provided that certain conditions are met, one of which is that no PHI is removed from the covered entity during the course of the review.³ Fulfilling its mandate under the Act, HHS OCR’s two new guidance documents clarify certain aspects of research authorizations and reviews preparatory to research.

I. Authorization Guidance

Under HIPAA’s original principles, an individual’s authorization to use and disclose PHI for research was required to be research study-specific, and thus could not authorize the use or disclosure for future research studies. This changed, however, in 2013, when HHS OCR modified its interpretation of this provision of HIPAA in the Omnibus HIPAA Final Rule, providing that authorizations may permit future research, provided such future research is described adequately in the authorization such that it would be reasonable for an individual to expect that PHI could be used or disclosed for such research.⁴ In the Act, Congress required HHS OCR to issue guidance relating to authorizations for future research purposes to clarify:

- a. The circumstances under which the authorization for use and disclosure of PHI for future research purposes contains a sufficient description of the purpose of the use or disclosure;
- b. The circumstances under which it is appropriate to provide an individual with an annual notice or reminder of the right to revoke an authorization; and
- c. Appropriate mechanisms by which an individual may revoke an authorization for future research purposes.⁵

¹ See 45 C.F.R. § 164.506.

² “Research” is defined in the HIPAA Privacy Rule to mean “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” 45 C.F.R. § 164.501. Note that this definition is the same as the definition of “research” under the Federal Policy on the Protection of Human Subjects, known as the Common Rule. See 45 C.F.R. § 64.102.

³ See 45 C.F.R. § 164.512(i)(1)(ii).

⁴ 78 Fed. Reg. 5566, 5611-5613 (Jan. 25, 2013).

⁵ See Pub. L. 114-255, § 2063(b).

On December 13, 2017, HHS OCR released guidance addressing these issues (the “Authorization Guidance”).⁶ The Authorization Guidance does not provide much additional detail regarding when an authorization for future research uses might adequately describe these uses such that the individual would reasonably be put on notice that his or her PHI could be used for such future research. Rather, OCR states that its guidance on this point is “interim guidance” and directs stakeholders to the interpretation provided by HHS OCR in the Omnibus HIPAA Final Rule preamble. The Guidance explains that HHS OCR still is exploring this issue, and working with federal partners within HHS to continue developing such guidance.

The Guidance provides more detailed information regarding revocations of authorizations for research purposes. With respect to reminders regarding the right to revoke, the Authorization Guidance clarifies that a covered entity is not required to, but may, provide reminders to individuals regarding their right to revoke a research authorization. For example, a covered entity might remind a minor participant who reaches the age of majority of her right to revoke a HIPAA authorization that originally had been signed by the minor’s personal representative.

With respect to the actual mechanics of revocation, the Guidance explains that entities may provide a standard revocation form or establish other reasonable procedures for revocation, provided that the selected process for revocation is not unduly burdensome and generally is available to all individuals. The Guidance notes, for example, that a covered entity cannot require all individuals to use a portal to submit a revocation if one or more individuals may not have easy access to the Internet. The Guidance also clarifies that while a revocation of authorization must be in writing, a covered entity may, if it wishes, cease using and disclosing PHI based on an individual’s oral request.

Importantly, the Guidance emphasizes how a covered entity may continue to use and disclose PHI that was obtained prior to revocation of an authorization to the extent the entity has acted in reliance on that authorization. A covered entity in the research context, for example, would be able to continue using or disclosing PHI to the extent necessary to maintain the integrity of the research (*e.g.*, conducting investigations of scientific misconduct or reporting adverse events). The Guidance also helpfully notes that, after an individual’s revocation of authorization, PHI collected for a research purpose pursuant to the authorization may continue to be used for purposes that do not require an authorization, including TPO Purposes like quality assessment and improvement activities. Making clear what many industry sponsors of research have long understood, the Guidance also states explicitly that the revocation of an authorization has no effect on the use of PHI by non-covered entity researchers that received PHI prior to revocation pursuant to the authorization.

