February 12, 2019

The Honorable Roger Severino
Director, Office for Civil Rights
U.S. Department of Health and Human Services
Hubert Humphry Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201
Attn: RFI, RIN 0945-AA00

Submitted electronically via: http://www.regulations.gov

RE: Request for Information on Modifying HIPAA Rules to Improve Coordinated Care

Dear Director Severino,

OCHIN appreciates the opportunity to submit the following comments in response to the request to address the Office for Civil Rights Request for Information on Modifying HIPAA Rules to Improve Coordinated Care. We appreciate the OCR’s effort to improve coordinated care and appreciate the opportunity to provide comments on how the OCR can modify HIPAA rules to remove regulatory burdens while increasing the efficiency of care coordination.

OCHIN is a 501(c)(3) not for profit community-based health information technology (HIT) collaborative based in Portland, Oregon. OCHIN receives support from the U.S. Department of Health and Human Services’ Health Resources and Services Administration (HRSA) and is an HRSA-designated Health Center-Controlled Network (HCCN). OCHIN’s mission is to pioneer the use of health information technology (HIT) in caring for the medically underserved. As such, OCHIN serves community health centers (CHCs), including Federally Qualified Health Centers (FQHCs), rural and school-based health centers, safety-net providers and public health and correction facilities across the nation. OCHIN’s comments will be through the lens of members we serve.

For over 18 years, OCHIN has refined our data privacy expertise, focusing on data sharing for the purpose of treatment and care coordination for the country’s most vulnerable patients. Serving over 500 health centers across 47 states, OCHIN has expanded as a national health data exchange and invested our learnings to continuously improve our network. Our comments provided here today reflect our strong understanding of as well as success in data privacy and security, and their pivotal role in interoperability. With a continuously evolving system of patient data and treatment needs, regulations must advance to enhance patient care and safety.

OCHIN advocates for modifying HIPAA rules for:

- 42 CFR Part 2 reform;
• Expanding the definition of “treatment” to explicitly include care management services provided by non-healthcare provider third parties;

• Expanding the “minimum necessary” exclusions to promote value based care efficiencies;

• Promoting interoperability and removing barriers to virtual care innovation; and

• Modifying existing rules and guidance to enhance and enable communication with third party care coordination and case management service providers.

OCHIN Overall Comments on HIPAA Reform:

• 42 CFR Part 2 Reform

    Modifying HIPAA is a beneficial step towards improving coordinated care, but updates to 42 CFR Part 2 are critical to this effort. Current drug and alcohol treatment information is siloed and over protected, preventing movement to necessary providers and subsequently putting patients at risk. When the necessary health data is not supplied, providers are left guessing and prone to prescribing a drug, or drugs, which may have dangerous interactions with an undisclosed prior prescription, or are unaware of drug use propensities, making patients vulnerable to past or waning addictions. These changes are paramount to successfully addressing the continuing harms of the opioid epidemic.

    o To increase interoperability and patient protections, it is necessary to align 42 CFR Part 2 with HIPAA.

    o Access to a patient’s full medical record, including addiction records, ensures the delivery of safe, effective, high quality coordination of treatment and care. Current 42 CFR Part 2 restrictions are antiquated, and place patients at risk of dangerous drug interactions and the possibility of relapse without extending protections which could be satisfied with current HIPAA regulations.

    o 42 CFR Part 2 must be aligned to allow the use and disclosure of patient information for treatment, payment, and health care operations, but protected from access by law enforcement, attorneys, employers, or others with malicious or retributive intent. Such violations should carry strong penalties and/or exclusion in any proceedings.

    o Public health organizations are often required to support multiple EHR systems as a workaround, and the lack of data sharing often results in tragic outcomes.

    o Encouraging entities to share treatment information with “caregivers, including family members and friends” to prevent threats to health and safety is a baseless effort to overcome the serious harms of these outdated data protections. Placing this responsibility on caregivers, family members, and friends requires their presence and participation in medical treatment efforts – a feeble workaround when Part 2 reform provides all necessary resolutions. Many would prefer to share the depth of their substance use disorder with medical professionals over caregivers, friends, and family members. This arbitrary transfer of responsibility has the potential to cause more complications than it resolves.
• Care Management as Treatment

OCHIN encourages the broadening of the treatment definition to specifically include care management activities provided by non-healthcare providers. Though the current definition can be read to include such disclosures, we recommend that the OCR provide confirmation that such uses and disclosures are permissible under HIPAA. For organizations like OCHIN, the ability to disclose PHI to non-health providers delivering care management services is essential to implementing value added services to improve care coordination. OCHIN, therefore, seeks confirmation that an appropriate “treatment” disclosure may include uses and disclosures for care management purposes between a health care provider and a non-health care provider. Further, OCHIN seeks clarification under 45 CFR 164.506(c)(3) that a covered entity may disclose PHI for treatment activities to a health care provider or a third party providing care management services on behalf of the patient.

