



**Comments of  
The Health Record Banking Alliance  
on the**

**Draft Trusted Exchange Framework and Common Agreement**

**(<https://www.healthit.gov/sites/default/files/draft-trusted-exchange-framework.pdf>)**

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**Introduction**

The Health Record Banking Alliance (“HRBA”) is recognized as a business league by the Internal Revenue Service under Section 501(c)(6) of the Internal Revenue Code. HRBA promotes technology to enable consumer-owned and controlled longitudinal (lifetime), aggregate, computable, easily used digital health records stored securely in consumers’ accounts in private sector repositories. HRBA is committed to three key principles:

- 1) Each patient’s records should be functionally stored in one place (but not all patient records in the same place);
- 2) Each patient should control access to his/her own medical records; and
- 3) Medical records should be stored under patient control by a trusted organization.

HRBA submits these comments in response to the Draft Trusted Exchange Framework and Common Agreement (“TEFCA” or the “Draft Framework”) published on January 5, 2018 by the

Office of the National Coordinator for Health Information Technology (“ONC”). Our comments build on previous comments HRBA submitted on August 24, 2017<sup>1</sup> and November 27, 2017.<sup>2</sup>

The 21<sup>st</sup> Century Cures Act gives statutory rights regarding digital health records to consumers, patients’ and physicians’ groups, and others similarly situated. Those rights include digital health data exchange implementation by the Office of the National Coordinator sufficient to enable health data to be moved conveniently and completely into and out of consumers’ digital, longitudinal health records for treatment and research purposes, among other uses. To serve those ends, “computable” data exchange is contemplated by, provided for, and prescribed in the Cures Act. HRBA’s interest in ONC’s Cures Act implementation rulemaking is in the timely adoption of an effective, enforceable, nationwide digital health data exchange standard to enable convenient, “computable” EHR data transfer that secure repositories, among others, will use to house patient-owned health records.

In 2004, President George W. Bush created the Office of the National Coordinator for Health Information Technology (ONC). Its purpose was to ensure that every American had electronic health records by 2014, a bipartisan goal that was later reiterated by President Obama. In 2009, the Health Information Technology for Economic and Clinical Health (HITECH) Act (part of the American Recovery and Reinvestment Act)<sup>3</sup> authorized \$30+ billion to incentivize providers to obtain and use electronic health records (“EHRs”) that ONC certified were interoperable. However, ONC unfortunately did not ensure the required interoperability by designating a health information exchange standard as part of its EHR certification requirements. While the majority of providers now have EHR systems, Americans today still do not have guaranteed access to their comprehensive longitudinal electronic health and medical records whenever and wherever they may seek care. As a result, the improvements in quality of care and reductions in cost that Congress expected have not yet materialized.

Congress recognizes that comprehensive records for each individual are necessary to improve care and reduce costs. Just as airplane mechanics require access to complete maintenance records for each aircraft, rather than being limited to records of work done in the *current airport facility*, health care providers must be fully informed about the prior care of each patient to avoid over-treatment, under-treatment, and medical errors. With the 21<sup>st</sup> Century Cures Act, signed into law in December 2016, Congress is seeking to refocus ONC and the nation toward assuring comprehensive longitudinal records for individuals that are accessed, exchanged, and used without special effort through the use of application programming interfaces or successor technology or standards. It directs the HHS Secretary to “ensure that a patient’s electronic health information is accessible to that patient ... in a single, longitudinal format that is easy to understand, secure, and may be updated automatically.” (Cures Act, §4006)

Up to now, the common approach to integrating disparate records for individuals has been institution-centric, leaving the records where they are created and attempting to integrate them in real-time when needed. Even with perfect interoperability, such an approach is hugely inefficient, because records from all sources must be retrieved each and every time they are needed, over and over. Furthermore, this approach is both extremely vulnerable to security breaches and highly

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<sup>1</sup>[http://www.healthbanking.org/uploads/9/6/9/4/9694117/hrba\\_comments\\_to\\_cures\\_act\\_section\\_4003\\_20170907.pdf](http://www.healthbanking.org/uploads/9/6/9/4/9694117/hrba_comments_to_cures_act_section_4003_20170907.pdf)

