***Template Language to Guide Your Organization’s Comment Letter on the HIPAA Proposed Rule***

***Comments are due no later than May 6, 2021 and should be submitted electronically to [www.regulations.gov](http://www.regulations.gov)***

*Contact RBowen@MROCorp.com with questions or for additional information or to have our Counsel review your comments before you file them. Also, kindly share with RBowen@MROCorp.com a copy of your final comments*

*N.B. It is not necessary to follow this template precisely. Indeed, personalizing your comment letter with real-life examples, statistics and information from your organization will only strengthen the letter. Note that the highlighted and bracketed sections should be deleted and replaced with information specific to your organization. If you wish to write a shorter letter, simply delete all that follows after “Set forth below are our detailed concerns” on page 2.*

*Be sure to coordinate with your organization’s federal government affairs office*

[insert date]

U.S. Department of Health and Human Services

Office for Civil Rights

Hubert H. Humphrey Building

Room 509F

200 Independence Ave, SW

Washington, DC 20201

**RE: Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement (RIN 0945-AA00)**

Dear U.S. Department of Health and Human Services:

[insert name of your organization here] is pleased to have this opportunity to comment on the “Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement” (Proposed Rule) issued by the Secretary.

[insert name of your organization here] is [insert description of your organization here].

[Insert a description of your organization’s commitment to protecting patient privacy here.]

We are very concerned about a provision in the Proposed Rule that would modify the HIPAA Privacy Rule by opening the door for commercial third parties to take advantage of the low- or no-cost “patient rate” for copies of medical records through a mechanism called the “third-party directive.” These commercial third parties are not involved in delivery or coordination of patient care, and they have historically paid charges that are closer to the reasonable costs of producing records. Adoption of the Proposed Rule as currently written would result in an enormous shift of production costs from commercial third parties to hospitals, integrated delivery systems, physician groups and other health care providers, as the commercial third parties use third-party directives to access the patient rate.  [Insert, if available, any cost shift information for your organization.]

Also extremely concerning is the inconsistency between the Proposed Rule’s definitions and the ONC Cures Act Final Rule definitions. The incongruence with the interoperability rules would unnecessarily complicate regulatory compliance and increase operational burden for us and other providers.

In our view, the timing of the rulemaking is poor. The Secretary has signaled that the COVID-19 public health emergency (PHE) is expected to extend throughout 2021, and President Biden recently signed legislation to help the nation recover from the COVID-19 pandemic. Now is not the time to increase health care costs and impose new burdens on the providers battling the pandemic. We strongly urge the Secretary to suspend the rulemaking until the PHE is over, and HHS and the public have a full and fair opportunity to evaluate not only the impacts of the COVID-19 pandemic but also the implementation of the ONC Cures Act Final Rule.

If the Secretary proceeds with the rulemaking, then we urge the Secretary to make changes in the final rule that (1) apply the Privacy Rule requirement to charge patients a reasonable, cost-based fee (the patient rate) *only* to patient access requests for personal use, or for electronic copies of protected health information (PHI) in an electronic health record (EHR) that patients direct to third parties involved in delivering or coordinating their health care, and (2) harmonize the final rule with the ONC Cures Act Final Rule, in particular, with respect to any limit on fees for third-party directives. Harmonization would ensure that any labor cost that is allowable under the Fees Exception for third-party directives would be a “reasonable cost” under the HIPAA Privacy Rule.

Set forth below are our detailed concerns:

Problems with Enabling Commercial Third Parties to Leverage the Patient Rate

[Insert name of your organization here] fully supports patient access to records at minimal or no cost, for purposes of delivering, coordinating, or receiving care. But, commercial third-party record requesters that seek to use records for other purposes—such as life insurance underwriting, health care payment audits, and tort litigation—should pay for the associated, reasonable costs of processing and fulfilling their requests for records. It is bad policy to enable commercial requesters to step into the shoes of patients, leverage the patient rate, and shift costs to hospitals when these requesters are not involved with actually delivering or coordinating any patient care.

HHS states in the preamble of the Proposed Rule that “limiting the right to direct PHI to a third party to only electronic copies of PHI in an EHR would significantly reduce covered entities’ burdens by increasing the number of requests based on an authorization.” HHS, however, does not appear to appreciate the current operational or economic realities of medical records retrieval from EHRs.

