

Subcommittee: Policy

Chair: Mr. Justin Palmer

Vice-Chair: Mr. Praveen Chopra

Date: October 24, 2019

Report Status: Final



District of Columbia Health Information Exchange Policy Board

Recommendations on the Trusted Exchange Framework and Common Agreement and Information Blocking Proposed Rules

I. SUMMARY

TEFCA. The 21st Century Cures Act mandated the establishment of a voluntary Trusted Exchange Framework and Common Agreement (TEFCA) to enable nationwide interoperability of electronic health information. In effect, TEFCA creates a network of health information networks that --

- Gives health care providers a “single on-ramp” for national connectivity
- Enables electronic health information to securely follow the patient
- Supports nationwide scalability

The Office of the National Coordinator for Health IT (ONC) within the U.S. Department of Health and Human Services (HHS) leads implementation of TEFCA and released TEFCA Draft 1 in January 2018. Among other things, Draft 1 provides for the establishment of a “Recognized Coordinating Entity” (RCE), responsible for supplementing, implementing, maintaining and updating a common agreement between health information networks. Among other things, TEFCA Draft 1 requires the RCE to be a nonprofit entity and implement a minimum required set of prescribed terms and conditions (the “Minimum Required Terms and Conditions”) applicable to “qualified health information networks” (QHINs) that sign the Common Agreement.

The District of Columbia’s Department of Health Care Finance (DHCF) offered comments on TEFCA Draft 1 in February 2018. Specifically, DHCF recommended that:

- The RCE be required to collaborate with state HIT coordinators
- HHS establish a funding mechanism to pay for implementing and sustaining TEFCA
- The Common Agreement explicitly permit the exchange of health information for population health improvement

In April 2019, ONC released Draft 2 of the TEFCA for comment; the comment period closed on June 17, 2019. TEFCA Draft 2 allows for data sharing for limited operations purposes, including quality measures and care coordination (i.e. population health), but does not explicitly address the DHCF’s comments regarding collaboration with state HIT coordinators or a funding mechanism. It also added responsibility to the RCE to develop a technical standards framework applicable to “qualified health information networks” (QHINs) that sign the Common Agreement.

On September 3, 2019, ONC announced that it entered into a cooperative agreement with The Sequoia Project to serve as the RCE. In its announcement, ONC stated that The Sequoia Project would engage stakeholders through virtual public listening sessions and propose sustainability strategies to support its RCE operations.

Information Blocking. In the Cures Act, Congress also enacted the information blocking provision, which broadly prohibits health care providers, developers of certified health IT, networks and exchanges from engaging in conduct that limits the availability and use of electronic health

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information for authorized and permitted purposes. In proposed rulemaking to implement the information blocking provision, ONC included a definition for “health information network” that leaves it unclear whether the DC HIE would be subject to the information blocking rule, or whether the rule would only be applicable to HIE entities that become a District Registered HIE entity or the District Designated HIE entity under the DC HIE Rule. ONC also identified seven reasonable and necessary activities that are excepted from the information blocking prohibition, including an exception for actors to recover their reasonably incurred costs. In order to qualify for this exception, actors must meet the proposed exception’s strict criteria in how these costs may be calculated.

II. PROBLEM STATEMENTS

1. Like the DC HIE, TEFCA is a voluntary framework. Conflicts may arise between the DC HIE Rule and the Common Agreement or the QHIN Technical Framework as these are developed and implemented by the RCE, with no clear case for legal preemption of one voluntary framework over the other. If material conflicts emerge between the two HIE frameworks, HIEs that choose to participate in TEFCA may decide not to participate in the DC HIE, to avoid legal risks or operational burdens.
2. There is little doubt that HIEs are subject to the ONC’s proposed information blocking rule. Less clear is whether ONC intends the proposed rule to apply to a local government - like the District - that implements a HIE framework. If the DC HIE Rule deters some HIEs from operating in the DC market, there is a risk of ONC asserting that the DC HIE Policy Board is a “health information network” engaged in information blocking, because ONC's proposed rule defines an HIN as “an individual or entity that determines, oversees, administers, controls, or substantially influences policies or agreements that define business, operational, technical or other conditions or requirements for enabling or facilitating access, exchange or use of electronic health information between or among two or more unaffiliated individuals or entities.”