<sup>2</sup> [http://www.healthbanking.org/uploads/9/6/9/4/9694117/onc\\_further\\_response\\_20171128.pdf](http://www.healthbanking.org/uploads/9/6/9/4/9694117/onc_further_response_20171128.pdf)

<sup>3</sup> Title XIII of the American Recovery and Reinvestment Act of 2009 (the Health Information Technology for Economic and Clinical Health Act, or “HITECH”).

prone to error, as the likelihood that one or more sources of records will be unavailable at any given time increases linearly with the number of sites of care,<sup>4</sup> even if every institution agrees to voluntarily share (which has proved difficult to ensure). This approach has resulted in incomplete records, with minimal value, obtained at high cost. The natural and expected consequence, as we have observed, is that organizations that attempt it have a very high rate of failure.

In contrast, a person-centric architecture, as is employed in other analogous personal information domains such as credit reporting and credit card billing, employs a separate account for each individual. New records for each individual are deposited when created in that person's account. Such a model is simple and low cost, and deposits can be mandatory (under the Health Insurance Portability and Accountability Act (HIPAA)) if requested by the patient. The requirement for deposits for each health care encounter forces universal participation. It also ensures more comprehensive records that are crucial to effective and efficient health care. By searching the record repositories (with patient permission), the substantial additional value of the information beyond individual care can also be captured to promote financial sustainability. This person-centric architecture is envisioned and supported within the ONC's Shared Nationwide Interoperability Roadmap.<sup>5</sup>

In these comments, HRBA urges ONC to fully develop and engage this person-centric path to create individually owned, aggregated medical records for each patient. Those records can be stored in patient-owned and controlled data accounts. Those accounts can be stored, among other options, in secure, private sector repositories chosen by each consumer.

Among its benefits, this nationwide medical record system architecture will encourage market-driven innovations and services through the use of application programming interfaces or successor technology or standards. That will directly support success in achieving the specific goals that Congress has specified in the 21<sup>st</sup> Century Cures Act.

In contrast, further pursuit of the existing institution-centric approach to medical records, which has proven unsuccessful in the past, will produce the same lack of success in the future. It will yield barely incremental gains while creating unnecessary complexity, additional cost, distraction and delay. It will postpone the day when the U.S. will realize the benefits that Congress has mandated and our country so desperately needs, more effective and efficient care based on comprehensive individual health records that patients can access easily and furnish to clinicians and researchers.

To do this, ONC needs finally to designate and enforce a mandatory nationwide health information exchange standard. ONC must further ensure that newly created electronic patient records are automatically deposited in standardized form (at no charge) in a secure repository account when requested by the patient. Literally dozens of small and large private sector entities stand ready to receive this information, keep it secure, and facilitate its use (as directed by each patient) for medical care, research, and population health.

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<sup>4</sup> Lapsia V, Lamb K, Yasnoff WA: Where should electronic records for patients be stored? *International J Med Informatics* 81(12):821-7, 2012.

<sup>5</sup> HHS ONC (2015). Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap, Final Version 1.0, December 2015. Retrieved from: <https://www.healthit.gov/sites/default/files/hic-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf>

The availability of standard, low cost, comprehensive electronic health records for each individual can truly bring the advances in health and health care efficiency and quality that we all desire. Individuals can also adopt other market innovations, such as applications (“apps”) that can assist patients with their care using longitudinal, patient-controlled records stored in repositories that eliminate the need for constant burdensome data entry, with the confidence and comfort of knowing that their individual and family health records are complete, secure and easily accessible.

### **1. ONC’s TEFCA proposal does not implement the mandated engineering features and functions in the 21<sup>st</sup> Century Cures Act**

The TEFCA draft proposed on January 5, 2018 by the Office of the National Coordinator (the “Draft Framework”) does not implement the required features prescribed in the 21<sup>st</sup> Century Cures Act (the “Cures Act”) and of HITECH as amended by the Cures Act. If adopted as a final rule, the TEFCA draft would not be consistent with the Cures Act. It would not survive judicial review in the United States Court of Appeals, which would further delay progress toward an effective health information infrastructure.

