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330 C Street SW
Washington, DC 20416

June 17, 2019

Dear Dr. Rucker:

We appreciate the opportunity to comment on the *Trusted Exchange Framework and Common Agreement - Draft 2* (TEFCA). Thank you for your dedication to both interoperability and meeting the needs of patients who need easy access to their electronic health information so they can make informed decisions about their healthcare.

We support ONC's goal to "enable electronic health information to securely follow the patient when and where it is needed." ***Real-time, easy, free electronic access to all electronic health information***, including Comprehensive Health Information[1] and Real Price Information[2], is critical to ensure the best quality healthcare at the lowest possible price. Providing this access to patients is the cost of doing business for all entities in healthcare in exchange for the benefits they receive from patient healthcare services, insurance, rebates, and other incentives. Each entity holding the important health information necessary for past, present and future care and past, present, and future payment for care should be required to provide such information in real-time, to patients and those working on their behalf. We believe that those entities should be penalized as in violation of information blocking for not providing free, real-time access to that information.

We support ONC's overall effort to establish a framework that supports patient access to their health information. However, we believe this framework is the wrong approach. We have a

[1] ***Comprehensive Health Information:*** The beneficiary's complete medical record and billing record, including but not limited to all information in a patient health record, lab tests, radiology results, images, medications including prescription drugs and other supplements, and physician notes.

[2] ***Real Price Information***: The sum and listing of all services and payment information, by all parties (including but not limited to healthcare providers, health plans, contractors, administrators, pharmacy benefit managers (PBMs), pharmacies, group purchasing organizations (GPOs), technology companies, health IT developers, laboratories, medical devices, brokers and other similar market players), including any contract terms, rebates or other forms of incentive payment or other form of remuneration that is or will be directly attributable to a specific service, patient charge or transaction, to a healthcare provider, facility, pharmacy, or medical equipment provider for the healthcare services, drugs, or equipment delivered. Real Price Information shall be real-time, dynamically updated, in machine-readable format, and readily searchable to reflect the true, real price. When it pertains to a specific patient, it shall include the total and the net negotiated amounts paid including itemized payments paid to providers, regardless of the combination of payers, and the patient's complete out-of-pocket cost information, based on the benefit plan (including deductibles and co-payments).

number of concerns with the TEFCA and believe it will stifle innovation and add complexity while doing little to improve patient access to their health information.

Our specific comments are as follows:

1. ONC should focus on regulations that promote patient access to data via APIs.

The draft TEFCA, if implemented, would add confusion and contravene the purpose of recent proposed ONC and CMS rules. Specifically, rather than increasing the flow of information and promoting innovation through open, standard APIs, as is addressed in ONC and CMS' recent proposed regulations, it builds on existing entities and antiquated approaches that have been unsuccessful to date. Entities that would be the Recognized Coordinating Entity (RCE), Qualified Health Information Networks (QHINs), and Participants under the draft TEFCA historically have not been focused on improving patient access to their data as this is antithetical to their business models. Building the TEFCA on current frameworks, which have been unsuccessful at meeting the goals of having health information follow patients, will suppress innovation that can meet patients' needs for seamless access to their data. This TEFCA adds many layers of complexity and chokepoints, whereby each entity will likely add time and cost for the exchange of data to and for the benefit of patients. ONC should focus on standard API access to data rather than complicated mechanisms for querying for EHI.

2. The definition of "electronic health information" (EHI) should not be limited to identifiable information.

As we stated in our comments to the ONC proposed rule for interoperability and information blocking, we recommend that ONC adopt a broad definition of "electronic health information" (EHI) that is not limited to identifiable information. This information should include the Real Price Information as defined above. ONC should not artificially narrow the definition of EHI to identifiable information.

Furthermore, to remain consistent with the definition of Health Information from HIPAA in 1996, we suggest that ONC clarify that "future payment" includes price information, including patient eligibility and benefits, billing for healthcare services, and payment information for services to be provided or already provided, including price information.

