VERISMA COMMENTS ON 2021 PRIVACY RULE NPRM

Many of the proposed changes to the HIPAA Privacy Rule in the NPRM issued by HHS/OCR last month, (86 Fed. Reg. 6446 (Jan. 21, 2021), appear to be reasonable ways to facilitate the use and disclosure of patient PHI – although they will require extensive staff re-training to ensure compliance. However, there are three items that Verisma believes would have significant impact on covered entities and for which feedback from your organization should be considered:

- Reducing requirements relating to the form of patient ROI requests for records to be delivered to third parties (so-called "patient-directed requests" or "third party directives"), in particular allowing oral patient requests
- Reducing the turn-around time (TAT) for fulfilling ROI requests from 30 to 15 calendar days
- Extending the patient access ($6.50) rate to cover patient-directed requests

Legislative and Regulatory Background to the NPRM

- HIPAA was enacted in 1996 to improve the efficiency and effectiveness of the healthcare system by requiring the establishment of standards and requirements to protect the privacy and security of patients' PHI.
- The Privacy Rule was enacted in 2000 to protect and enhance the rights of consumers by providing them access to their health information and controlling the inappropriate use of that information, to improve the quality of healthcare in the U.S. by restoring trust in the healthcare system, and to improve the efficiency and effectiveness of healthcare delivery by creating a national framework for health privacy protection.
- HITECH was enacted in 2009 to promote the widespread adoption and standardization of a nationwide health information technology infrastructure that allows for improved electronic use and exchange of information, and specifically promoting utilization of electronic health records (EHRs).
- 21st Century Cures Act was enacted in 2016 in part to accelerate the interoperability and exchange of health information.

1. Form of Patient ROI Requests.

HITECH enables patients with the right to make patient-directed requests provided that the request is "clear, conspicuous, and specific." (42 U.S.C. § 17935(e)(1)) The NPRM does require that covered entities eliminate unreasonable requirements for patient requests generally (*e.g.*, requiring that patient requests be submitted on a specific form or through a specific portal), which seems reasonable. However, given that many patient-directed requests will designate law firms as the recipients and thereby extend the reduced TAT proposed in the NPRM to these request types, Verisma is concerned that not requiring patient-directed requests to be in writing can unfairly expose covered entities to lawyer complaints.

2. 15-Day TAT.

The proposed TAT reduction to 15 days will create significant demands on covered entity HIM staffs and/or business associates when requested records are not maintained in EHR format. The NPRM states only that "[t]he Department believes that entities can provide individuals access to their information within a time limit less than 30 days" (86 Fed. Reg. at 6459), referencing limited anecdotal evidence to support this belief, (*e.g.*, eight states currently require covered entities to provide records to patients in less than 30 days and covered entities operating in those states have been able to comply with those requirements. (86 Fed. Reg. at 6460). While Verisma understands the desire to have records produced more quickly, Verisma believes that there is insufficient evidence that the benefits accruing from this change would outweigh its costs.

3. Rate Limitations on Third Party Directive Requests.

The goals of the NPRM are: promoting information disclosure for care coordination and case management, promoting parental and caregiver involvement related to addressing the opioid crisis and serious mental illness, and whether to modify or eliminate Notices of Privacy Practices.

Nothing in the legislative/regulatory background to the NPRM or in the purposes/goals of the NPRM pertain to making it easier for commercial enterprises – primarily law firms and insurance companies – to access, and profit from, medical records.

Medical records requests fall into three categories: 1) patient requests related to treatment, 2) continuity of care requests between healthcare providers related to treatment, and 3) requests from non-healthcare commercial enterprises to support their activities.

Historically, the majority of records requests are from these commercial enterprises, and currently these requests are invoiced under state statutory fee schedules (or, in the case of audit requests, contracted rates). Patient requests are subject to a cap in the Privacy Rule, known as the "patient access rate" or "Patient Rate" (basically $6.50), and continuity of care requests generally are processed at no fee.

Because processing patient requests and continuity of care requests is not costless, the collections from commercial enterprises for fulfilling their record requests historically have subsidized the processing of patient and continuity of care requests. Across the 180,000+ covered entities, the amount of this subsidy is tens (if not hundreds) of millions of dollars per year.

The NPRM proposes to impose the patient access rate fee limitation on patient-directed requests so long as the records are maintained by the covered entity in an EHR format and are to be delivered electronically to the third party. Verisma estimates that approximately 50% of all non-audit commercial enterprise requests would be covered by the proposed fee limitation, which would result in a significant cost shift from law firms and insurance companies to covered entities.

The NPRM justifies the proposed rule under a provision of HITECH (42 U.S.C. § 17935(e)(3)), that clarifies the Privacy Rule's limitation (in 45 C.F.R. § 164.524(c)) on the patient access rate to the labor cost of responding to a patient request pertaining to treatment (as opposed to a patient-directed request) for records in EHR format:

> "notwithstanding paragraph (c)(4) of such section, any fee that the covered entity may Impose for providing such individual with a copy of such information … shall not be greater than the entity's labor costs in responding to the request for the copy." (emphasis added)

A previous effort by HHS to create this same rule in "Guidance" issued by OCR in 2016, was rejected in *Ciox Health, LLC v. Azar*, 435 F. Supp. 3d 30, 67 (D.D.C. 2020): "the court does not read the HITECH Act to support the agency's expanded treatment of the Patient Rate to third-party directives." The court added that, in adopting the patient access rate as part of the Privacy Rule, HHS was very clear both that "[w]e do not intend to affect the fees that covered entities charge for providing protected health information to anyone other than the individual" and that "[t]he proposed and final rule establish the right to access and copy records only for individuals, not other entities; the [Patient Rate] is only applicable to the individual's request." (435 F. Supp. 3d at 66-67.)

The *Ciox* case did not preclude HHS from attempting to resurrect the proposed rule in a notice and comment rulemaking proceeding, but noted that this would, at a minimum, require reconsidering the limited scope of the patient access rate announced in the Privacy Rule. In this regard HHS, states only in the NPRM:

> "[T]he same policy rationales expressed in the 2000 Privacy Rule for limiting fees for Individual requests for access, to ensure that the right of access 'is within reach of all Individuals,' apply when the individual requests to direct a copy of PHI to a third party: In both cases, the individual is choosing where to send their own PHI and often, if not always, will be responsible for paying the fee themselves." (86 Fed. Reg, at 6466)

HHS also states in the NPRM, in direct contradiction to the *Ciox* court's interpretation, that HHS still "believes the HITECH Act contemplated access fee limitations would apply" to patient-directed requests. (86 Fed. Reg, at 6466)

Neither of these rationales are correct. First, as noted, nothing in the legislative or regulatory background to the NPRM, including both the Privacy Rule and HITECH, pertained to or referenced economically supporting (by extension of the patient access rate) the provision of records to commercial enterprises for profit-making activities. Second, it is largely not true that patients "often, if not always" pay the fee for delivering records to commercial enterprises. For example, law firms pay the fee and only are permitted to pass the expense on to the patient if there is an economic recovery, which often does not occur. The law firm fully assumes the reimbursement risk.

Verisma believes that any proposed expansion of the scope of the patient access rate must consider both the specific purposes of HIPAA, HITECH, and the 21st Century Cures Act – all of which were intended to promote healthcare and treatment, not the profits of law firms or insurance companies – and the very significant cost transfer to healthcare providers that the proposed rule would affect.