The Draft Framework bypasses interlocking and interdependent Cures Act provisions that specify engineering features and functions that, together as a system, will enable successful, secure interchange of and access to health record data among patients, clinical providers, researchers, and other authorized users. It is not sufficient to address the requirements of any specific section of the Cures Act in isolation. Congress enacted this systems design, with all its specified elements, to liberate medical records now siloed in proprietary, non-interoperable electronic medical record (“EHR”) systems installed in hospitals and physicians’ offices throughout the U.S. The ONC’s present proposal would not only thwart Congress’s express reasons for enacting the Cures Act, but would clearly be *detrimental to patient care by denying patients the opportunity to maintain, use, and share their own longitudinal, lifetime records.*

Were the draft TECFA framework implemented, it would continue this waste of more billions of dollars on legacy medical record systems that cannot exchange digital data.<sup>6</sup> Worse, it would further put off the time when patients finally will be enabled to extract their encounter data from EHR systems to create longitudinal, lifetime health records that they, as consumers, can use to obtain better health care and to participate in medical research project as they wish. It would thus perpetuate the problems Congress sought to solve in the Cures Act. Our country and patients cannot afford this waste and delay any longer.

Congress, in the Cures Act, requires a nationwide health data exchange system connecting otherwise incompatible EHR systems to make them interoperable (able to exchange digital health data easily, reliably, and routinely). Congress specified the following explicit operating features and components, all required, as part of a *comprehensive* engineering systems design.<sup>7</sup>

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<sup>6</sup> See, e.g., *Veterans Affairs Wasted Closer to \$2 Billion On Failed IT Projects*, available at: <http://m.nextgov.com/it-modernization/2018/01/veterans-affairs-wasted-almost-2-billion-failed-it-projects/145626/>.

<sup>7</sup> Statutory citations for each of these Cures Act provisions may be found in HRBA’s August 24 Comments submitted in response to ONC’s Request for Information on Implementing the Cures Act. *Id.*, note 1 above.

- EHR data must be exchangeable “*without special effort*” on the part of users. (Patients and physicians are among “users” under the Cures Act.) (HITECH as amended, new §3000(10)(A), as added by Cures Act §4003(a); emphasis added.)
- EHR data exchange must allow “*complete* access, exchange, and use of all electronically accessible health information for authorized use [under applicable law].” (HITECH as amended, new §3000(10)(B), as added by Cures Act §4003(a); emphasis added.)
- EHR data exchange cannot be implemented by ONC in ways that restrict “exporting *complete information sets*” as part of access to, or exchange of, health information. (HITECH new §3022(a)(2)(C)(i), as added by Cures Act §4004; emphasis added.) This means export of all of a patient’s health records in the EHR system if a patient so requests.
- EHR data exchange must allow “*access to all data elements* of a patient’s electronic health record” permitted by privacy laws. (HITECH new §3001(c)(5)(D)(iv) as added by Cures Act §4002; emphasis added.)
- EHR data exchange *cannot* be implemented by ONC in ways that “*are likely to substantially increase the complexity or burden*” of access to, or exchange of, health information. (HITECH new §3022(a)(2)(B) as added by Cures Act §4004; emphasis added. This provision perforce imposes a specific requirement for nationwide standardized exchange.)
- EHR data exchange must be enabled through the use of application programming interfaces or *successor technology or standards*. (HITECH new §3001(c)(5)(D)(iv) as added by Cures Act §4002; emphasis added.)
- EHR data exchange must provide *the patient or an authorized designee* with a *complete copy* of his or her health information from an electronic record *in a computable format*. (HITECH new §3000(10)(B) as added by Cures Act §4003; emphasis added.)
- EHR systems must be capable of exchanging health data with “clinician-led clinical data registries” that are “designed to collect detailed, standardized data . . . for medical procedures, services, or therapies for particular diseases, conditions or exposures,” and that meet data quality standards including “using standardized data elements . . . to verify the completeness and validity of those data.” (Cures Act §4005(a), (b).)
- A key Congressional goal is “offering patients access to their electronic health information *in a single, longitudinal format that is easy to understand, secure, and may be updated automatically*” and supports patients’ ability to add “patient-reported information” electronically as well as patients’ access (at each patient’s option) for research purposes. (HITECH new §3009(e)(2)(A) as added by Cures Act §4006; emphasis added.)

