



**Comments of
The Health Record Banking Alliance
In response to**

**Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Comments on Proposed Rule: Interoperability, Information Blocking, and
The ONC Health IT Certification Program
[RIN 0955-AA01]**

Submitted 3 June 2019

The Health Record Banking Alliance (“HRBA”)¹ offers these comments in response to the captioned Notice of Proposed Rule, 84 Fed. Reg. 7424 (No. 42, March 4, 2019).

HRBA generally supports the rules proposed by the Office of the National Coordinator (“ONC”) (collectively, the “Proposed Rule”) to effect a national digital health information exchange standard. HRBA believes that such an exchange standard is essential to allow patients more access to and control over their lifetime medical information, improve medical care and outcomes, reduce burdens on clinicians, foster more rapid, widespread progress in medical research, and lower healthcare costs.

ONC is required to develop and promulgate this exchange standard by the HITECH Act, as amended by the 21st Century Cures Act. Adopting the exchange standard is, HRBA believes, the core task for ONC, for it will enable consequential progress in the long, heretofore intractable, search for routine, dependable, affordable “interoperability” of patient records.

¹ The Health Record Banking Alliance, headquartered in Portland, Oregon, is recognized as a business league by the Internal Revenue Service under Section 501(c)(6) of the Internal Revenue Code.

Remove Broadcast Query Requirement

There are provisions in the Proposed Rule that might require entities to respond to QHIN Broadcast Query requests. HRBA's succession of earlier comments to ONC consistently highlight the fact that "Broadcast Query" cannot be used for reliable and affordable exchange of health records nationwide, regionally, or even locally.² Demonstration projects repeatedly confirm this reality.³

Broadcast Query, were ONC to retain it in the final rules for the exchange standard, would in certain circumstances introduce a crippling requirement. It would, when employed, produce an enormous volume of requests, virtually none of which would ever be pertinent to the records held among the vast number of possible respondents.

Thus, retaining Broadcast Query would hamper operation under the final rules for interoperability and for the Trusted Exchange Framework and Common Agreement ("TEFCA"). It would unnecessarily introduce a host of security and privacy vulnerabilities due to the vast volume of messages that malefactors could target and exploit. It would force use of patient identity matching technologies that are insufficiently reliable and therefore multiply security and privacy vulnerabilities. And it would unnecessarily burden QHIN networks with high message volumes.

All of these deficiencies are the more unfortunate because Broadcast Query is unnecessary to efficient and affordable exchange of digital health records. QHIN Targeted Query in support of Individual Access Services and to the variety of provider and other institutional requests is adequate for the exchange functions ONC expects and that HITECH and 21st Century Cures require.

Because Broadcast Query is an unworkable technology for the functioning of efficient, cost-effective, reliable health information exchange, *HRBA urges ONC to delete Broadcast Query from the Proposed Rule and from the final version of TEFCA.*

Share Now and Standardize Later

HRBA applauds ONC for translating ambitious statutory intent from the Cures Act into regulation. We support many of these proposals and we note that numerous provisions in this Proposed Rule will fundamentally transform the current landscape for health IT.

² Lapsia V, Lamb K, Yasnoff WA: Where should electronic records for patients be stored? *International J Med Informatics* 81(12):821-7, 2012.

³ See, e.g., Robert H. Miller and Bradley S. Miller, *The Santa Barbara County Care Data Exchange: What Happened?*, *Health Affairs* 26, no.5 (2007):w568-w580; see generally, W. Rishel, et al. (Gartner, Inc.), *Summary of the NHIN Prototype Architecture Contracts*, Report for the Office of the National Coordinator for Health IT, May 31, 2007 (documents, inadvertently, why health record broadcast query cannot be made to work at scale).

Despite these important and foundational changes to the current state, this Proposed Rule must not let patients, clinicians, and researchers wait for health IT developers to determine that standards are sufficiently mature before releasing data to patients. While HRBA supports the development of standards for biomedical, clinical, and health data, we reject a policy that requires data to be standardized before it can be used for patient care. Sharing all the data now, even in the absence of standardization, allows market forces to find uses for all the unstructured data, which will create the demand for standards among health IT developers, providers, researchers, and patients. This policy establishes a baseline expectation that all EHI, not just data supported by C-CDA or FHIR, are available to patients, clinicians, and researchers when authorized. Further it positions patients, clinicians, and researchers, rather than health IT developers, to identify data types in need of concerted standardization.

Clinical Notes and the Operative Note

HRBA strongly agrees with including the eight standard note types in USCDI. In addition, we suggest ONC also include the Operative Note, as it details previous procedures crucial to subsequent treatment of patients.

Unstructured Data and EHI Export

HRBA applauds ONC for requiring providers to send the full Electronic Health Information (EHI) to patients on their request. In addition to the 15 data classes and approximately 50 data elements already covered by USCDI, EHI Export will provide access to substantially more useful data. Further, EHI Export will launch a wave of innovation among companies attempting to organize and understand the data, inform the patient, and cogently summarize and index the previous health record for the next new provider.

