



Recommendations to Improve Individuals' Health Data Access

Background

For more than twenty years, Congress has prioritized individuals' access to their health information as a key lever to improve care, enable research, and empower Americans to live healthy lifestyles. But across the paper-based world of HIPAA to the digital aspirations of 21st Century Cures, the ability of individuals to access and use their health information continues to be a challenge. While Congress has passed, and HHS has implemented, a host of policies and programs to improve individual health data access, further clarity is needed on how document-centric concepts should evolve for our data-centric future.

Specifically, policymakers should Modernize HIPAA by:

1. **Converging HIPAA with Health IT Certification**

- a. Establish a new term, "Health Data Set," which includes all clinical, biomedical, and claims data maintained by a Covered Entity or Business Associate. This Health Data Set would support individual HIPAA right of access and be supported by ONC's Certification Program so individuals could view, download, or transmit to a third party this information electronically and access this information via application programming interface (API); or
- b. Revise the HIPAA "Designated Record Set" definition and require Certified Health IT to provide the amended DRS to patients electronically while maintaining computability. This revision would provide greater clarity and predictability of what constitutes the DRS to providers & patients; and

2. **Extending the HIPAA individual right of access to Non-Covered Entities (NCEs)**

- a. NCEs manage individual health data, such as mHealth and health social media applications. The goal is uniformity of health data access policy, regardless of covered entity, business associate, or other commercial status.

3. **Encouraging note sharing with patients in real-time**

- a. Promote efforts such as OpenNotes through Medicare and Medicaid payment programs, such as the Merit-based Incentive Payment System.

4. **Clarifying existing regulatory guidance on third-party access to patient data**

- a. Especially related to third-party legal requests that seek information without appropriate patient-direction and beyond what is part of the DRS.