In summary, patients’ complete records in EHRs must be easy to exchange (requiring no special effort from users) and assemble into a single, longitudinal format that is easy to understand, use, and update automatically, and that uses standard data elements under the Cures Act. To achieve what Congress has insisted upon as an engineered system, ONC needs to adopt a

single standard mechanism for EHRs to use for purposes of exchanging medical records nationwide (to avoid “complexity or burden”). ONC can update this exchange standard through annual rulemaking proceedings to keep up with technology (for example, the ongoing development of Fast Healthcare Interoperability Resources, or FHIR). We see no other engineering path to meet the statute’s specifications.

Under the Cures Act, ONC implementation of the proposed TEFCA framework is not feasible within the statutory timeline, especially when considering added time for both activating the proposed Recognized Coordinating Entity (“RCE”) organization, and for it to develop and establish workable operational guidelines for participating health information networks (“HINs”).

The TEFCA draft is based on an institution-centric, record locator architecture. In contrast to a system architecture that permits patients to access and aggregate their data into lifetime compilations stored and used securely, record locator services entail keeping patient records in disparate, ever multiplying atomic units held in a shifting variety of locations. This creates multiple points of vulnerability that are repeatedly exposed to attack and error-generation. They are prone to producing incomplete records because inevitably some of the distributed data may not be accessible when requested. Record locator architecture at this scale – massive, incompatible index systems scattered across the country – is also massively inefficient because each patient’s records from the disparate sources must be requested and retrieved error-free, and integrated with unerring precision in real-time each and every time the record is needed.<sup>8</sup>

Imagine such a system for credit card billing, where queries were sent to every merchant where a purchase had been made to assemble each person’s monthly bill (or, worse yet, “broadcast queries” to every possible merchant to find the transactions of a specific person). The result would be substantial unnecessary computational costs even if done just once each month, but patient records are often needed much more frequently. In contrast, depositing encounter records once in a person’s lifetime account immediately after the record is created has been demonstrated to be much more efficient and reliable.<sup>9</sup>

The idea of making record locator problems worse by inserting regional brokers and disparate, local, voluntary exchange standards into such a system only makes it more costly and chaotic, and even more fraught with security and privacy issues. Access control and user authentication are well known problems that multiply at an accelerated rate with scale in such systems.

The record locator architecture was initially contemplated for health records because of fear of large-scale data loss if large numbers of comprehensive electronic health records were aggregated into a single database. However, recent developments in computer security methods can affirmatively prevent such large-scale data loss,<sup>10</sup> negating the original justification for the massive inefficiencies and predictable errors of the record locator approach. Therefore, there is no longer any reason to continue to support this inefficient, error-prone architecture.

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<sup>8</sup> *Id.* Note 4 above

<sup>9</sup> *Id.* Note 4 above

<sup>10</sup> Yasnoff WA: A Secure and Efficiently Searchable Health Information Architecture. *J Biomed Inform*, 61:237-46, 2016. Available at: <http://dx.doi.org/10.1016/j.jbi.2016.04.004>

Congress, in creating the Cures Act's new Health Information Technology Advisory Committee, further prescribed a policy framework for Cures Act implementation. The framework helps define engineering design features for health data exchange. The Advisory Committee is charged with recommending standards, architectures, and software schemes for access to patients' identifiable health information "*across disparate systems* including user vetting, authentication, privilege management, and access control." (HITECH new §3002(b)(2)(A), added by Cures Act §4003(e); emphasis supplied.) ONC and the Advisory Committee are directed to "identify existing standards and implementation specifications" to support health information exchange.

