May 6, 2021

*Submitted electronically via www.regulations.gov*

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**

To Whom It May Concern:

On behalf of the [Insert Organization Name], thank you for the opportunity to comment on the Office for Civil Rights’ (OCR) proposed changes to the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. [Insert Organization Name and Boilerplate Introduction].

We begin with a summary of our comments, and then discuss each in more detail in the following pages.

**Summary of Comments from the** [Insert Organization Name]

* Access of Individuals to Protected Health Information (PHI):
	+ [Insert Organization Name] believes that OCR’s proposed modifications to the access right to inspect PHI do not align with current care models and developments in health information technology that provide individuals with access to their PHI. The proposed modifications would be overly burdensome on covered entities, requiring covered entities to change their policies and procedures and hire additional staff.
	+ As OCR’s Right of Access Initiative has demonstrated, covered entities of all sizes and types struggle to respond to patient requests for access under the current timeframes. Decreasing the number of days by which a covered entity would be required to provide access would be challenging for behavioral health providers due to the complex laws and regulations that protect such records and because such providers have limited medical records staff and often store records off-site.
	+ Requiring covered entities to implement a policy to prioritize urgent requests for access would be difficult given that covered entities cannot require individuals to reveal the purpose of their request for access.
	+ [Insert Organization Name] requests that OCR provide guidance as to how a covered entity is to determine when an oral request is clear, conspicuous and/or specific and to clarify that, if a covered entity determines an oral request is not clear, conspicuous and/or specific, the covered entity may require the individual to complete an access request form. Further the [Insert Organization Name] request that when the aforementioned request is made, that OCR would not consider such a requirement an interference with the individual’s right of access.
	+ [Insert Organization Name] requests that OCR provide updated guidance on: (1) permitted content for access request forms, including a sample form; (2) permitted fees for providing PHI under the right of access and under an authorization; and (3) permitted verification methods when individuals request access to PHI by phone.
* Disclosures to carry out treatment, payment, or health care operations:
	+ [Insert Organization Name] requests that OCR require covered entities to discuss with individuals the disclosure of PHI to a social services agency, community-based organization, home and community based services provider, or similar third party that provides health or human services to specific individuals (“certain third parties”) for individual-level care coordination and case management as part of treatment or health care operations prior to such disclosure and to document such disclosures in the individual’s record.
	+ [Insert Organization Name] requests that OCR state explicitly that while disclosures to certain third parties (social services agencies, community-based organizations, home and community based services providers, etc.) would be permitted for individual-level care coordination and case management as part of treatment or health care operations under the proposed modifications without an individual’s written authorization or consent, covered entities would not be required to make such disclosures and covered entities could implement a consent process for such disclosures.
	+ [Insert Organization Name] requests that OCR update its sample notice of privacy practices to reflect changes to the disclosures permitted for purposes of treatment and operations.
* Disclosures requiring an opportunity for the individual to agree or to object:
	+ [Insert Organization Name] believes that covered entities should not be permitted to substitute their judgement regarding a use or disclosure of PHI when an individual has decision making capacity and has made their request known, except in the case of an emergency circumstance.

**Detailed Comments**

**Access of Individuals to PHI**

**45 CFR § 164.524**

* Strengthening the Access Right to Inspect and Obtain Copies of PHI

The Notice of Proposed Rule Making (NPRM) would modify an individual’s right to inspect PHI to include the right to view, take notes, take photographs, and use other personal resources to capture their PHI (*see* proposed 45 CFR §164.524(a)(1)(ii)) and to require covered entities to provide an individual with the right to inspect PHI that is readily available at the point of care in conjunction with a health care appointment without delay (*see* proposed 45 CFR §164.524(c)(3)).

The proposed modifications would be overly burdensome for covered entities. As described in more detail below, the proposed modifications would require covered entities to increase staffing and training in order to respond to requests from individuals to inspect their PHI in person. OCR’s proposed modifications to an individual’s right to inspect their PHI in person do not align with the recent changes in care delivery models and health information technologies focused on developing capacity for virtual care delivery. OCR should clarify that the right to inspect PHI at the point of care in conjunction with a health care appointment only applies to in person appointments and does not apply to virtual visits.