First, HHS seems to misjudge the current state of EHR integration in the United States. For most healthcare providers, an EHR is not just one system - it is different data and information maintained in multiple different systems.  The continuing, widespread use of multiple legacy systems means that locating all PHI responsive to a request in an EHR is not an easy or straightforward process. Rather, it typically requires accessing multiple EHRs to ensure that a request is fulfilled correctly. [Insert a description of how complex, cumbersome, and resource-intensive it can be to respond to medical records requests, including a discussion of how many information systems PHI is stored in throughout your facililty(ies). Talk about the extent to which manual labor is needed to locate, retrieve, aggregate, and compile health care records. The more specifics the better!]

Despite these complexities, we typically do not charge any fees to fulfill these patient requests in furtherance of our mission to serve patients. Moreover, due to limitations under current law, true patient requests for records are fulfilled by [insert name of your organization here] and other HIPAA-covered entities where the amount charged is often far *less* than the actual costs associated with even retrieving the records let alone processing and distributing them. We urge HHS to recognize the costs of the manual labor that is typically needed to fulfill requests for electronic health information.

At [insert name of your organization here], we work hard to ensure that patients are able to timely access their medical records. Indeed, [If possible, insert description of how you help patients access their records quickly, efficiently and at little or no cost. Consider including a discussion of your patient portal and what percentage of patients use the portal, the number of records provided to patients/third parties free of charge in a given year, the average time it takes to fulfill patient requests for medical records, etc.] Just because we have a patient portal and EHR technology from [insert Epic, Cerner, and/or name of your EHR vendor(s) and utilize APIs] doesn’t mean we can produce electronic copies of medical records with the click of a mouse. The Cures Act Final Rule reflects this reality, and allows for recoupment of the costs of the manual labor needed to fulfill requests for electronic PHI. Any final rule should, too.

With the operational burden of the release of information function so significant and the liability risks so substantial, like many health care providers, we made a decision to outsource this function to a vendor. Our vendor uses proprietary technology, workflow, and highly skilled specialized staff. They have a patient advocate and are always at the ready to provide us additional staff and resources during peak times. Working with a vendor that supports our release of information functions enables us to focus more of our resources on patient care and building out our interoperability infrastructure since we have reduced our release of information costs by [insert a description of the cost savings]. If the changes to the Proposed Rule that we are advocating are not made, then we will likely have to take the release of information functions back in house. We do not have the technology nor the trained staff or the legal team skilled in preemption analysis to maintain the current extremely high level of timely, efficient and highly accurate patient service that we do today by outsourcing. We also would bear a much greater compliance burden, which is the last thing we need right now.

Second, the Proposed Rule’s fee limitations on third-party directives (proposed as a new 45 CFR 164.524(d)) would have the effect of extending the patient rate to substantially all requests for PHI maintained electronically – particularly to commercial third-party requesters and others who claim to be acting on behalf of patients, but are making record requests that have nothing to do with care delivery or care coordination. As proposed, the only types of requests that would fall outside the patient rate would be “requests to send non-electronic copies of PHI in an EHR, or electronic copies of PHI that is not in an EHR, to third parties.” This broad extension of the patient rate would enable commercial third-party requesters to leverage the patient rate and shift additional unreimbursed costs to healthcare providers for servicing these requests that are wholly unrelated to the delivery of care or care coordination. What HHS has proposed would enable commercial third parties not involved in the patient’s care to shift their business costs to health care providers.

Third, the artificially low “patient rate” is workable only when healthcare providers (and the medical records release of information vendors serving them) can charge life insurance companies, law firms, and other commercial third parties a rate that is either specified by state law or contractually agreed upon.  Unfortunately, the commercial requesters of medical records have in the past managed to leverage the patient rate in ways that are inconsistent with the § 13405 of the HITECH Act, which mandates only third-party directives for PHI in EMRs, and does not apply the patient rate to such directives. This misuse of the patient rate was previously halted by a federal court decision in *Ciox Health v. Azar* in 2020.

