VIA EMAIL (to: http://www.regulations.gov)

May 5, 2021

U.S. Department of Health and Human Services
Office for Civil Rights
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue, SW
Washington, DC 20201

Re: Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement NPRM, RIN 0945-AA00

Dear Sirs:

Verisma Systems, Inc. ("Verisma"), a release of information (ROI) medical records services and technology provider, respectfully submits these comments on the Department's notice of proposed rulemaking (NPRM) describing proposed modifications to the Privacy Rule.

Verisma is a member of the Association of Health Information Outsourcing Services (AHIOS), and we have reviewed and endorse fully the comments submitted by AHIOS regarding the NPRM. Submission of Association of Health Information Outsourcing Services, May 4, 2021 (the "AHIOS Comments").

Verisma's clients are hospital systems and clinics, and we similarly endorse the comments submitted by the American Hospital Association and the American Medical Association. Submission of the American Hospital Association, Mar. 10, 2021 (the "AHA Comments"); Submission of the American Medical Association, May 5, 2021 (the "AMA Comments").

Verisma particularly calls the Department's attention to the comments of AHIOS, AHA, and the AMA regarding the need for a renewed commitment to the privacy and security of patient protected health information (PHI) and urges the Department to consider extending the safeguards and requirements of the Privacy and Security Rules to third parties who receive PHI via TPDs. (AHIOS Comments at 7, 10; AHA Comments, at 7-8; AMA Comments, at 2

In these comments, Verisma highlights three proposed changes in the NPRM of particular concern:

- the proposal that patient requests to direct copies of EHRs be delivered electronically to third parties – what the Department designates as "third party directives" (TPDs) – should be fulfilled at the patient access rate rather than at the

rates prescribed by state laws;

- the proposal that TPDs may be submitted orally rather than in writing; and
- the proposal that patients be allowed to physically inspect and copy their records.

1. Individual Access Right to Direct Copies of PHI to Third Parties

It is important to keep in mind that the Department's authority to issue regulations regarding the privacy and security of PHI derive from the Health Insurance Portability and Accountability Act (HIPAA), the Health Information Technology for Clinical and Economic Health Act (HITECH) and, to a lesser extent, the 21st Century Cures Act (Cures Act).

Verisma agrees with the Department that HITECH, 42 U.S.C. § 17935(e), limits TPDs to records maintained in EHR format that are requested by a patient to be delivered electronically to a designated third party, and with the Department's proposed clarification to 45 C.F.R. 164.524(c) to reflect that limitation. This was the conclusion reached by the court in Ciox Health, LLC v. Azar, 435 F. Supp. 3d 30 (D.D.C. 2020). We would, however, encourage the Department to clarify in any final rule that "electronic access" means delivery by electronic, as opposed to physical, methods, e.g., would not include requests for CD copies of records.

However, Verisma fundamentally disagrees that the Department's proposal to pre-empt state statutory regimes in order to allow commercial enterprises to utilize TPDs to obtain copies of medical records at the patient access rate for economic, as opposed to

healthcare-related, purposes is authorized by HIPAA, HITECH, or the Cures Act. The Department's position here directly conflicts with the conclusion reached by the Ciox court in overruling the Department's 2016 Guidance – which, like the proposed rule, stated that TPDs should be provided at the patient access rate rather than at state statutory rates – as contrary to HITECH: "the court does not read the HITECH Act to support the agency's expanded treatment of the Patient Rate to third party directives." (435 F. Supp. 3d at 67.) The proposed rule simply attempts to reinstate – without any additional justification or support – the TPD fee rules in the 2016 Guidance that were rejected in the Ciox decision.

As a matter of legislative authority, the proposed rule finds no support in the Congressional intent underlying HIPAA, HITECH, or the Cures Act, or even in the expressed goals of the NPRM.

- HIPAA was enacted 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. (HIPAA, Sec. 261.)
- HITECH was enacted 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). (HITECH, Sec. 3001; 86 Fed. Reg. at 6451.)
- the Cures Act was enacted in pertinent part to accelerate the interoperability and exchange of health information. (86 Fed. Reg. at 6452.)
- The goals of the NPRM are to promote information disclosure for care coordination and case management, promote parental and caregiver involvement and addressing the opioid crisis and serious mental illness, and whether to modify or eliminate Notices of Privacy Practices. (86 Fed. Reg. at 6453-54.)