Permitting individuals to take photographs and use other personal resources to capture their PHI would require many behavioral health providers to revise their policies and procedures on the use of devices. Many behavioral health care providers have carefully crafted these policies and procedures to protect the confidentiality of all individuals (from those sitting in the waiting room to those participating in group sessions) and to ensure compliance with federal and state laws and regulations.

Providing individuals with the right to inspect PHI that is readily available at the point of care in conjunction with a health care appointment without delay would require covered entities to hire additional medical records staff and train clinical staff on determining what PHI may be disclosed under the various federal and state laws that protect behavioral health records. Covered entities would also have to adjust their schedules to ensure space is available for individuals to inspect their PHI. OCR should provide clarification indicating that records that are “readily available” include only those that are stored on site or are readily available via an electronic health record.

[Insert Organization Name] believes OCR should **not** modify the right to inspect PHI at this time and should focus instead on ensuring patients have access to their PHI through health information technology.

* Modifying the Implementation Requirements for Requests for Access and Timely Action in Response to Requests for Access

The NPRM would modify the timeframe for covered entities to act on a request for access from 30 calendar days to 15 calendar days (*see* proposed 45 CFR §164.524(b)(1)(2)(i)) and would permit a 15 calendar day extension only if the covered entity implemented a policy to prioritize urgent or otherwise high priority request (*see* proposed 45 CFR §164.524(b)(2)(ii)(C)).

OCR’s own Right of Access Initiative has demonstrated that covered entities of all types and sizes struggle to meet the current 30 calendar day timeframe. Reducing the timeframe would be especially challenging for covered entities with limited medical records staff, those with off-site record storage, and those with sensitive records, such as behavioral health records protected by state laws and regulations.

Implementing a compliance policy to prioritize urgent requests would be nearly impossible, given that covered entities cannot require an individual to reveal the purpose of their request for access. While OCR suggests that an individual may voluntarily reveal the purpose of their request, it is unclear how covered entities would develop such a voluntary process. For example, an individual may not volunteer enough information or the right information for the covered entity to prioritize the request. A covered entity may receive multiple requests in one day, each for PHI needed in preparation for urgent medical treatment, but not be able to prioritize the requests without additional information from the individuals. Asking individuals whether their request is urgent or high priority is unlikely to provide answers that would help to prioritize requests. For covered entities with limited medical records staff and with behavioral health records that require careful review prior to disclosure, implementing a policy to prioritize urgent requests would be especially challenging. OCR should provide guidance for covered entities on developing and implementing a policy to prioritize urgent requests, including sample policy language and access request forms,

[Insert Organization Name] believes OCR should **not** decrease the number of days covered entities have to act on a request for access and OCR should **not** require covered entities to implement a policy to prioritize urgent requests in order to extend the time for responding to requests for access unless OCR provides guidance on developing and implementing such a policy.

* Addressing the Individual Access Right to Direct Copies of PHI to Third Parties

The NPRM would require covered entities to respond to an individual’s oral or written request to transmit an electronic copy of PHI in an electronic health record to a third party if the individual’s request is clear, conspicuous and specific (*see* proposed 45 CFR §164.524(d)(1)).

Implementing a process for responding to oral requests to disclose PHI would require additional staff training to ensure the recipient of the initial request responds appropriately. For many behavioral health providers, state laws require additional diligence when disclosing PHI to third parties, including written consent requirements. Behavioral health providers want to ensure an individual understands that a request to disclose “all records” could include sensitive information about their diagnoses, prescription history, participation in group and individual therapy, and other clinical information. Most covered entities require individuals to request disclosures to third parties in writing to ensure the individual understands the scope of PHI to be disclosed. Covered entities would need to develop a process for receiving, documenting, and responding to oral requests. As discussed below, this process would have to consider how to verify the identity of an individual requesting disclosure of PHI by phone, a process that is difficult for many covered entities.

[Insert Organization Name] believes OCR should provide guidance as to how a covered entity is to determine when an oral request is clear, conspicuous and/or specific and to clarify that, if a covered entity determines an oral request is not clear, conspicuous and/or specific, the covered entity may require the individual to complete an access request form and that OCR would not consider the requirement to complete the right of access form an interference with the individual’s right of access. OCR should provide updated guidance on permitted content for access request forms, including a sample form.

* Adjusting Permitted Fees for Access to PHI and ePHI

The NPRM would modify the access fee provisions to establish a fee structure based on the type of access request (*see* proposed 45 CFR §164.524(c)(3)).