3. TEFCA should not be a safe harbor for information blocking.

We vehemently oppose using TEFCA as a safe harbor for information blocking. It is deeply concerning that a bad actor participating in TEFCA could avoid penalties by voluntarily engaging in a network that has no enforcement capabilities. A violation of TEFCA requirements, which are not as strong as the proposed information blocking requirements, would not lead to penalties, as TEFCA will only be enforced by a non-governmental entity, which lacks this authority. Also, checking the box on participating in TEFCA should not immunize an entity from violating information blocking.

4. *Any effort to make data available should be in service to the patient, not the healthcare industry.*

The framework, as proposed, is designed to benefit the healthcare and health IT industries but not the patient. Patients have a very difficult time getting real-time, free, electronic access to the health information that they need. Specifically, any effort to exchange data should be designed solely to support patient access to their data and for treatment of that patient. This draft TEFCA would require disclosure of information for many business purposes, including to support the business planning and development needs of the QHINs themselves. Congress did not specify the broad purposes and complexity that ONC has put forth. The importance of the government involvement is to ensure that information is accessible by patients and follows patients for their treatment. We believe that these are the purposes that Congress intended in the Cures Act. The broad purposes that ONC included in this proposed TEFCA are so expansive as to go beyond any purposes for which health information is shared through networks today. Healthcare entities that want to share data to address the needs of their patients should not be required to send data to other entities for the business and management purposes of said entities that are part of this framework as a condition of participating in the network. The ONC should limit any trusted exchange framework to the purposes of patient access and treatment.

5. *The proposed TEFCA will add unnecessary complexity and opacity.*

We believe this approach will add complexity and we are extremely concerned that deferring the development of specific requirements to the RCE will lack transparency and openness that the government should seek to employ and the patients should expect. It appears as though the ONC is suggesting that it would delegate a governmental function to a private actor. As the only HITAC member representing the interests of patients, I am acutely aware of and see regularly the participation of the entrenched stakeholders. These players seek to control this effort and ensure that the outcome supports their dominance over others that may have a more novel way to access and share data in the interest of patients. Innovative technology companies are not at the table in these discussions and are unlikely to be participants in a governance process that is designed for the benefit of the current industry players. Even more unlikely is that patients will be able to track, participate in, or understand the mechanisms by which these decisions about the sharing of their health data will be made. When government sets policies through regulation or guidance, the processes are intended to be public and individuals have an opportunity to weigh in. We know individuals care about these issues and weigh in when there is an accessible and transparent process – as evidenced by more than 1,000 comments from patients and individual doctors to ONC's recent proposed rule.

6. *TEFCA should support competition, not consolidate power in one coordinating entity.*

This TEFCA would consolidate power. Identifying a single RCE and a small number of QHINs would provide a lot of control and authority in a small number of entities and would limit competition. The RCE, as proposed, will have sufficient influence over not only policies for the network, but for contractual provisions among private actors. The process for developing these policies is likely to be developed by the "insiders" who have an interest in maximizing their business needs for data and unlikely to include the voice or interest of the consumer. We have seen this model before where entrenched interests develop protectionist policies that block

innovative competition.[3] Furthermore, we are concerned that enabling a single point of access for all data through one framework can raise significant security issues and potentially national security issues. Healthcare has been identified by the Department of Homeland Security (DHS) as "critical infrastructure" for cybersecurity purposes.[4] We encourage HHS to engage with DHS before establishing a vulnerable structure for our sensitive healthcare data and vesting oversight of this in one private sector entity that will have limited ability to manage this significant risk.

7. The scope and approach of TEFCA should be scaled back to meet the intent of Congress.

We recommend that the ONC revisit the scope and approach of TEFCA because it is inconsistent with innovation in health information exchange, it exceeds Congress' mandate to ONC, and it establishes an implementation process that is not transparent to or for the benefit of patients. The ONC has been working on a health information exchange model for fifteen years since the *Framework for Strategic Action* was published in July 2004. This approach has been limited and has not resulted in improvements in patient access to their own data.[5] The industry finally has begun to move beyond this approach to the more nimble and seamless health information exchange through open, standardized APIs, and it would be a huge mistake to set this approach in stone just as we are seeing progress. We believe that this complex framework will serve as a barrier to more simplified and effective solutions.