By this reasoning, ONC could refer the DC HIE Policy Board to the HHS Office of Inspector General, which could then make a determination that the District’s implementation of the DC HIE Rule violates the information blocking provision. The consequences are potentially severe, with Congress empowering the OIG to impose civil money penalties (up to \$1 million per violation) and authorizing it to refer potential violations to CMS. In turn, an information blocking violation could be probative of a false claim if CMS’s proposed rule for promoting interoperability is implemented as proposed (for that to happen, though, the District would need to have made an attestation to CMS that it promotes interoperability). The likelihood that this cascade of events could happen may be unlikely, but it illustrates the legal risks that flow from the lack of clarity in ONC’s authority to preempt a state HIE framework.

3. The financial sustainability strategies of HIEs that register and apply for designation under the DC HIE will be constrained by the information blocking rule’s recovery of reasonable costs exception, if it is finalized as proposed. To the extent that the District plans to develop financial sustainability

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strategies for its own HIE-related operations, these might be subject to the same constraint under the proposed rule’s definition for “health information network.” Likewise, any effort by the District to regulate HIE fees could implicate the information blocking rule, as currently proposed.

III. SUBCOMMITTEE GOAL AND ACTIVITY

The Subcommittee’s examined TEFCA and the proposed information blocking rule as part of the following Goal and Activity:

Goal. Make recommendations to the District Government on strategies to inform the impact of local and national HIT/HIE policies on the exchange of health information in the District.

Activity. Provide ongoing recommendations and guidance on national policies impacting health information exchange.

IV. FINDINGS/ANALYSIS

- ONC’s efforts to date, ranging from TEFCA, the Minimum Required Terms & Conditions, the QHIN Technical Framework and the proposed information blocking rule, collectively articulate ONC’s vision for promoting health information interoperability across the health information ecosystem, which is a vision that is compatible with the DC HIE’s.
- The Sequoia Group, as the RCE selected by ONC, will have significant influence in further shaping the ground rules for health information exchange.
- Regardless of whether the DC HIE falls within the ONC’s definition of “health information network” when it publishes its final information blocking rule, the District might wish to align its implementation of the DC HIE Rule with the Common Agreement, or at least not conflict with it as the RCE builds it out, as a way of avoiding potential conflicts with the information blocking rule or deterring HIEs from operating in the District.
- The Sequoia Group will also shape a financial model for sustaining its operations. The Sequoia Group’s role as RCE for TEFCA is similar to the District’s role with respect to the DC HIE Rule. To the extent the District can collaborate and align with the Sequoia Group’s development of a financial sustainability model, the District may find itself better positioned to propose a financial sustainability model for the District’s HIE-related activities.
- Depending upon how the Common Agreement and information blocking rule are finalized, the DC HIE Policy Board might want to consider the pros, cons and feasibility of the DC HIE signing onto the Common Agreement as a QHIN.

V. RECOMMENDATION(S) FOR BOARD ACTION

In light of the foregoing discussion, the HIE Policy Subcommittee recommends that:

1. To table this recommendation to be reviewed again by the Policy Subcommittee "For the DC HIE Policy Board to designate a government representative of the DC HIE Policy Board to participate in the TEFCA Recognized Coordinating Entity’s (RCE) stakeholder sessions as the RCE develops

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the Common Agreement's final legal and technical requirements for the following purposes: (1) to determine the pros and cons of aligning the District's implementation of the DC HIE Rule with the Common Agreement and QHIN Technical Framework and (2) to inform the District's financial sustainability model for the DC HIE."