[Insert Organization Name] believes OCR should provide updated guidance on the fees permitted for providing PHI under the right of access and under an authorization, including specific guidance as to when a covered entity would be permitted to charge per page fees permitted by state laws and regulations.

**Reducing Identity Verification Burden for Individuals Exercising the Right of Access**

**45 CFR §164.514(h)**

The NPRM would expressly prohibit a covered entity from imposing unreasonable identity verification measures on an individual exercising a right under the HIPAA Privacy Rule (*see* proposed 45 CFR §164.514(h)(2)(v)).

[Insert Organization Name] believes OCR should provide guidance for covered entities on how to verify the identity of individuals requesting access by phone, including examples of what OCR would consider unreasonable identity verification measures for requests by phone. OCR should clarify that, if a covered entity cannot verify the identity of the individual making a request by phone, the covered entity may require the individual to complete an access request form and that OCR would not consider the requirement to complete the right of access form an interference with the individual’s right of access.

**Clarifying the Scope of Covered Entities’ Abilities to Disclose PHI to Certain Third Parties for Individual-Level Care Coordination and Case Management that Constitutes Treatment or Health Care Operations**

**45 CFR** §**164.506**

The NPRM would permit covered entities to disclose PHI to social services agencies, community based organizations, home and community based services providers, and other third parties that provide health-related services to specific individuals (“certain third parties”) for individual-level care coordination and case management, either as a treatment activity of a covered health care provider or as a health care operations activity of a covered health care provider or health plan (*see* proposed 45 CFR §164.506(c)(6)). In the NPRM, OCR stated that its “understanding is that, in general, the third party entities receiving PHI under this proposed permission would not be covered entities and thus, the PHI disclosed to them would no longer be protected by the HIPAA Rules” (86 Fed. Reg. 6476).

[Insert Organization Name] has serious concerns that permitting disclosure to certain third parties without an individual’s consent would result in disclosures and redisclosures that neither individuals nor covered entities expected. While an individual may expect a covered entity to make certain disclosures for treatment purposes without an authorization or consent, an individual is unlikely to expect their PHI to pass from certain third-party recipients to others for any reason and without any protection. Given the stigma linked to receiving behavioral health services and the potential impact of such disclosures on an individual’s employment, educational opportunities, parental rights, and involvement with law enforcement, covered entities should provide clear notice to individuals that once disclosed to certain third parties, their PHI is no longer protected by the HIPAA Privacy Rule. Failing to disclose this possibility would seriously damage the treatment relationship.

[Insert Organization Name] believes OCR should require covered entities to discuss disclosures to certain third parties with individuals and to document such disclosures in the individual’s record. OCR should clarify that while such disclosures would be permitted without an individual’s written authorization or consent, **disclosures to certain third parties for individual-level care coordination and case management would not be required** and that covered entities may implement a consent process for such disclosures. OCR should update its sample notice of privacy practices to reflect any changes to the disclosures permitted for purposes of treatment and operations.

**Encouraging Disclosures of PHI when Needed to Help Individuals Experiencing Substance Use Disorder (Including Opioid Use Disorder), Serious Mental Illness, and in Emergency Circumstances**

**45 CFR** §**164.510**

The NPRM asks whether covered entities should be permitted to disclose the PHI of an individual who has decision making capacity to the individual’s family member, friend, or other person involved in care, in a manner inconsistent with the individual’s known privacy preferences (including oral and written expressions), based on the covered entity’s good faith belief that the use or disclosure is in the individual’s best interests, in any situations outside of an emergency circumstance (*see* Request for Comments, consideration “c” at 86 Fed. Reg. 6483).

[Insert Organization Name] believes OCR should **not** revise the HIPAA Privacy Rule to permit covered entities to substitute their decision regarding a use or disclosure of PHI when an individual has decision making capacity and has made their request known, except in the case of an emergency circumstance. Covered entities should not be permitted to substitute their beliefs as to what is in the best interest of the individual when the individual has decision making capacity and their preference is known. Allowing such a practice would undermine the individual’s decision-making capacity and could discourage individuals from seeking care.

The [Insert Organization Name] appreciates the opportunity to provide these comments. We welcome any questions or further discussion about the recommendations described here. Please contact [Insert Organization Point of Contact]. Thank you for your time and consideration.

Sincerely,

[Insert Organization Authorized Signer]