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 Trusted Exchange Framework and
Common Agreement Draft 2

Submitted June 17, 2019

The Health Record Banking Alliance ("HRBA")[1] offers these comments in response to Draft 2 of the Trusted Exchange Framework and Common Agreement (TEFCA).[2]

Introduction

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.[3] 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 and TEFCA 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. That in turn will be the operational underpinning of the Trusted Exchange Framework and of the relationships set forth in the Common Agreement. They are all facets of Congress's initiative to bring about "interoperable" health records.

The National Digital Health Data Exchange Standard Will Enable the Rise of Health Record Banks as an Industry, Bringing Great Benefits to Patients.

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[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.

[2] Accessed at https://www.healthit.gov/sites/default/files/page/2019-04/FINALTEFCAQTF41719508version.pdf .

[3] Notice of Proposed Rule, 84 Fed. Reg. 7424 (No. 42, March 4, 2019).

Once an effective exchange standard goes into effect, HRBA believes that patients will begin to assemble their lifetime, longitudinal health records. They will create digital, "interoperable" Personal Health Records ("PHRs") or Individual Health Records ("IHRs"). Patients will be enabled to do so because they will have secure, reliable, easy-to-use, affordable means to obtain records from diverse providers. Patients will be able to compile and store those records in secure, personal accounts in, among other places, health record banks (HRBs).

Patients will be able to review their lifetime health records and update them efficiently and easily. The will be able to grant clinicians, hospitals, and other providers access to those records, or selected portions of them, with similar ease.

Further, patients will be able to ask their health record banks to notify them whenever medical researchers notify the health record banks of research projects that may be of interest to particular patients. Patients then will have the option of contacting those researchers and granting those researchers access to their full or partial medical records for use in that research.

Patients can anticipate these rights because their medical records, in their possession and under their ownership and control, are not constrained by HIPAA's privacy rules. Patients will know, however, that research using their medical records will be protected by federal and state privacy and security regulations. Among these are the Common Rule (the Federal Policy for the Protection of Human Subjects), rules of the Federal Trade Commission, and state privacy laws. Thus many patients will understand there is appropriate protection under law when they furnish all or part of their aggregated health data to clinicians for care, to researchers for medical research purposes, to payors to help document claims, or to family or friends (among others) as patients may decide.

These decisions by patients will result in better care and care outcomes. Patients will be more equipped and inclined to deal knowledgeably with the health care system. They will be better prepared to shop for health care and health insurance. Potential results include lower health care costs for individuals and for society.

Patients also will be enabled to support medical research of interest to them, their families, and their friends. Likely results are faster and better research, lower research costs, and – with application of advanced research methods to much larger and better standardized data sets – greater potential for progress due to use of innovative research methods.[4] Medical researchers will be able to exchange some data with clinicians to enhance current care. From that perspective, medical care and medical research are aspects of a continuum.

[4] See, e.g., Knaus WA, Marks RD. New Phenotypes for Sepsis: The Promise and Problem of Applying Machine Learning and Artificial Intelligence in Clinical Research. *JAMA.* Published online May 19, 2019321(20):1981–1982. doi:10.1001/jama.2019.5794.

As might be anticipated, the Health Record Banking Alliance foresees the rise of health record banks as an industry. Corporations and other entities, large to small, will see opportunities to offer HRB services to the public.

There will be different HRB business models. All will offer security and other features such as authentication and identity-proofing of patients and their authorized representatives. Thus, as the HRB industry grows and patients increasingly learn about HRBs and open PHR-IHR accounts at health record banks, patient identity matching problems will be substantially ameliorated, if not almost eliminated, for patients who are HRB account holders.

The development and proliferation of health record banks will bring fundamental improvement to health care in the United States. HRBs herald the era of patient-centric health data exchange, and thus a far more patient-centric health data system. This highly desirable, fundamental shift becomes possible only because of the implementation of a national digital health data exchange standard. The capabilities unleashed by ONC's adoption of the exchange standard will empower patients to maintain and use secure lifetime health records under their ownership and control.

ONC Should Clarify that the Digital Health Data Exchange Standard Will Apply Nationally, and Explain How Yet-To-Be Standardized and Emerging Data Categories Can Be Exchanged Consistent with the Evolving National Exchange Standard.

