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Dr. Donald Rucker National Coordinator Office of the National Coordinator for Health Information Technology Department of Health and Human Services Mary E. Switzer Building 330 C Street SW Washington, DC 20201

RE: Trusted Exchange Framework and Common Agreement

Dear National Coordinator Rucker:

Thank you for soliciting comments on the second draft of the Trusted Exchange Framework and Common Agreement (TEFCA) to implement provisions from the 21st Century Cures Act (Cures). TEFCA aims to support the exchange of health care data so that clinicians, patients, and caregivers can make more informed medical decisions. The development of the draft TEFCAwhich creates a series of requirements to enable the exchange of information across health care organizations—by the Office of the National Coordinator for Health Information Technology (ONC) offers an opportunity to advance two key aspects of health data exchange: better patient matching and the use of application programing interfaces (APIs).

The Pew Charitable Trusts is a non-profit research and policy organization with several initiatives focused on improving the quality and safety of patient care, facilitating the development of new medical products and reducing costs. Pew's health information technology initiative focuses on advancing the interoperable exchange of health data and improving the safe use of EHRs.

ONC has articulated three primary goals for TEFCA: to provide a single "on-ramp" to nationwide data sharing; to allow data to follow patients wherever they seek care; and to support a national infrastructure of data exchange among health care organizations.¹ The draft TEFCA proposes policy, technical, and governance requirements for the exchange of healthcare data among Qualified Health Information Networks (QHINs) and their participants. A QHIN is a network of organizations that agree to the same technical infrastructure to share data. The draft TEFCA lays out the principles and requirements for a technical and governance infrastructure to support data exchange across QHINs. The Trusted Exchange Framework aspect of TEFCA describes principles that define rules for interoperability, while the Common Agreement establishes the terms and conditions that apply to organizations exchanging data through this approach. In addition, ONC has indicated that it will select a nonprofit entity to serve as TEFCA's Recognized Coordinating Entity (RCE), which will develop, update, implement, and maintain the requirements for data exchange under the framework.

While ONC lays the groundwork for addressing interoperability challenges in TEFCA, the agency can take additional actions to overcome barriers to data exchange through the adoption of modern approaches and techniques. Specifically, ONC should work with the selected RCE to ensure that TEFCA focuses on ineffective patient matching—which is the ability to correctly link records for the same individual that are held in different locations—and modern approaches to data extraction from electronic health records (EHRs) through APIs.

Patient matching enhancements needed to advance data exchange

Patient matching often depends on identifying and comparing demographic data. This process can fail to accurately link records up to half the time exchange is attempted between organizations because of: incorrect or missing information; similarities in names and birth dates; different data used and formats; and many other reasons. Matching failures can cause delays in care when information needed to inform a patient's treatment is not found. Even worse, a person may receive inappropriate treatment due to a record mistakenly linked due to similar demographics like a shared name or birth date.

TEFCA recognizes the importance of accurate patient matching as essential for electronic health information exchange among QHINs. Specifically, TEFCA states QHINs "must be capable of accurately resolving requests to match patient demographic information with patient identities under its domain." To achieve that goal, ONC proposes that QHINs use patients' name and date of birth for data exchange. However, use of these two non-unique data elements is insufficient to address patient matching challenges. For example, the Harris County health system, which includes Houston, found in 2011 that it had 2,488 patient records named Maria Garcia, where 231 shared the same birthdate. Many of these records likely referred to the same person and were duplicates.²

ONC requests comment on whether QHINs should use a broader set of patient demographic data to correctly identify and match patients, and what those elements should comprise. Pew's research identified two ways to more effectively collect and use demographic data, described in more depth below.

Standardize certain demographic data already collected

Many organizations—including the ONC contractor Audacious Inquiry—have for years recommended using the same standards (e.g. formats) for demographic data, however its effects had not yet been tested. Pew collaborated with Indiana University to test whether standardization improves match rates. The results, recently published in the *Journal of the American Medical Informatics Association*, indicate that use of the U.S. Postal Service (USPS) standard for address can increase match rates by approximately 2-3 percent. An organization with a match rate of 85 percent, for example, could reduce the number of unlinked records by 20 percent with standardizing address alone. The research also indicated that match rates could increase further with standard formats for both addresses and last names used simultaneously. For example, the research indicated that match rates could improve from approximately 81 to 91 percent through both address and last name standardization.

Employing the USPS standard for address does not necessary require the input of information in this format or workflow changes at the point of patient registration. API-based software that automatically converts addresses to the USPS standard after they are entered into the system is available in the commercial market; it is the reason many websites, for example, automatically make format changes to addresses at the time consumers place online orders. To further promote the use of this standard, ONC and the RCE should coordinate with the USPS to evaluate the use of its API, which converts addresses into this standard, in health care to improve patient matching.

Adopt additional data elements for patient matching

Additionally, experts from academia and the health care industry have recommended use of additional data elements to improve patient matching. Health records contain other demographic data routinely collected that aren't typically used or made available to match records. For example, research published in 2017 showed that email addresses are already being captured in more than half of patient records, yet organizations often do not use email addresses for matching. The documentation of email is likely higher today given the adoption of patient-facing tools, like portals, that often require emails to register. Other data elements—such as health insurance policy number—may also be in patients' records. Therefore, ONC should require that organizations are able to use email addresses—when documented in records—for matching. ONC should also identify other data elements—such mother's maiden name or insurance policy identification number—that health information technologies could use for matching.