One of ONC's stated goals is a "single 'on-ramp'" for health data exchange.<sup>11</sup> ONC's proposed Trust Framework also asserts laudable goals involving provider and patient access to health records and encouraging private sector innovation to develop application programming interfaces (APIs) to help access health data.<sup>12</sup> APIs, including FHIR, are becoming increasingly common, but FHIR still requires more implementation guides to limit optionality and improve its interoperability, as well as a trust agreement. While waiting for FHIR to mature, all 12 C-CDA document templates can carry all of the significant data classes within EHRs. The C-CDA standard is widely used now and is extensible to cover other use cases and data types. In addition to Query/Retrieve, "Push" methods such as Direct messaging have great value for consumers and patients because they allow patients to easily receive data from EHRs by simply entering their Direct address into the EHR's patient portal and they allow patients to securely send data payloads to providers, payers, and research organizations. Further, APIs alone do not today offer the extensive systems capabilities required under the Cures Act to exchange complete patient records using standard data elements in computable format.

A vendor's commercial decision to offer a certified EHR system in interstate commerce is voluntary, as is the vendor's decision to seek to have the EHR system certified as complying with HITECH and Cures Act certification criteria. Once an EHR system vendor seeks certification post Cures Act, however, the system's capacity to exchange health record data is mandatory to satisfy the statute. Otherwise, ONC should not under the statutory scheme certify the EHR system for HITECH and Cures Act purposes. Despite the statutory scheme, however, ONC's TEFCFA proposal envisions a system of multiple voluntary standards. Without adoption, implementation, and enforcement of a mandatory health data exchange standard, it will be impossible to achieve the statutory goal of avoiding complexity and unwarranted burden on users (including patients and clinicians).

ONC further proposes to designate a new entity, the Recognized Coordinating Entity ("RCE"),<sup>13</sup> to shepherd the voluntary standards process according to a time schedule that exceeds the time allowed under the Cures Act. This approach would guarantee that implementation could meet neither the Cures Act's design specification for data exchange nor the Act's stringent deadline for promulgating rules to enable computable health data exchange. A reviewing court could well conclude that ONC cannot avoid its responsibility to adopt workable rules within the Cures Act's deadlines by transferring the task to an entity, the RCE, that cannot meet those time frames.

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<sup>11</sup> Office of the National Coordinator, *Draft Trusted Exchange Framework*, January 5, 2018 (available at: <https://www.healthit.gov/sites/default/files/draft-trusted-exchange-framework.pdf>), at 5.

<sup>12</sup> *Id.* at 6.

<sup>13</sup> *Id.* at 9.

ONC's current TEFCA proposal is aimed in part at fostering compatibility in data exchange among existing, prominent health information networks (HINs) – an institution-centric, rather than a patient-centric, model. However, the Cures Act imposes no such design requirement. Rather, many models of health information exchange are permissible under the Cures Act – so long as ONC's system design incorporates all the Act's specific engineering features. While many existing HINs might become obsolete once the Cures Act's mandatory engineering features become available, effective access to complete patient records rather than preservation of existing organizations is the priority of the Cures Act.

The availability of a mandatory health data exchange standard would enable bi-directional patient-institution data exchanges, including consumer-directed exchange (“CDEX”). This momentum for consumers will open a wide range of opportunities for private sector innovation in the use of application programming interfaces (“APIs”) and other technologies for an ever-expanding variety of health applications. The exchange standard would aid pharmacies and many other providers across care settings. It would allow them easily to expand care coordination efforts with other providers and with consumers themselves. It would support payor applications. It would bolster public health applications. So, in contrast to the current TEFCA proposal, a mandatory exchange standard could be the foundation for reaching the four goals ONC has set out for the exchange framework.<sup>14</sup>

In summary, the currently proposed TEFCA would interfere with, or outright prevent, meeting the data exchange goals and design requirements prescribed by Congress. The current proposal is inconsistent with the Cures Act, and does not support the promise of routine, easy-to-use health data exchange that the Cures Act heralds and Congress believes it has enacted.

## **2. Meeting Cures Act requirements requires a national health data exchange standard**

The requirement for complete exchange of patients' EHR records in a “computable format” must be implemented in the Trusted Exchange Framework ONC adopts. The Cures Act requires exchanging all data elements among EHR systems in standard ways, so as not to increase the burden on users or require their special effort.

