May 5, 2021

Robinsue Frohboese
Acting Director and Principal Deputy
Office for Civil Rights
U.S. Department of Health & Human Services
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 [RIN 0945-AA00]

Dear Acting Director Frohboese,

On behalf of OCHIN, I appreciate the opportunity to provide comments on the U.S. Department of Health and Human Services (HHS) Office for Civil Rights’ (OCR) Proposed Modifications to the Health Information Portability and Accountability Act (HIPAA) Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement. OCHIN is a nonprofit health innovation and research organization that serves a virtual nationwide health care system of locally controlled community-based providers in underserved communities. OCHIN applauds the effort of OCR to create regulatory alignment and to increase patient and provider access to essential patient health information in order to drive better health outcomes. OCHIN urges careful evaluation of the proposed regulatory changes to ensure they reflect equity by design as well as user-centered design principles for patients and providers, particularly in underserved communities where resources are limited, and the impact of COVID-19 has fallen heaviest.

OCHIN has long advocated for updates to HIPAA, given the rapidly changing health information technology (HIT) landscape and need to innovate to advance equity. Due to the 21st Century Cures Act Information Blocking and Interoperability rules, HIPAA modification is an essential step to align these two regulatory regimes which would reduce complexity and administrative burden. As you consider new regulations, the impact of COVID-19 on patients, their communities, and their clinicians should be assessed. It is concerning that record levels of clinician burnout continue to rise. OCHIN recommends that OCR, the Office of the National Coordinator for Health Information Technology (ONC), the HHS Office of the Inspector General, the Centers for Disease Control and Prevention (CDC), and the Centers for Medicare & Medicaid Services collaborate to develop a comprehensive framework and roadmap for HIT and digital health information regulatory modernization that harmonizes requirements and standards. Fragmentation and conflicting or complex program requirements undermine the ability of providers and

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1 Racism and inequity are products of design. They can be redesigned. EquityXdesign, November 15, 2016 [Link]
patients to navigate changing systems and diverts scarce resources from the delivery of direct patient care and public health campaigns.

RECOMMENDATIONS

Summarized below are OCHIN’s recommendations. In addition, I have included an enclosure with detailed comments concerning these proposed changes.

Improving Care Coordination. OCHIN supports expanding the definition of treatment, payment, and operations (TPO) to include social service agencies and community-based organizations in order to improve patient safety and outcomes. To meet the holistic needs of patients who are more medically and socially complex, we need to streamline secure communication along the full continuum of clinical and social services providers to reduce errors and duplication, particularly for patients/clients. When patients already face undue burden due to structural inequality, having the ability to share records between clinical providers and care coordination or social service entities improves patient outcomes.

Identity Verification. OCHIN supports reducing the documentation burden on patients and providers in the process of verifying a patient’s identity. We support flexibility in allowing varied documentation as long as these are reasonably likely to minimize incorrect patient identification, reduce duplicate patient records, avoid undue burden on patients, and prevent unauthorized disclosure of patient health information. OCHIN strongly urges that OCR issue education and detailed sub-regulatory guidance that includes examples and best practices.

Disclosure of Personal Health Information (PHI) to a Third Party and New Definition for “Personal Health Application.” OCHIN supports efforts to empower patients to use their health information to engage more fully in their care, coordinate with an extended care team, and support prevention measures and research. It is important to consider, however, that there is a proliferation of applications that are not regulated under HIPAA and the growing divide between the HIPAA covered environment and the non-covered environment. OCHIN urges OCR to address the impact on underserved communities, equity, and meaningful consent. Patients may not understand that their PHI will not be subject to HIPAA and that state privacy laws may or may not apply when their PHI is released to third parties. OCHIN strongly urges OCR to require written or verifiable digital requests to authorize release to third parties. Furthermore, OCHIN strongly urges OCR to coordinate with the Federal Trade Commission (FTC) and State Attorneys Generals to ensure that third party app developers authorized by a patient to obtain or receive digital PHI (1) provide clear and standard disclosure of risks, (2) identify all authorized uses of the previously HIPAA covered PHI (not simply initial intended uses), and (3) specify recourse that the consumer/patient has under state and federal consumer protection laws if the recipient of the information fails to provide adequate disclosure, uses information in an unauthorized manner, or otherwise violates state or federal law. OCHIN recommends that OCR coordinate with the FTC to draft standard release language that personal health applications must use to ensure that patients are aware of the risks of disclosure.

New Definition of “Electronic Health Record.” OCHIN strongly supports aligning the HIPAA definition of electronic health record with the 21st Century Cures Act’s “designated record set” as well as “information

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3 This information should be provided in the consumer/patient’s preferred language and developed to ensure comprehension as opposed to legalistic boilerplate.
that is included in the patient record resulting from a provider’s direct encounter with the patient.”