Commercial third-party requesters are not typically in the business of delivering or coordinating the delivery of care for patients, and so it is appropriate for them to pay a rate that better approximates the costs of responding to their requests. HHS should not allow commercial requesters to leverage the patient rate in ways that jeopardize low-cost access to medical records for use in care delivery and coordination for patients.

Fourth, HHS underestimates the number of commercial third-party requesters that would leverage the patient rate following such a policy change. Indeed, past experience suggests that finalization of the Proposed Rule in its current form would cause a spike in commercial third-party requests and, by extension, shift these unreimbursed costs to healthcare providers. Between the publication of the OCR’s Access Guidance in 2016 and the *Ciox* decision in 2020, release of information vendors and healthcare providers saw a dramatic increase in commercial third-party requests made via third-party directives in order to leverage the patient rate. [If available, discuss the rise in commercial third-party requests during the time between the 2016 OCR Guidance and the *Ciox* decision in early 2020 and the unworkable economics.] The finalization of the Proposed Rule as currently written would yield an even worse policy outcome given the more sweeping extension of the patient rate and widespread reliance on legacy systems.

In short, the policy rationale for the Proposed Rule is to enable the coordination and delivery of care. Commercial third-party requesters play no role whatsoever in these critical functions. HHS has now proposed regulations that would once again enable commercial requesters to obtain the patient rate.  If commercial third-party requesters increase their leverage of the patient rate—and pay for fewer requests at typically higher state or contractual rates—then the cost of fulfilling records requests at the patient rate will pass through to healthcare providers, like [insert name of your organization here.]

The Need for Harmonization of OCR’s Proposed Rule with the ONC Cures Act Final Rule

Any limit on fees for the third-party directive should align with the ONC Cures Act Final Rule. It does not make sense to have two overlapping and inconsistent standards for permissible fees. Under the Fees Exception of the ONC Cures Act Final Rule, an actor may charge a requester a reasonable cost-based fee for the manual effort to fulfill a request for an individual’s electronic health information, provided that the fee is not based in any part on “electronic access” (as defined by the ONC Cures Act Final Rule). Since the definition of electronic access excludes all manual effort that is required to fulfill a request, an actor may recover costs associated with reviewing the access request and searching for and retrieving protected health information, including locating and reviewing the PHI from an EHR, and segregating or otherwise preparing the PHI that is responsive to the request. Any limit on fees in the Privacy Rule should align with the Fees Exception. This would ease compliance burden, operational difficulties and would also ensure that commercial third-party requestors are not enabled to inappropriately leverage the patient rate.

Conclusion

[Describe how your organization and your patients benefit from your current ability to outsource your medical records release function. Discuss how fully occupied you are with vaccine administration, pivoting to televisit implementation, deciphering the plethora of coronavirus response legislation, regulation, and guidance documents along with gathering the required data and filing paperwork for the Provider Relief Program and/or the Paycheck Protection Program. Talk about how patients will benefit most if your organization can focus its resources on keeping them healthy and looking after them if they are unwell. Note that any additional resources spent on medical records release will siphon resources from building out your interoperability infrastructure.]

Requiring hospitals and other providers already saddled with the economic difficulties of delivering care during the pandemic to absorb a cost currently borne by third-party commercial businesses not involved in care delivery does nothing to advance care delivery and care coordination. Moreover, the Proposed Rule inequitably shifts costs that should be borne by commercial enterprises to healthcare providers already facing over-burdened budgets.

**We believe this rulemaking should be suspended until after the end of the PHE so that the full effects of the pandemic can be considered in the rulemaking. Should HHS decide to go forward with this rulemaking during the pandemic, we ask that any final rule (1) apply the patient rate** **only to patient access requests for personal use or for electronic copies of PHI in an EHR to be shared with third parties involved in their health care and (2) any limit on fees for the third party directive harmonizes with the Cures Act Final Rule.**

Please do not hesitate to contact me or [insert name and contact information for your federal government affairs officer] with questions or for additional information. We appreciate this opportunity to share our views.

Sincerely,

Name

Title

Contact information

Cc: Robinsue Frohboese, Acting Director, Office for Civil Rights (robinsue.frohboese@hhs.gov

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