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Judge Limits HIPAA Access Right to Designate 3rd Party to Receive PHI

Decision May Undermine Part of HHS's Interoperability Initiative

In January 2013, the Department of Health and Human Services ("HHS") published the Omnibus HIPAA Amendments to implement provisions of the Health Information Technology for Economic and Clinical Health ("HITECH") Act. Among other things, the Omnibus HIPAA Amendments expanded the HIPAA "right to access" protected health information to give an individual the right to designate a third party to which a covered entity must provide his/her records. On January 23 of this year, Judge Amit P. Mehta of the U.S. District Court for the District of Washington, D.C., ruled that this expansion of the right to access was arbitrary and capricious and "declare[d] unlawful and vacate[d that aspect of] the 2013 Omnibus Rule." *See Ciox Health, LLC v. Azar, et al.*, No. 18-cv-0040 (D.D.C. January 23, 2020), available here.

Under the *Ciox* decision, the Privacy Rule continues to allow individuals (or their personal representatives) the right to access and obtain copies of protected health information in a designated record set for themselves. Pursuant to a provision of the HITECH Act, patients continue to have the right to designate a third party to whom their health care providers[1] must provide the contents of an Electronic Health Record ("EHR"). But individuals no longer have the right to designate a third party to whom covered entities must provide other protected health information (*i.e.*, protected health information not maintained in an EHR). The ruling also (i) appears to undermine a key aspect of HHS's "interoperability" initiatives and (ii) affects fees that covered entities may charge for furnishing records under the Privacy Rule's right to access. See headings, below.

[1] The HITECH Act granted the right to designate a third party to receive protected health information only with respect to information maintained in an Electronic Health Record. An Electronic Health Record is "an electronic record of health-related information on an individual that is created, gathered, managed, and consulted ***by authorized health care clinicians and staff***." HITECH Act § 13400(5) (42 U.S.C. § 17921(5)) (emphasis added). Accordingly, health plans (and health care clearinghouses) generally will not maintain information subject to this requirement.

At this time, there is no indication that HHS plans to appeal the ruling. Click here for HHS's statement on the case. For my compilation of the HIPAA Privacy, Security, and other Administrative Simplification Rules, which include amendments published through January 24, 2020 as well as annotations addressing the *Ciox* decision, click here (see first line under "Compiled Rules") (or see the "Resources" page at tbixbylaw.com). See page 117 of for the provisions relevant to the *Ciox* decision (45 C.F.R. §§ 164.524(c)(3)(ii), (c)(4)).

Right to Designate Third Party to Receive Protected Health Information

The HITECH Act dictated that an individual has "a right to . . .direct [a] covered entity to transmit [a copy of protected health information that the covered entity maintains in an EHR] directly to an entity or person designated by the individual"—a right that the *Ciox* court refers to as the "third-party directive." In the 2013 Omnibus HIPAA Amendments, HHS expanded the third-party directive to ***all*** covered entities and ***all*** protected health information in a designated record set, notwithstanding HHS's acknowledgement that the HITECH Act's mandate was limited to protected health information in EHRs. *See* 45 C.F.R. § 164.524(c)(3)(ii). HHS claimed it had license to expand the third-party directive beyond the language of the HITECH Act pursuant to its rulemaking authority in the original HIPAA statute. The court questioned whether that authority remained valid, but determined that, in any event, the "agency's [general] rulemaking authority cannot be used to expand a congressionally imposed restriction." Since the HITECH Act was clear and specific about the scope of the third-party directive, HHS's expansion of the directive was arbitrary and capricious.

Interoperability: Disclosure of Claims Information Through APIs

Last year, HHS proposed rules "intended to move the health care ecosystem in the direction of interoperability." Among the proposals was to require certain health plans to "implement and maintain an open Application Programming Interface (API) that permits third-party applications to retrieve, with the approval and at the direction of an individual" data including adjudicated claims, encounter data, and certain clinical data. Click here for my Health Law Alert on the subject. This would allow application developers to quickly and easily access member data for use on smart phone Apps. An underlying premise for this proposal was the individual's right to designate a third party to receive the individual's protected health information. As HHS explained:

> "HIPAA covered entities ***must*** comply with [individuals'] requests to receive their data under the HIPAA Right of Access, including having to transmit [protected health information] to a third party. As noted in guidance from [HHS], disagreement with the individual about the worthiness of the third party as a recipient of PHI, or even concerns about what the third party might do with the PHI, are not grounds for denying a request." (Emphasis added.)

The *Ciox* decision invalidates this premise for requiring health plans to comply with the API Interoperability requirement—without this mandate for health plans to comply with

an individual's designation of a third-party to receive protected health information, there does not appear to be a basis under the Privacy Rule for requiring disclosures to App developers through an API. HHS may, of course, advance a different basis to support this aspect of its Interoperability initiative.

Fees for Copies of Protected Health Information

The Privacy Rule establishes limits on the fees that covered entities may charge for copies of an individual's protected health information in a designated record set. *See* 45 C.F.R. § 164.524(c)(4). The Rule does not explicitly state that the fee limits apply only to copies of records furnished to the individual (or the individual's personal representative). HHS issued guidance in 2016 dictating that the fee limits applied to copies furnished to third parties under the "third-party directive" provision. The *Ciox* decision struck down this guidance, holding that the guidance should have been promulgated as a formal Rule. Thus, the Privacy Rule's fees apply ***only*** to copies a covered entity makes for an individual (or the individual's personal representative) pursuant to the individual's right to access.

The court upheld HHS guidance clarifying the type of labor that could be included in the Privacy Rule's fees. Specifically, fees for copies of protected health information provided to the individual (or the individual's personal representative) may include only "[l]abor for copying the protected health information," which does not include "costs associated with verification; documentation; searching for and retrieving the PHI; maintaining systems; recouping capital for data access, storage, or infrastructure." Click here for the HHS guidance. *See* last sentence under heading "Fees for Copies."

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