2. To amend the Policy Subcommittee's charge to include the monitoring of the progress in how the Common Agreement and information blocking rule are finalized and at an appropriate time determine their impact upon the DC HIE Rule and the District's role with respect to the DC HIE.

VI. CONCLUSION

Robust health information exchange in the District depends upon the active participation of HIE partners. To the extent HIEs participate in TEFCA, they are more likely to operate in the District if compliance with the DC HIE Rule imposes minimal operational burdens on top of what the Common Agreement may require. Further, given the ONC's directive to The Sequoia Group to develop a financial model to sustain the activities they manage on ONC's behalf, the District might avoid risks of implicating the information blocking rule, when finalized, if its own financial sustainability model is at least comparable to that proposed by the RCE for its own activities.

Committee Members: Mr. Praveen Chopra, Dr. Melissa Clarke, Ms. Jill DeGraff, Dr. Greg Downing, Ms. Evelyn Gallego, Ms. Mara Kash, Mr. Luigi LeBlanc, Ms. Alice Leiter, Ms. Rachel McLaughlin, Ms. Genevieve Morris, Mr. Justin Palmer, Dr. Elspeth Ritchie, Dr. Jamie Skipper, Ms. Rita Torkzadeh, Ms. Amelia Whitman

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***** VOTING RECOMMENDATION 1 – TABLED *****

FIRST MOVEMENT: Dr. Eric Marshall

SECONDED BY: Ms. Alice Leiter

QUORUM: 10

TIME: 4:31 PM

Public Members	<u>Ayes</u>	<u>Nays</u>	<u>Abstain</u>	<u>Not Present</u>
Osinupebi-Alao, Olubukunola				✓
Clemmons, Zinethia	✓			
Herstek, Jessica	✓			
Hettinger, Zach (Aaron)	✓			
Johnson-Ramos, Donna	✓			
Leiter, Alice	✓			
Marshall, Eric	✓			
Moghimi, Yavar	✓			
Orlowski, Janis				✓
Palmer, Justin J. (Vice-Chair)	✓			
Rein, Alison	✓			
Rhoads, Amanda				
Turner, James				✓
Wade, Lucinda	✓			
Pending Appointment				
Lewis, Barry				
Ex-Officio Members				
DBH Vacancy				
Byrd, Melisa	✓			
Hasan, Dena	✓			
Holve, Erin (Chair)	✓			
Krucoff, Barney	✓			
Nesbitt, LaQuandra (designee Lauren Ratner)	✓			
Ex-Officio (Non-Voting) Member				
Whitman, Amelia				

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***** VOTING RECOMMENDATION 2 - AMENDED *****

FIRST MOVEMENT: Dr. Eric Marshall

SECONDED BY: Dr. Yavar Moghimi

QUORUM: 10

TIME: 4:32 PM

Public Members	<u>Ayes</u>	<u>Nays</u>	<u>Abstain</u>	<u>Not Present</u>
Osinupebi-Alao, Olubukunola				✓
Clemmons, Zinethia	✓			
Herstek, Jessica	✓			
Hettinger, Zach (Aaron)	✓			
Johnson-Ramos, Donna	✓			
Leiter, Alice	✓			
Marshall, Eric	✓			
Moghimi, Yavar	✓			
Orlowski, Janis				✓
Palmer, Justin J. (Vice-Chair)	✓			
Rein, Alison	✓			
Rhoads, Amanda				
Turner, James				✓
Wade, Lucinda	✓			
Pending Appointment				
Lewis, Barry				
Ex-Officio Members				
DBH Vacancy				
Byrd, Melisa	✓			
Hasan, Dena	✓			
Holve, Erin (Chair)	✓			
Krucoff, Barney	✓			
Nesbitt, LaQuandra (designee Lauren Ratner)	✓			
Ex-Officio (Non-Voting) Member				
Whitman, Amelia				