Nothing in the legislative background to the NPRM or in the purposes/goals of the NPRM pertain to making it easier for commercial enterprises not related to medical treatments or care coordination – primarily law firms and insurance companies – to access, and profit from, the delivery of medical records.

If any further demonstration of the proposed TPD fee rule's lack of any healthcare-related benefits were needed, it was not listed or even mentioned among the Department's lengthy list of "Non-quantified Benefits" of the proposed changes of the NPRM (86 Fed. Reg. at 6498-6503.)

The Ciox court's reading of HITECH followed the plain language of Section 17935(e) of the Act, 42 U.S.C. § 17935(e)(3), which related to the Privacy Rule's limitation (in 45 C.F.R. § 164.524(c)) concerning application of the patient access rate with respect to a patient's request for records:

> "(e) … in the case that a covered entity uses or maintains an electronic health record of an individual –
>
> …
>
> "(3) 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.)

Nothing in the plain language of Section 17935(e) suggests that HITECH was intended to affect rates charged for TPDs.

Verisma does not oppose, and has never opposed, providing records for low or no cost to patients or to healthcare providers or for the purpose of improving treatment or care coordination. But, the vast majority of TPDs are arranged by recipients who are not involved in treatment or care coordination.

Nor can the proposed change be justified as reasoned policy using the Department's cost/benefit analysis.

In estimating the economic impact of the proposed rule, the Department correctly noted that requests for medical records fall into three categories: (a) patient personal use requests, (b) continuity of care requests in connection with carrying out treatment, payment, or healthcare operations, and (c) requests authorized by a patient for third party commercial use.

Under the current Privacy Rule and most state statutory regimes, requests in the first two categories generally are provided by covered entities or their business associates at no or very low pricing (patient access rate). This does not mean that there are no costs associated with fulfilling such requests, only that such costs are not recovered in connection with those requests. In this regard, the Department may find instructive the exhibit submitted by AHIOS illustrating the numerous steps in the Release of Information Process, each of which involve labor time and costs. (AHIOS Comments, Exhibit A.)

Following the Ciox v. Azar ruling, requests in the third category -- commercial requests, including requests styled as TPDs – are today not covered by the patient access rate and generally are provided at rates prescribed by state law. State rates permit the amount collected for commercial requests to partially subsidize the unrecovered costs for patient personal use requests and continuity of care requests.

The Department's NPRM analysis of estimated costs and benefits of the proposed change is erroneous because it assumes that TPDs are provided at the patient access rate today, thereby minimizing the economic impact of the proposed change. For example, the Department asserts that the under the proposed change, TPDs regarding non-EHRs and/or non-electronic delivery could be provided at state-authorized rates "that previously would have been made under the right of access to direct copies to a third party" and then suggests – with no factual support – that the proposed change would transfer costs from covered entities to third party recipients. (86 Fed. Reg. at 6492-93.)

Many of the assumptions used in the Department's analysis appear to have little connection to the real world of ROI requests. For example:

- the Department assumes there are 2.46 million record (access) requests per year (86 Fed. Reg. at 6505.) AHIOS members alone process nearly 15 million requests per year. (AHIOS Comments, at 11.)
- the Department assumes that patient requests and continuity of care requests comprise 75% of all ROI requests and third party requests comprise 25% of all requests (86 Fed. Reg. at 6505.) In Verisma's experience, those percentages are roughly backwards, that is, third party requests comprise approximately 75% of all requests processed by Verisma.
- the Department assumes that it takes 3-5 minutes of labor to process an ROI request (86 Fed. Reg. at 6507.) In Verisma's experience, the average labor required to verify, retrieve, review, and deliver records requested by a third party is approximately 10 times that amount, and often is much longer, especially when the requested records are maintained in multiple EHR systems. (AHIOS Comments, at 11-13.)

In fact, as AHIOS estimates, the economic impact of the Department's proposal to require the TPD subset of commercial requests be provided at the federal patient access rate as opposed to state-authorized rates would be to transfer as much as $1 billion in costs annually from healthcare providers – which either bear the brunt of this transfer directly or will do so indirectly through their business associates – to non-healthcare commercial enterprises that use the records for profit-making purposes. (AHIOS Comments, at 11.) AMA also opposes imposing the transfer of costs on physician practices. (AMA Comments, at Att.19-20.)