In the executive summary to the Proposed Rule, ONC states:

> This criterion provides developers with the ability to create innovative *export* capabilities according to their systems and data practices. *We do not propose that the export must be executed according to any particular standard*, but propose to require that the *export* must be accompanied by the data format, including its structure and syntax, to facilitate interpretation of the EHI therein. Overall, this new criterion is intended to provide patients and health IT users, including providers, a means to efficiently *export* the entire electronic health record for a single patient or all patients in a computable, electronic format.[5]

This subject also is discussed in subsequent text under the heading of Export Format.

> The proposed certification criterion does not prescribe a content standard for the EHI export. However, it requires health IT developers to provide the format, such as a data dictionary or export support file, for the exported information to assist the receiving system in processing the EHI without loss of information or its meaning to the extent reasonably practicable using the developer's existing

[5] 84 Fed. Reg. No. 42, Monday, March 4, 2019, at 7428 (emphasis supplied).

> technology. Providing EHI export information is consistent with emerging industry practices and capabilities to offer requestors the ability to access, download, and move their information without unreasonable burden. Companies such as Facebook, Google, and Twitter offer publicly- available links which provide requestors necessary information on how to download their personal information including, in some cases, several download options for requestors alongside their export instructions. Public access to comparable EHI export information would further support third-party companies in this space, as they would have additional information and general knowledge for use of available data. Accordingly, we propose that the developer's export format should be made publicly available via a hyperlink as part of certification to the ''EHI export'' criterion, including keeping the hyperlink up-to-date with the current export format.[6]

HRBA urges clarification of this language as follows. The rules will require all export and other exchanges using TEFCA to use the format standards spelled out in the final version of (currently proposed) sections 170.205(a)(4)[7] and 170.315(g)(10)[8] *for data or other content where format standards already exist and have been formally adopted into the national exchange standard pursuant to the Common Agreement or other Trusted Exchange Framework governing protocols and procedures.*

In instances where format standards for the data or other content in question (in whole or particular part) have not yet become incorporated into the national digital health data exchange standard, the approach must be different. Such data or other content could be transmitted either as unstructured data or content – actually a part of the national exchange standard – or, in the vast number of instances where that approach to unstructured content or data is inconvenient or otherwise impractical, in whatever format is reasonable technically or commercially, or is otherwise reasonably suitable for the particular data or content in question. Such export should be accompanied by an EHI export format document. That requirement is already in the Proposed Rule.

In summary:

The process for incorporating new content and data categories and types into the national exchange standard will be ongoing, will take time, and will always lag the development of new clinical and research data categories. It is essential that all such new content and data be available. It must be transmitted ("exported") pursuant to appropriate requests under the Common Agreement.

Data and other content in categories whose formats are already standardized should not be exported in ways, and using formats, other than via their standardized

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[6] Id. at 7448 (footnotes omitted, emphasis supplied).
[7] Id. at 7589 (content exchange standards and implementation specifications for exchanging electronic health information).
[8] Id. at 7590-91 (updated 2015 Edition health IT certification criteria).

TEFCA formats. To allow otherwise would change a mandatory exchange standard to one that is optional. That would vastly complicate health data exchange for patients and clinicians; increase operational burdens on patients and clinicians; increase costs; and cause frustration with data exchange under TEFCA. That is not consistent with policy or systems design under the Cures Act's specifications.

Using mandatory formats to exchange data and other content categories that already have been incorporated into the national standard is basic to the systems design and engineering specifications in the Cures Act. Assuring that data or other content categories can be exchanged before their incorporation into the exchange standard is critically important as well. ONC can clarify that this is how TEFCA content and data exchange will be structured.

As clinical and research progress expands and accelerates, whole new data types and other content categories will emerge. Much of it will never be standardized because of the dizzying pace of clinical improvement and research progress. Other content and data will, however, be appropriate for the standards-setting process; and it will inform continuous updating of the national exchange standard. Data categories developed by medical specialties are examples. ONC can clarify how it expects to accommodate all these realities under TEFCA.

ONC Should Delete Broadcast Query as an Exchange Modality Required Under the Common Agreement and Under the Proposed Rule.