Congress provided that the ONC should develop or support a trusted exchange framework and common agreement. However, the heavy-handed approach that was proposed is not required by the 21st Century Cures Act (the Cures Act). In our view, the ONC has developed this strategy in consultation with the entrenched healthcare stakeholders, and without the perspective of the innovative technology companies that can develop a more efficient and seamless approach for patients or the perspective of patients whose data is being shared for the benefit of others. Specifically, we request that the ONC look to simpler models that have worked in other industries and that work to establish patient trust, and should support those frameworks rather than creating a new one.

8. Patients should have real-time, free, electronic access to their health information under any ONC policy.

The recent ONC and CMS rules clearly demonstrate that patient access to health information is critical and must be included in any discussion about the use, exchange, and access of health information. The TEFCA did not address this issue in a meaningful way. While the TEFCA notes that patients and authorized caregivers should have easy access to their EHI, it states that they should be provided at "virtually no cost". We disagree—access for or on behalf of a patient should be free. Patients must have real-time, easy access to their EHI at no cost, just as there is no charge for sending the bill or a statement. This data is part of the service that has been rendered to the individual and paid for, and thus the patient is entitled to her records, including

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[3] *See, e.g., FTC Staff Guidance on Active Supervision of State Regulatory Boards Controlled by Market Participants,* https://www.ftc.gov/system/files/attachments/competition-policy-guidance/active_supervision_of_state_boards.pdf

[4] https://www.dhs.gov/cisa/healthcare-and-public-health-sector

[5] "Assessment of U.S. Hospital Compliance With Regulations for Patients' Requests for Medical Records," *JAMA Network Open*, Vol. 1, No. 6 (October 5, 2018).

pricing, comprehensive billing, explanation of benefits, and receipt of payment, as part of the healthcare service. All of this information is digital and in the cloud. Just like other areas of our lives where we have easy, electronic access to all of our data through mobile apps, we should have access to our health care data.

We are also concerned that the focus on query-based exchange is overly burdensome to the patient. A framework set up for trusted exchange should support and require routine, persistent access to their EHI. A patient will not know how to query for their data and the framework should not be set up to require the need for a sophisticated third-party service to access their data. Patients should be able have their data “pushed” to them (or to the app of their choice) immediately following a healthcare service, similar to the timely ADT alerts that providers are able to receive, and have persistent access to their data. The complexity to support a query-based model does not meet the needs of most patients. Transparency to individuals through easy electronic access to much needed patient clinical information and provider notes will result in better care. Similarly, transparency to pricing and payment information can eliminate price gouging, surprise out-of-network and facilities billing, and fraudulent billing.

Conclusion

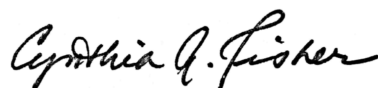
We live in a digital world and manage our monetary, retail, and transportation needs through smart apps on our mobile phones. Like the banking industry model, clinical data, pricing, and payment can all be processed, distributed, and delivered securely and accurately to patients via open, standard APIs, as in other industries. The TEFCA structural design is based on EHR systems that were built on billing information, not best practice clinical information. Current EHRs are built to maximize revenues to hospitals and healthcare providers and end up controlling the practice of medicine. We caution ONC against enabling “one” public/private nonprofit to have monopolistic control whose oversight could be used, through the influence of the special interests, to prohibit innovation and protect the status quo.

After fifteen years of work on the health information exchange model, it is time for ONC to open the pipes and let the data flow with secured access to open, standard APIs across the healthcare system. Like Uber was to the taxi industry and Priceline was to the travel industry, ONC can enable innovative technology to benefit consumers with quality, value, efficiencies, and convenience. Furthermore, there is no reason why patient data cannot have traceability through a “breadcrumb” trail for the patient.

Disruptive innovation will drastically improve transparency, provide efficiencies, and drive down the cost of care and communications for our patients, employers, and government. ONC must support this innovation. This draft TEFCA does not meet this goal.

Thank you again for the opportunity to submit comments.

Sincerely,



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