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

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

*Personalizing your comment letter with real-life examples, statistics and information from your organization will strengthen the letter. Note that the highlighted and bracketed sections should be deleted and replaced with information specific to your organization.*

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

[insert date]

Robinsue Frohboese

Acting Director and Principal Deputy, Office for Civil Rights

U.S. Department of Health and Human Services (HHS)

Attention: RIN 0945-AA00

Humbert H. Humphrey Building, Room 509F

200 Independence Avenue, SW

Washington, D.C. 20201

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

Dear Acting Director Frohboese:

[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.]

Our concerns are categorized as follows:

1. **All data entities should be held to equal privacy standards to maintain patient privacy safeguards**

We support efforts to give patients greater access to their health information, and we applaud OCR for addressing this need in the NPRM. However, it is important to acknowledge that there have been significant changes to the ROI process since HIPAA was enacted in 1996. Additionally, there are a growing number of new platforms by which consumers can access their health care data, many of which rest outside the scope of HIPAA. We strongly believe that any changes to HIPAA should build upon the existing law and ensure that the proposed changes will improve the delivery of care without sacrificing privacy. Unless non-HIPAA covered entities, such as third-party application (app) developers and other commercial requestors, are held to privacy and security standards equal to those in HIPAA, we believe there is an insupportable trade-off between expanded patient access as laid out in the NPRM and patient privacy safeguards, namely that OCR miscalculates the negative impact on patient privacy and the security of the sensitive data being released through some methods that it seeks to expand in the NPRM.

1. **Tighter definitions of what constitutes a “third-party” and patient authorization are necessary to protect the security of PHI**

We strongly recommend that OCR limit the definition of the term “third-party” to health care providers, social service organizations with whom PHI may be shared for care coordination, and caregivers. This narrow definition would better protect patient privacy by guaranteeing that non-health commercial entities cannot exploit the patient right to access to circumvent record retrieval fees and other required HIPAA protections, such as the need to obtain a written HIPAA authorization, in order to obtain patient records for non-healthcare commercial purposes. We urge OCR to amend the NPRM to make it clear that a third-party access request without patient authorization should be for care coordination only and not for commercial or economic purposes. A patient authorization requires specification on what portion of a patient’s record may be provided to a third-party and ensures that a third-party does not receive more information than is necessary for carrying out their economic purpose.

1. **Rule inconsistencies with the ONC Cures Act complicate compliance and add to regulatory burden**

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.

1. **HIPAA changes during the pandemic distract from our focus on recovery**

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.

1. **Third-party requests should not qualify for the “patient rate” for copies of medical records**

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. 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 a significant 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.

**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.]

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: Micky Tripathi, National Coordinator for Health Information Technology (micky.tripathi@hhs.gov)