There are provisions in the Common Agreement and the Proposed Rule that, in combination, would require response to QHIN Broadcast Query requests. HRBA's succession of earlier comments to ONC consistently highlights the fact that "Broadcast Query" cannot be use for reliable and affordable exchange of health records nationwide, regionally, or even locally.[9] Demonstration projects repeatedly confirm this reality.[10]

Broadcast Query, were ONC to retain it in TEFCA's final rules for the exchange standard and health data exchange, would introduce a crippling requirement nationwide. 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.

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

[10] *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).

Thus retaining Broadcast Query would hamper operation under the final rules for interoperability and for 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 for provider and other institutional requests, along with the push-based QHIN Message Delivery modality, are fully sufficient 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, nationwide health information exchange, HRBA urges ONC to delete Broadcast Query from the Proposed Rule and from the final version of TEFCA.

ONC Should Clarify the Secretary's Authority to Create the Recognized Coordinating Entity as Proposed.

The Recognized Coordinating Entity (RCE) is at the center of ONC's plan for administering the Common Agreement, and hence at the center of how the Trusted Exchange Framework will be supervised, will function, and evolve. Yet neither Draft 1 nor Draft 2 of the Trusted Exchange Framework and Common Agreement explains in any detail or justifies the statutory basis for the Secretary's authority to create the RCE and delegate to it the various functions set out in Draft 2 of TEFCA.

This is an omission that ONC can and should correct. Otherwise, TEFCA's administrative structure may be subject to threats of litigation. They would be based on assertions that the Secretary, in establishing the RCE as proposed, is overstepping his statutory authority under the HITECH Act and the Cures Act.

This would not simply undermine confidence in ONC's plans for TEFCA. It might delay their implementation significantly. The country urgently needs the proposed digital health data exchange standard to go into effect as soon as possible. Any significant delay that can reasonably be foreseen should be dealt with now, and doubts put to rest.

ONC can anticipate and answer a list of questions about the statutory basis for the RCE's creation. For example, what specific language in the Cures Act authorizes the Secretary to invest the RCE with rulemaking (legislative) and adjudicatory (judicial) functions and powers in how the Common Agreement is developed and enforced? The language in Sec. 4003 of the Cures Act, amending Sec. 3001(c) of the Public Health

Service Act (42 USC 300jj-11(c)), discusses public-private or public-public conventions to build consensus and develop or support a trusted exchange framework, including a common agreement. The statutory text further authorizes developing common rules for trusted exchange, organizational and operational policies to enable exchange, and a process for filing and adjudicating non-compliance with terms of the common agreement. This language, however, does not in terms appear to authorize the Secretary or ONC to delegate any legislative or adjudicatory functions or activities to a non-governmental entity.

A court might recognize that some functions of the RCE are subject in theory to ONC's approval. Courts might also likely rule, however, that practical, day-to-day functioning of the Exchange Framework under the Common Agreement is realistically under the RCE's control. The reason is that ONC's closely supervising the RCE, much less overruling or modifying the RCE's day-to-day actions under the Common Agreement, are both unlikely because of the volume of transactions and other network activity. There will be too much going on in overseeing national health data exchange for ONC to keep track of and review the RCE's adjudications. The same will be true for the essentially legislative decisions that the RCE makes as trusted exchange practices and standards evolve.

The plain meaning of text in the Cures Act commands the Secretary to create the Common Agreement in connection with establishing the Trusted Exchange Framework. But does the Cures Act or any other enabling legislation authorize the Secretary to delegate substantial adjudicatory and enforcement authority for these tasks to a non-governmental entity?

Federal courts may not be prepared to defer to an executive department's creating an elaborate new regulatory structure such as the RCE without Congress's specific direction in statutory text. The HITECH and Cures Acts are extensive, but they are not a general grant to the Secretary or ONC over healthcare in the United States. Courts therefore would look at the plain meaning of the statutory text. They would assess whether the Secretary is permitted to create the RCE at all, and to invest the RCE with comprehensive administrative powers and adjudicatory supervision over a new federal regulatory structure.

These functions appear to be inherently governmental. Consequently, without explicit delegation authority, the Secretary's authority is circumscribed by the Cures Act's provisions; the Secretary may do only what is specified in the legislative delegation of authority to him. Otherwise there are, among other issues, separation of powers problems. Thus there may be substantial questions about the Secretary's authority to create the RCE as proposed.