In order to make EHI Export even easier to access by the patient, their family, and their designated third party apps, HRBA proposes that ONC include the C-CDA document-level template for Unstructured Documents⁴ and the corresponding C-CDA-on-FHIR IG⁵ as part of USCDI's Clinical Notes. This approach would establish an expectation that health IT can exchange emerging, candidate, and unstructured data – not just the supported data elements named as part of the USCDI at §170.213. While we acknowledge that both HIPAA and forthcoming enforcement of the Information Blocking provision will compel actors to share non-standard and unstructured EHI when such data are requested, there will remain a wide disparity in capability to fulfill such requests if those data are separate from the USCDI policy.

“Produces OR electronically retains” is a reasonable way of describing EHI for Export because providers store and manage data they don't produce. We agree that

⁴ HL7 Implementation Guide for CDA®, Release 2: Unstructured Documents https://www.hl7.org/implement/standards/product_brief.cfm?product_id=259

⁵ C-CDA on FHIR Implementation Guide (IG) <http://www.hl7.org/fhir/us/ccda/>

images and image narrative text should be included in data accessible by the patient, although images are not likely to be delivered by EHI Export. Public-private standards bodies that update DICOM standards would be best to specify exactly which image metadata fields should be included.

Provenance

HRBA completely agrees with the inclusion of Provenance in the USCDI v1. As health record banks and personal health records acquire more data and more structured data from many different offices and facilities, provenance will make it more likely that patients and providers alike will know with certainty where the data came from. Having such source identification will also make it easier for patients to suggest updates or corrections to professionally-derived data. We agree that the three data elements ONC has proposed -- author, author's timestamp, and author's organization -- are useful and necessary. In addition, a fourth field, validity, would be helpful to PHRs and HRBs because it would certify to the receiving provider that the document being viewed has not been tampered with since it left the control of the author. HRBA recommends ONC make Provenance a functional requirement, rather than a named standard because more work needs to be done before an industry consensus standard and consensus-based best practices for tagging and use are available.

Information Blocking and EHI Export

HRBA believes that all EHI should be subject to the information blocking rule. This way, all data, including standardized and non-standardized, are available to the patient and there will be no delay in the patient getting access to their data. As part of the “Share Now and Standardize Later” approach, we do not want any important data to be left outside the reach of this policy. Not only will patients find such data useful; required data access will promote widespread development of effective third party apps.

Information Blocking and EHR Patient Portals

HRBA appreciates ONC pointing out the possibility of information blocking by a provider not enabling a crucial patient portal feature. We suggest that this capability to allow patients to enter their secure email address or the address of their designated third party application explicitly be a Certified EHR requirement in this proposed rule. Further, we encourage ONC to require automatic updating of the patient's designated third party app whenever a Certified EHR receives new information on the patient, to avoid the need for the patient to frequently and repeatedly login to the portal or their app in order to check for and download new data. Once the EHR is so configured, this requirement does not place a burden on providers.

Information Blocking and Patient Fees

We applaud ONC for making it abundantly clear that providers and health IT developers cannot charge patients any fee for providing patients' data electronically to them or to third party applications they designate. The marketplace will sort out how much patients are willing to pay for third party apps that provide features and functions beyond simple access to their provider-supplied data.

Patient-Authorized Representative

We agree with ONC calling out that providers not require multiple requests from the patient for each of the different types of data. We agree with the specification that data exports be "timely," although that word will be subject to wide interpretive variation. We appreciate the mention of "innovative and patient-centric approaches" that will benefit from the patient directly requesting his or her data.

We suggest that ONLY the patient and his or her authorized representative be the requestor of their electronic health information. In today's environment, consumers and patients are losing trust in companies exchanging data about them without their knowledge and consent. Patients want their providers to have their data when treating them. Transparently involving patients in this information loop will promote patient trust in the healthcare system.

HRBA encourages ONC to define "patient-authorized representative" narrowly as "a person within the continuum of medical care or with a medical power of attorney or legal guardianship" for purposes of EHI Export for Patient Access (§170.315 (b)(10)(i)) as it defines "users" of such functionality. This would be distinguishable from requests made by insurers or third-party legal requests that seek information without appropriate patient-direction and beyond what is part of the HIPAA "Designated Record Set."

Conclusion

HRBA is deeply appreciative of the substantial and persistent efforts of ONC to help patients and their families access their healthcare data. With such access to data, patients and their families can begin to experience some of the benefits promised by this country's enormous investment in electronic health records. HRBA looks forward to working with ONC to bring about this aspect of a brighter future.

Respectfully submitted,
The Health Record Banking Alliance
By

/s/ Richard Gibson
Richard Gibson, MD, PhD
President
richard.gibson@healthbanking.org

/s/ Richard D. Marks
Richard D. Marks
Vice President

Health Record Banking Alliance
PO Box 91334
Portland OR 97291

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