• Minimum Necessary

OCHIN supports the expansion of the Privacy Rule’s minimum necessary standard for care coordination and case management services to improve care coordination and reduce compliance burden. Care coordination and case management are necessary components of treatment. Current minimum necessary standards compliance is burdensome in itself, and further complicated by the varying organizational definitions of minimum necessary standards.

  o Expanding exceptions to exclude disclosures of PHI to non-health care providers for care coordination and/or case management has the potential to improve data sets, reduce compliance burdens and costs, and improve care coordination and case management.
  o OCHIN is aware of the difficulty in revising these standards, and suggests where OCR decides to revise, making exceptions clear and unambiguous to ensure organizations meet the same minimum necessary standards to improve data transfer for patient care, while simultaneously reducing compliance burdens.

• Barriers to Innovation

Synchronization and collaboration between the OCR and ONC are necessary to ensure clear, aligned rules for healthcare providers, business associates, and software companies. Discrepancies between these two agencies creates varied results, putting patients in the path of harm. Rules under the 21st Century Cures Act and HIPAA Privacy and Security Standards are undeniably intertwined, as PHI is transferred electronically and these transfers must comply with both technical standards and rules of disclosure.

By focusing on the anti-data blocking and interoperability rules, issues with PHI transfer can be resolved by allowing for automatic transfer to qualified healthcare entities. Current national framework standards will meet these goals given time and more strict standardization of data storage. By requiring disclosure of PHI for health care operational purposes generally, treating physicians have a full history of the patient, allowing them to avoid dangerous drug interactions, exposing patients to substances of waning addictions, and generally allowing them to make holistic treatment decisions which would
otherwise be unavailable based on limited health information as provided by the patient. A single, complete medical record for each patient and optimal interoperability makes this possible.

- **Organized Health Care Arrangements**

  OCHIN advocates for a revision to the Organized Health Care Arrangements (OHCA) rules which would further solidify OCHIN’s approach to configuring and permitting access to Epic. In 2013, 45 CFR 164.506(c) was modified to make clear a covered entity in an OHCA may disclose PHI to other participants in the OHCA for health care operation activities of the OHCA generally, even if such other participants are not covered entities themselves. The commentary to the rule clarified that this modification was warranted because not all health care providers in an OHCA are covered entities. The commentary also clarified that an OHCA may contract with a business associate to provide certain functions or services. OCHIN suggests that further broadening the definition of who can participate in an OHCA will better enable the provision of care coordination services. For example, there are entities that provide essential services to individuals that do not do so on behalf of the OHCA or participating covered entities, but rather perform these services specifically for the welfare of the patient, independent of the covered entities. Examples of these entities include public health organizations, governmental bodies performing case management, or housing service providers. Allowing their participation in an OHCA arrangement would better facilitate a holistic approach to providing meaningful patient care. Further, it would enable these non-covered entity social service agencies to participate in the shared medical record infrastructure provided by organizations such as OCHIN.

  In addition, OCHIN is also seeking clarification that a provider can “hold itself out” as participating in an OHCA through a notice on its web site instead of including a revision to the Notice of Privacy Practices (NPP). Due to the number of entities involved in large OHCA's making multiple modifications to the NPPs can be quite burdensome and time consuming.

- **Accounting of Disclosures**

  OCHIN discourages the enactment of regulations that would require detailed record keeping for the accounting of disclosures pertaining to treatment, payment and healthcare operations. Further, OCHIN supports and agrees with the OCR’s conclusion that the proposed access report requirement would create an undue burden for covered entities without providing meaningful value to individuals in return.

  Implementation of an auditing and reporting scheme which includes disclosures for treatment, payment and health care operations is costly and would require significant investment in software development. If such expansion is allowed, the costs to organizations like OCHIN and its providers would be significant and the process overly burdensome.

- **Permitted Disclosures without Patient Authorization**

  Recognizing the public benefits provided by care coordination services and other social service agencies, OCHIN recommends broadening the permitted disclosures allowed under 45 CFR 164.512(b) to
allow disclosures without patient authorization to social service agencies, community-based support programs, and care coordination services to the extent those agencies can demonstrate (1) they have a relationship with the individual (for example, a frequent user of EMS services) and (2) they are proposing to provide the individual with certain services (for example, shelter or substance abuse treatment).

- Disclosure for Treatment Purposes

  A barrier to efficient care coordination is timely access to PHI even when a patient treatment relationship has been established (i.e., when the case manager is another HIPAA covered entity with a treatment relationship). Often healthcare providers require that a patient submit an authorization permitting the disclosure to the treatment provider, even though such authorization is not required under HIPAA. OCHIN suggests guidance from the OCR encouraging covered entities to comply with disclosure requests from other covered entities and third party case managers/care coordination services with treatment relationships without authorization by the patient. We further recommend guidance that a good faith/reasonable belief standard may be applied to alleviate the concern from some covered entities that the entity requesting the disclosure truly has a treatment relationship with the patient.

  OCHIN appreciates the OCR’s willingness to evaluate the impact the current rules have on case management and care coordination. We hope that our comments provide insight into the challenges we see with the current regulatory framework. We appreciate your consideration of our comments. Please contact Jennifer Stoll at stollj@ochin.org should you have any questions.

Sincerely,

Jennifer Stoll
EVP, Government Relations and Public Affairs