OCHIN is concerned that the OCR proposed definition which is far more expansive and less clear would be difficult for community-based providers to implement, is unwieldy in scope, and would create significant compliance challenges given the ambiguity with regard to what is included.

**Timeframe for Providing PHI Access.** OCHIN supports harmonizing the timeframe for responding with the Information Blocking Rule so that disclosures should be done as soon as practicable, but no later than **30 days with extensions, as needed.** OCR’s proposed 15-day period could negatively impact community-based providers with limited resources in underserved communities as they could end up diverting scarce administrative staff time to support more expansive requests in combination with a shorter response time.

**Videos and Photos of PHI.** Because the Information Blocking Rule as well as the proposed changes to the Privacy Rule would expand digital access to health information, OCHIN strongly urges OCR to permit covered entities to provide digital copies, electronic transmissions, third party authorized digital transfers or paper copies of PHI in lieu of in-person inspection in general, but most certainly when deemed necessary to protect public health and safety, such as during a pandemic. Authorizing taking notes, photos, and videos during an appointment would create workflow interruptions, divert limited clinician time, and create a higher risk of inaccurate and incomplete disclosures. Further, arranging such in-person inspections would also divert staff time and resources away from clinical care and care coordination when other more timely, less costly, and complete disclosures could be made.

**CONCLUSION**

OCHIN welcome the opportunity to work with OCR to systematically evaluate the impact of these regulatory changes on patients and providers in underserved communities. All of the stated goals outlined by OCR are shared by OCHIN, but it is essential to evaluate implementation of these regulatory changes to address unintended adverse consequences while making necessary adjustments to meet the goals, particularly in underserved and under-resourced communities. Please contact me at stollj@ochin.org should you have any questions.

Sincerely,

Jennifer Stoll  
Executive Vice President  
Government Relations & Public Affairs

**ENCLOSURE**
OCHIN DETAILED RECOMMENDATIONS

Improving Care Coordination

OCHIN supports expanding the definition of treatment, payment, and operations (TPO) to include care coordination entities that are subject to HIPAA in order to improve patient safety and outcomes. Providers serving medically and socially complex patients need to access community social service networks and have the ability, at a minimum, to provide referrals for housing, transportation, and food. When providers access closed-loop referrals to these social service agencies and organizations it enhances care coordination along an expanded continuum of care. Furthermore, including these entities in the definition of TPO increases clinician and staff confidence that these services are available to their patient, while simplifying and strengthening the referral process. Over time, we anticipate closed-loop referrals will increase and supply more actionable data for more successful patient treatment and support.

Identity Verification

OCHIN supports reducing the documentation and verification burden on patients and providers in the process of establishing a patient’s identity. We support flexibility in allowing varied documentation, as long as these are reasonably likely to minimize incorrect patient identification, reduce duplicate patient records, avoid undue burden on patients, and prevent unauthorized disclosure of patient health information. Finding a satisfactory middle ground between substantial documentation and no documentation requires balance. On the one hand, a de minimis documentation requirement puts patients at risk of misidentification/ unauthorized disclosure. On the other hand, overly burdensome documentation requirements serve as another structural barrier to access for patients who have been marginalized and underserved. For example, home address and phone number are often used to verify a patient’s identity. While some patients may have an unchanged phone number or address for years or even decades, other patients may be experiencing homelessness and using temporary cellphones. Communities of color are often disproportionately affected by health record mismatching and duplication, thus undermining health equity and contributing to structural inequality:

- Hispanic/Latinx patients make up 21% of the population that our members serve, yet they make up 35% of the duplications.
- Black patients represent 13.6% of patients, 22% of the duplicates.

OCHIN supports the use of a national unique patient identifier. OCHIN recommends that OCR, ONC, CDC, CMS and OIG ask stakeholders to share the current patient identifiers in use and evaluate the implications for identification verification, electronic exchange, administrative complexity and costs, as well as effects on patient safety, public health and clinical research of multiple, non-standard, or varied identifiers. The lack of national standardization creates inefficiencies in interoperability, increases technology costs, and adds to duplicate and mismatched patient records. Without the ability to create a unique patient identifier, states are bringing forward alternative proposals. Currently, there is at least one

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Although the U.S. Department of Health and Human Services (HHS) is prohibited from spending any federal dollars to promulgate or adopt a national unique health identifier standard, this would allow Congress to have information on the impact of this prohibition on innovation, interoperability, privacy and security, as well as patient safety and equity in healthcare.
state legislature considering a bill that would mandate a state-specific patient identifier. Multiple “unique” identifiers for patients who move among states, providers, health plans, and public health jurisdictions undermine efforts to improve interoperability as well as privacy, security, patient safety, and equity.