Notably for covered entities participating in research studies in which another party, such as the research sponsor, obtains the subject’s authorization for PHI to be used and disclosed for research, the Guidance clarifies that the revocation is not effective until the covered entity “knows” that the authorization has been revoked. The Guidance further clarifies that the HIPAA Privacy Rule cannot require non-covered entity researchers, such as researchers at many life sciences companies, to inform the covered entity once they have knowledge of the revocation, and thus there may be a delay in the covered entity’s learning of the revocation. This may militate in favor of informing individuals in authorizations collected by non-covered entity researchers that the individual should contact the covered entity directly rather than the non-covered entity researcher if he or she wishes to revoke the authorization. The Guidance also discusses the example of a researcher obtaining an authorization for disclosure of PHI by “all providers who have seen the individual in the last year,” suggesting that HHS OCR would see such a broadly worded authorization as valid in the research context. This clarification likely will be helpful to life sciences companies conducting “big data” research that increasingly seek to collect broad authorizations from individuals that permit the company to collect PHI from several of the individual’s health care providers through a single authorization.

⁶ See *Guidance on HIPAA and Individual Authorization of Uses and Disclosures of Protected Health Information for Research*, HHS.GOV, <https://www.hhs.gov/sites/default/files/research-and-authorizations-12132017.pdf>.

II. Preparatory to Research Guidance

On December 15, 2017, HHS OCR released its second research-related guidance, clarifying certain aspects of the preparatory to research provision (the “Preparatory to Research Guidance”).⁷ The Preparatory to Research Guidance fulfills HHS OCR’s mandate under the Act to issue guidance clarifying that the “preparatory to research” provision of the HIPAA Privacy Rule does not prohibit remote access provided that reasonable security safeguards are in place and PHI is not copied or retained by the researcher.⁸

The preparatory to research provision of the HIPAA Privacy Rule requires a researcher to make three representations to the covered entity before the covered entity may permit the researcher to use PHI for research purposes, one of which is that no PHI will be removed from the covered entity during the course of the review.⁹ Specifically, the Guidance explains that “removing” PHI includes both physically taking such PHI out of a facility and downloading PHI onto a device. The Guidance, however, clarifies that remote access connectivity does not necessarily constitute a removal of PHI, provided the PHI is not printed, downloaded (except in limited circumstances, described below), copied, saved, data scraped or faxed. The Guidance notes that if the covered entity has a system whereby files containing PHI are downloaded automatically to the researcher’s device, the covered entity also must implement safeguards to ensure that the PHI downloaded to the third party device is not retained.

The Guidance states that the covered entity must conduct a risk analysis when choosing to allow remote access to files with PHI. The Preparatory to Research Guidance describes how, in conducting any risk analysis relating to allowing researcher access to PHI, covered entities may rely on representations from persons requesting access to PHI, provided the reliance is reasonable. According to the Guidance, reliance on the researcher’s representations may be reasonable, for example, when the researchers are employees or contractors of the covered entity, and, conversely, potentially unreasonable where the researcher has no relationship with the covered entity and the covered entity has not received any guarantees that technical safeguards are in place to prevent copying, printing, etc.

III. Implications

The application of HIPAA to research activities likely will take on increasing importance in the coming years given that the revisions to the Federal Policy on the Protection of Human Subjects (the Common Rule, currently effective January 2018) contain a new exemption category for many secondary research activities (*i.e.*, activities that use information collected in another initial activity, such as clinical care) that will exempt such activities from the jurisdiction of the Common Rule provided that the activities are subject to HIPAA.¹⁰ Covered entities and non-covered entities that draw data out of covered entities in the course of their research activities will need to have a thorough understanding of the application of HIPAA to research in order to avail themselves of this exemption while also remaining compliant with their HIPAA obligations. The additional guidance issued by HHS OCR should be helpful in this regard.

If you would like further information regarding the implications of these guidance documents, please contact your usual Ropes & Gray attorney.

⁷ See *21st Century Cures Act Guidance: Remote Access to PHI for Activities Preparatory to Research*, HHS.GOV, <https://www.hhs.gov/sites/default/files/remote-access-research-12-15-17.pdf>.

⁸ Pub. L. 114-255, § 2063(a).

⁹ The other two representations are (1) that use or disclosure is sought solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research and (2) the PHI for which use or access is sought is necessary for the research purposes. 45 C.F.R. § 164.512(i)(1)(ii).

¹⁰ See 82 Fed. Reg. 7149, 7194 (Jan. 19, 2017).