Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing - General Comments

Preamble FR Citation: 88 FR 23746

Public Comment Field: Enter comments on Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing – General Comments.

The Black Health Informatics Working Group at the Black Health Heritage Data Lab at Brown University has reviewed the Patient Requested Restriction Certification Criterion. We would like to note that we appreciate the Office National Health Coordinator's efforts to center health equity in Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing Proposed Rule (HTI-1). However, it is important to recognize that equitable data practices are not solely about technological standards and technical infrastructure. Rather, they are also about working with other governing bodies and federal departments' policies and rules to make sure they are aligned with proposed changes to Health IT.

Preamble FR Citation: 88 FR 23821 **Specific questions in preamble?** Yes

Regulatory Impact Analysis: Please see 88 FR 23898 for estimates related to this proposal.

Public Comment Field: Enter comments on § 170.315(d)(14) - Patient Requested Restrictions Certification Criterion.

The Black Health Informatics Working Group at the Black Health Heritage Data Lab at Brown University has reviewed the Patient Requested Restrictions Certification Criterion. Overall, we believe the proposal to enable a certified health IT user to implement a process to restrict data from use or disclosure in response to a patient request in an effort to support the HIPAA Privacy Rule's "right to request a restriction" on uses and disclosures is a step in the right direction. It provides patients with an Internet-based option to request restrictions on sharing their USCDI data with external covered entities beyond their clinical or provider's office. However, we are concerned that patients may not be adequately informed about their right to flag and request restrictions for specific data elements in their medical records (and the fact that these requests may be denied). In addition, it is not clear in the proposed rule that the covered entity needs to explain the patient restriction, specifically whether patients can to request to restrict their data in multiple ways and with different levels of granularity (rather than just having the binary choice to either share or to not share data globally), and if and how patients should be informed about these options. For example, patients might want to restrict access to data relating to a particular health condition, or they might want to restrict data from specific individuals and groups–family members or specific entities/organizations. Additionally, the

language in the proposed rule does not mention if the patient requesting the restriction will be told who will have access to any records of their restriction requests. We believe it is important for patients to be clear about who will be notified of these requests, as some may be concerned that their provider seeing their request may negatively impact their relationship with their healthcare providers and/or healthcare institutions. Finally, the current proposal provides virtually no guidance to health IT developers regarding any standards for developing a process for patients to request the restriction of sharing specific data elements.

In order to address some of our concerns and respond to the ONC's requests for guidance on the merit of a standards-based patient requested restricted criterion versus a standards-agnostic one, we request that the ONC consider our guidance as outlined below:

Establish a set of minimum standards for the health IT developers followed by a set of recommendations. We take this position in order to allow enough flexibility for health IT developers to create a process that is centered in health equity as well as one that is culturally-specific and addresses and aligns with diverse understandings of privacy and data sharing governance.

Our minimum standards include:

- A notification that is triggered by patient enrolling or logging into patient portal that they have the right to restrict data elements from being shared outside of their clinician or provider's office
- A process that allows patients to select sensitive categories of data. For example, patients might want to restrict all social determinants of health data or medication history
- A reporting documentation framework that requires covered entities to explain and enumerate reasons for denying a patient's request to restrict a sensitive data element
- A process that allows patients to download request, response, and data sharing history
- A process that allows patients to decide how long they would like to restrict sensitive data from being shared and notifies them when the restriction is near expiration
- A process that allows patients to appeal a covered entity's decision to reject their request to restrict sensitive data
- A process for testing the request for data restriction with patients from communities, specifically communities of color before implementation (eg, usability testing of EHR/EMR for request to restrict data)

Our recommended standards include:

- A process that allows covered entities to include explanations for why sharing specific USCDI data elements may aid a patients' health
- A process that provides patients with an explanation of the potential harms and privacy risks of sharing certain USCDI data elements
- A process that allows patients to better understand their rights under the HIPAA Privacy Rule by linking them to pertinent information
- A process that triggers a notification to patient that they can restrict data when new USCDI data elements are added EHR/EMR
- A process that periodically reminds patients that they can restrict data

We recognize that healthcare organizations have varying levels of financial support and IT capability, and some of these recommendations may increase the cost of developing a process for patients to restrict their data from being shared. Therefore, in some cases, it may be appropriate to consider whether our recommendations may create undue expense and time.

Signed:

Dr. Melissa Creary, University of Michigan
Dr. Kadija Ferryman, Johns Hopkins University
Dr. Amelia N. Gibson, University of Maryland College Park
Ms. Odia Kane, Johns Hopkins University
Dr. Terika McCall, Yale University
Dr. Charles Senteio, Rutgers University
Dr. Megan Threats, University of Michigan
Dr. Kevin Wiley, Medical University of South Carolina
Dr. Karmen Williams, The City University of New York
Dr. Kim Gallon, Brown University, Director of Black Health Heritage Data Lab
kim_gallon@brown.edu