**Timeframe for Providing PHI Access**

To accommodate individual obstacles that may exist for organizations struggling to meet the proposed shortened timeline, OCHIN urges OCR to adopt the “as soon as practicable” requirement while maintaining the current 30-day timeline with a 30-day extension. This will allow providers to respond in a more timely manner when able, but provide 30 days when needed. This will allow OCR the authority to investigate possible cases of obstruction but avoid unnecessary burden on providers who are unable to meet the 15-day deadline. The length of time it takes to fulfill requests is dependent upon a number of factors. A significantly smaller clinic may not have the administrative staff to support a large request of documents involving a number of patients simultaneously. It is possible that not all of the records are readily available electronically, adding increased burden to what may already be a taxed administrative support staff. A larger organization may also run into similar issues given that they may receive a high number of competing requests at once from multiple requestors.

**Right of Disclosure of PHI to a Third Party and New Definition of “Personal Health Application”**

The proposed expansion of the right of disclosure of PHI to a third party generally aligns with changes made by the Information Blocking Rule, with some caveats. **OCHIN does not support removing the authorization form requirements nor does OCHIN support authorizing oral requests.** Where requests are made orally, even to another provider, the lack of documentation of a request leaves room for human error and could result in the wrong documents being disclosed, or disclosure to the wrong provider. **Given the possible sensitivities around a patients’ PHI, keeping systems in place for documenting requests is essential to prevent mistakes, particularly when there are language barriers or under-resourced organizations with limited administrative support.**

Furthermore, the transmission of health information from a HIPAA-covered entity to a non-HIPAA regulated environment could place patients at risk and expose providers to significant liability. There is currently minimal oversight of how non-HIPAA covered entities, often application developers, use patient data once it has possession of such data. Although a number of organizations are focused on developing standards to help patients determine a trustworthy source from an untrustworthy source, there is nothing preventing patients from choosing any application on the market and becoming the victim of identity theft, discrimination, or other harm. Misuse of PHI by a third party could subject providers to litigation and undermine the clinician-patient relationship, as patients may hold the provider responsible for releasing their information to an untrustworthy source.

For these reasons, we must put greater patient protections in place to prevent exploitive practices as well as unauthorized use of PHI. The opportunity has arisen where defining the term “personal health application.” Where the definition clarifies that the information is “managed, shared and controlled by or primarily for the individual...not by or primarily for... the application developer,” this can continue on to state that resale of patient data or use for advertising or other secondary methods of profit are prohibited.
With the possible harms resulting from the movement of patient health information from a HIPAA-regulated environment to one with fewer protections, OCR should include clear regulatory language underscoring that providers are to be held harmless from patients seeking to pursue lawsuits against their providers when a patient has provided authorization (whether verbal or in writing) to third parties. While clinicians should not be held liable while complying with federal obligations, litigation could place providers in financial duress.

**New Definition of “Electronic Health Record”**

OCR proposes to define “electronic health record” (EHR) to encompass the same scope as “individually identifiable health information,” or IIHI. In order to reduce complexity and confusion, the definition of EHR should be limited to the “designated record set” and any other information that is included in the patient record resulting from a provider’s encounter with the patient. IIHI includes a broad array of non-treatment related information and is a term that could easily be interpreted differently by various providers. Furthermore, the volume of documents would not only overwhelm providers, but patients who would be flooded with non-germane information that is not relevant to their clinical care. Defining electronic health record to align with related regulations, as well as what is currently standard practice within the health care community, will minimize the potential for confusion and errors and avoid an industry-wide need to update electronic health record, operations, and other systems containing information to accommodate this large array of data.

If the designated record set is too narrow, it can be expanded to include the legal medical record, which includes electronic health information generated by a covered entities’ interaction with the electronic medical record system. This will include individually identifiable data collected and directly used in documenting health care services or health status. This does not include administrative, derived, or aggregate data. This record then allows for the greatest level of care coordination and treatment but does not overwhelm the provider with patient information that is not pertinent to their patient encounter or treatment plan.

**Recording PHI**

OCHIN recommends maintaining the current methods for patients to access their PHI through previously approved methodologies, including requesting digital and paper copies. Permitting photos of the EHR could compromise other patient’s privacy and also provide inaccurate, misleading, and incomplete information. If there are concerns around the cost burden to a patient when requesting a hard copy of their records, we recommend either creating a sliding scale or eliminating costs for patients receiving government assistance, for example. The additional complications to health information technology providers and health care providers resulting from this provision as proposed is unnecessary given alternatives to access.

Currently, patients are authorized to request PHI both digitally through an app as well as a paper copy from their health care provider. This addresses a patient’s express right to access their health care information without creating disruptions to health care delivery and avoiding incomplete and inaccurate data capture. Where a patient has the technology to take photos of their PHI, they similarly have the ability to download the necessary applications to access their data. Patients are already authorized under HIPAA to take notes.