TEFCA should align with and build on ONC's other patient matching efforts

ONC has already taken steps to use more data for matching through its proposed US Core Data for Interoperability (USCDI) set of elements intended to support more comprehensive electronic health information exchange. As part of the USCDI, ONC has proposed to add patients' addresses and phone numbers to the list of demographic data exchanged that already includes first and last name, dates of birth, and other demographic data.

ONC should further improve match rates by adopting the USPS standard for address and including other data, like email, in the USCDI. ONC's Health Information Technology Advisory Committee recently approved recommendations that support address standardization and the use of a broader set of demographics for matching and exchange. Several health care stakeholders have also echoed these recommendations in comments to ONC's proposed rule that implements Cures' provisions.

To conform with the terms and conditions outlined in TEFCA, QHINs will need to support the exchange of USCDI data elements—but demographic data contained may not necessarily be used for matching. As a result, ONC's efforts to expand the USCDI may not realize the patient matching improvements sought. Working with the RCE, ONC should more closely align the matching requirements with the USCDI demographic data and expand upon them through adoption of the USPS format for address and addition of email address, among other data elements.

Identity proofing can help validate information for matching, but alone is insufficient

ONC is also proposing that all individuals—whether patients or clinicians—that use QHINs to access information be verified through a process known as identity proofing. A patient, for example, could present validating information—such as a driver's license—to health care providers to prove his or her identity. ONC proposes to require identity proofing to criteria developed by the National Institute of Standards and Technology.

Identity proofing can help reduce fraud and ensure more up-to-date information is entered into records at the time individuals are identity proofed. While helpful, this approach on its own does not fully resolve matching challenges. For example, different systems may still contain outdated information—such as an old address for a patient. In other cases, identity proofing may not be possible for some populations, such as those who may not have permanent addresses or stable forms of documentation. ONC should coordinate with the RCE to clarify that, while identity proofing can help improve the security around accessing and using information, it is not sufficient on its own for improving the matching of records.

ONC should examine API-based exchange via TEFCA

Aside from patient matching, the success of TEFCA also relies on the ability for health organizations to effectively exchange clinical data. Currently, health care facilities exchange documents containing health data. This practice enables health care organizations to share all the information contained in a document, which could include a complete summary of care of the patient, for example. However, this approach can contribute to clinicians receiving too much unnecessary information, which results in time sorting through unneeded data to locate the specific information that they seek rather than providing care to patients. For example, a physician may want to know what medications a patient has taken or known allergies. Instead of getting just that information, the clinician may receive a lengthy document with blood pressure measurements, laboratory test results, or other data unrelated to the clinician's request.

ONC has indicated that TEFCA will initially focus on the document-based exchange processes health care facilities currently use. In addition to documents-based processes, ONC should also examine how to use TEFCA to advance API-based data exchange among providers to enable the transmission of only those data elements that patients and clinicians need.

APIs are the backbone of the modern internet. These tools allow websites to aggregate flight information, track personal financial habits, and display social media posts in real time. APIs operate in the background, connecting and transferring information between different systems.

Leverage other ONC efforts to foster API-based data access

ONC has already taken steps to advance the use of APIs in recent rulemaking. As part of proposed regulations implementing Cures, ONC developed new criteria for EHRs to make critical health data—such as medication lists and clinical notes—available via APIs. ONC's proposed regulations would require EHRs to have APIs built with a common, industry-established standard known as Fast Healthcare Interoperability Resources (FHIR). FHIR-based

APIs allow for exchange of individual data elements, rather than the entire record.³ By one estimate, more than 80 percent of hospitals and about two-thirds of clinicians already use EHRs that leverage FHIR.⁴ ONC should take the API infrastructure the agency is already building in regulation and apply it to additional use cases, including TEFCA, to ensure that data can be easily exchanged between providers and with patients, no matter where patients are in the country.

As part of future iterations of TEFCA, ONC should work with the RCE to build on the availability of FHIR-based APIs, in conjunction with document-based exchange, to improve provider-to-provider exchange of information. ONC should direct the RCE to examine how to use APIs for provider-to-provider exchange even if APIs are not explicitly referenced in this iteration of TEFCA.

Conclusion

The development of TEFCA marks an important step in advancing interoperability so that patients and clinicians can have complete and accurate medical information on which to inform decisions. Through TEFCA, ONC has the opportunity to foster development of an innovative infrastructure for nationwide data exchange that builds on modern approaches to improve patient matching and the effective availability of clinical data.

Thank you for the opportunity to comment on these proposed regulations. Should you have any questions or if we can be of assistance, please contact me at 202-540-6333 or bmoscovitch@pewtrusts.org.

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Ben Moscovitch Project Director, Health Information Technology The Pew Charitable Trusts

¹ Office of the National Coordinator, "Trusted Exchange Framework and Common Agreement,"

https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement.

²Harris Health System, "Harris County Hospital District Puts Patient Safety in the Palm of Your Hand,"

https://www.prlog.org/11430165-harris-county-hospital-district-puts-patient-safety-in-the-palm-of-your-hand.html

³ Andrea Ribick, "HL7 Publishes FHIR Release 4,"HL7 International (blog), Jan 2, 2019, http://blog.hl7.org/hl7-publishes-fhir-release-4.

⁴ Steve Posnack and Wes Barker, "Heat Wave: The U.S. is Poised to Catch FHIR in 2019," Health IT Buzz (blog), October 1, 2018, https://www.healthit.gov/buzz-blog/interoperability/heat-wave-the-u-s-is-poised-to-catch-fhir-in-2019.