Such a massive cost transfer from the healthcare system to lawyers and insurance companies – or to other parties that seek to arbitrage the system by obtaining records through TPDs and then marketing access to them – is not reasoned public policy.

Finally, the fact that the third party recipients in some situations – e.g., when legal claims are settled – pass the costs back to the patient does not justify the proposed rule.

First, in a sizable percentage of situations, e.g., when there is no recovery on a claim or in a life insurance application, the costs are not as a matter of fact passed back to the patient. Certainly it is not true, as the Department asserts, that patients "often, if not always, will be responsible for paying the fee themselves." (86 Fed. Reg. at 6466.) Second, when the costs are passed to the patient, it is as an offset to a greater economic recovery. The patient may receive a bit less financially, but the patient is not out-of-pocket for the cost. Most importantly, none of these situations affect patient treatment or care coordination.

In the absence of any expressed legislative intent, statutory language, or facts to support making TPDs available to non-treatment commercial enterprises at the patient access rate, if the Department adopts the proposed change as a final rule, the courts likely will overturn it again.

2. Oral Requests for TPDs.

The Department proposes to change the existing requirement in 45 C.F.R. § 164.524(c)(3)(ii) that a TPD must be in writing and signed by the patient to one allowing such requests to be oral, so long as the request is "clear, conspicuous, and specific." (86 Fed. Reg. at 6463.) Verisma disagrees with this proposed change, and questions whether oral requests can ever be "conspicuous" as required by HITECH. (AHIOS Comments, at 8.)

In Verisma's experience, most TPDs are actually submitted by the intended third party recipient (e.g., a law firm) rather than by the patient. For example, most law firms and other recipients draft the patient directive, have the patient sign it, and then submit the request along with a standard HIPAA authorization form. It is not a burden for commercial requesters to submit their requests in writing, and a written request provides the additional benefit of specifying precisely what records are requested so patient privacy can be safeguarded. In light of the ease of using, and growing availability of, request portals and apps, which do not sacrifice authentication or the ability to account for the disclosure, Verisma sees no real benefit to requiring covered entities to accept oral requests.

Moreover, when combined with the Department's proposed reduction in permitted processing time from 30 to 15 days, it will be even more important to be able to document when the TPD request was received. Permitting these requests to be unwritten risks creating unnecessary disputes over whether responses were timely.

Verisma agrees with AHA and AMA that covered entities should have the discretion, but not be required by rule, to accept oral TPD requests. (AHA Comments, at 7; AMA Comments, at Att. 15-16.)

3. Patient Right to Inspect and Obtain Copies of PHI.

The Department proposes to allow patients to take notes, videos, and photographs, and to use other personal resources to view and capture their PHI. (86 Fed. Reg. at 6457-58.) Verisma recognizes that today patients have a right under 45 C.F.R. § 164.524(a)(1) to inspect and obtain a copy of their PHI. However, patients generally are content to obtain free copies of their medical records. Typically, patients do not have a reason to physically inspect their records.

The Department invited comment on whether covered entities should be permitted to provide copies of patents' medical records in lieu of in-person inspection. Verisma supports this suggestion. Particularly given the limits on hospital visits imposed by the current pandemic, Verisma sees little basis for requiring covered entities to permit patients to come into provider premises – and require the provider or its designee to provide personnel to supervise the inspection and ensure that other patients' PHI is not recorded – simply to view their records when free copies of the records and/or portal and request app access to the records are readily available.

Versima agrees with AHA and AMA that while covered entities should have the discretion to allow patients physical access to their medical records, it should not be required by rule. (AHA Comments, at 5; AMA Comments, at Att. 7-8.)

Verisma appreciates the Department's efforts and thought underlying the NPRM and the need to update the Privacy Rule to better reflect the current ROI environment. If there are any questions regarding Verisma's comments, please contact me at mmckenna@versima.com or our corporate counsel Michael Salsbury, at msalsbury@verisma.com.

Very truly yours,

Marty McKenna, CEO