Applying precedent, federal courts could ask how such delegation is documented in statute; whether the Secretary is asserting implied, rather than explicit, power in statutory text to justify such extensive delegation; and whether relying on the Secretary's

assertion of implied authority satisfies established judicial tests applied to supervise executive departments, especially with regard to inherently governmental acts.

Also, and as an example, courts might inquire how, or the extent to which, the RCE is subject to effective oversight under generally applicable statutes such as the Administrative Procedure Act.[11]

In summary, questions may exist whether ONC is outsourcing a significant portion of TEFCA's creation and ongoing operations. Is statutory authority for the outsourcing sufficient? Does it exist at all?

Draft 2 of the Common Agreement is premised on many parties' entering the Common Agreement with the RCE, which has powers of coordination among the potentially large number of contracting parties. The RCE is also expected to evolve the Common Agreement and standards under it, and enforce the agreement subject to certain procedural features and safeguards such as appeal processes.

These are wide-ranging functions and powers; but they appear to be essentially governmental functions in this context. ONC, through the Secretary, has the option and authority to administer TEFCA itself. The RCE, as a coordinating entity to supervise the Common Agreement, is not essential to TEFCA's implementation.

ONC Should Clarify that the "Network" Provisions of the Cures Act Do Not Require the Trusted Exchange Framework or the Common Agreement to Protect Existing Health Information Networks from the Need to Accommodate Change or from Obsolescence.

With Cures Act implementation, existing networks, including Health Information Exchanges ("HIEs") among others, can continue exchanging health data. Some comments already submitted on interoperability suggest that ONC's implementation of the Proposed Rule in combination with TEFC may disrupt and duplicate the operations of HIEs and other existing health data networks. They intimate that these consequences might be inconsistent with Congress's intent in passing the Cures Act.

This line of reasoning is however consistent with the Cures Act's specification of new systems design and engineered functions. The Cures Act requires ONC to incorporate new engineering and new technology to achieve the goal of vastly improved health data exchange. Congress intended these mandated rule changes, including TEFCA, to put the nation on the path to ready, reliable, affordable exchange of medical records and other health data, with patients at the center of data exchange.

The introduction of new systems design and engineering specifications, incorporating new technology, makes it inevitable that existing networks must

[11] 5 Pub.L.79-404, 60 Stat. 237, codified at 5 USC §551 et seq. (1946).

accommodate to those changes under the Cures Act. HIEs and other incumbent networks of all sizes will be affected, whether they are networks in single hospitals, hospital systems, state or regional HIEs, clinician networks, networks in small clinician offices, or other networks exchanging digital health data. ONC satisfies the Cures Act's provisions if TEFCA and the Proposed Rule, once in final form, facilitate standardized, secure health information exchange.

One consequence of progress under these legislated changes is that existing networks that do not change how they exchange health data may face becoming obsolete. None of that is contrary to the Cures Act.

ONC may reasonably anticipate that many HIEs will apply to become Qualified Health Information Networks (QHINs) under TEFCA. Many if not most of these HIEs serve particular geographic areas. They are typically local, statewide, or regional. Many are likely to meet requirements to become NHINs.

If ONC does not assure that the nationwide digital health data exchange standard is enforced uniformly throughout the nation – that is, if it is not implemented from the start as a national standard applicable to and through all QHINS – reliable health data exchange as contemplated by the Cures Act will be postponed unnecessarily. That would not be consistent with Congress's aims in passing the Cures Act or HITECH.

QHINs may be analogized to specialized Internet Service Providers (ISPs). Congress's systems design goal in the Cures Act is to enable seamless health data exchange nationwide. If that goal requires procedural and technical changes among existing networks, or revision of contracts and other legal arrangements, that degree of disruption is integral to the systems design Congress mandated. It is both contemplated and acceptable.

Conclusion

For the foregoing reasons, ONC should consider amending or otherwise revising TEFCA as suggested in these comments.

Respectfully submitted,
The Health Record Banking Alliance
By

/s/ Richard D. Marks
Richard D. Marks
Vice President
richardmarks@earthlink.net

Health Record Banking Alliance
PO Box 91334

Portland, Oregon 97291

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