The only engineering approach identified to perform these exchanges requires the capacity in each EHR system to map their output of medical records using a mandatory, standard format that ONC specifies. This is the “single on-ramp” ONC seeks, but has yet to propose in reliable system design and system engineering terms.

EHR systems must be able to map their outputs and inputs using the mandatory medical record format. When an EHR system receives records in that format, this mapping will direct each data element to its correct location(s) in the receiving EHR. That functionality will make the received data easy for clinicians to use. Clinicians on the receiving end of an exchange will be able to search for and quickly locate the data they need for an encounter. They will be able to analyze specific data using tools in their EHR systems (e.g., graph a patient's historical data). In the context of the Cures Act, no other interpretation of “computable format” makes sense, because no other approach makes possible the “ease of use,” “complete data,” and “standard data element” design requirements of the Cures Act.

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<sup>14</sup> *Id.* at 4.

A nationwide digital health data exchange standard is well within ONC's reach. Congress directed ONC to adopt and implement existing, consensus industry standards for the Trusted Exchange Framework. The Consolidated-Clinical Document Architecture ("C-CDA") is the only existing, widely-implemented content and format standard that meets the needs ONC faces, as HRBA has detailed in earlier comments (see footnote 1). The C-CDA is amenable to further development, to technological improvement (such as, for example, potential instantiation using FHIR, or Fast Healthcare Interoperability Resources), and can be expanded to include data transfer to clinical registries and medical researchers. The Cures Act requirements and time frame necessitate mandatory use of C-CDA to develop content mapping rules for EHRs.

To summarize: Rules that ONC adopts must be based on a systems design that achieves all the interdependent engineering goals in the Cures Act. The rules must contain mandatory standards for a nationwide data exchange standard to enable EHR data to flow into a *single, longitudinal format that is easy to understand, secure, and may be updated automatically*. Using the new Cures Act system, patients (and their designees) will be able to move complete medical record data sets, including all their standard data elements, back and forth, in and among various proprietary EHR systems. That is so even though those EHR systems are presently incompatible, that is, incapable of exchanging complete health records and all the data elements in those records.

The current TEFCA proposal unfortunately does not meet these statutory requirements.

### **3. Consumers' control of and access to their health records, improved outcomes, and medical research all require a national health data exchange standard**

A national health data exchange standard should be the "on-ramp" that ONC seeks for medical records. The exchange standard would open the door to consumers' aggregating records of health care encounters from providers wherever located, storing the records securely, and using them to improve interactions with the health care system. It would give consumers new means to help manage their health and healthcare. It would allow patients to give providers access to all or selected parts of their health records at the point of care, where providers could easily search the records and go directly to data relevant to the particular encounter. This would apply to all data elements of complete digital medical records, across disparate EHR systems, using computable formats, and without special effort by patients or their doctors.

Consumers could then, among other options, aggregate their health records in accounts they own and control. Those accounts could be stored securely in private sector repositories or with selected providers in portals or other provider systems.

Market innovation will no doubt address and solve many high-need use cases in health care. For example, consumers with lifetime health record accounts in secure depositories could voluntarily put themselves on lists maintained by the depositories so each patient could be notified about research projects in which they have an interest. With ownership and control over their medical records, consumers would then be placed in contact with researchers. The consumers could, if they wished, allow the researchers access to their full or partial, identified or anonymized records for research purposes. Some consumers might elect to sell such access. While that prospect may be troubling to some, it is a legitimate market mechanism, probably inevitable, that

will accelerate research and reduce its costs. A national health data exchange standard that ONC adopts to implement the Cures Act is the key to opening all these opportunities.

We note that these system operations are feasible and practical, in contrast to the TEFCA proposal for brokered broadcast query capabilities in the proposed Common Agreement.<sup>15</sup> Broadcast query, or “pull” queries from all available medical databases, has been proven to be unworkable at scale<sup>16</sup> and in simulations.<sup>17</sup> It cannot be implemented nationwide, regionally, or even locally. Yet broadcast query capacity is a major focus of the TEFCA proposal. This unnecessary and unrealistic proposal overcomplicates any TEFCA plan and should be dropped.

#### **4. To fulfill the purpose of the Cures Act, ONC should adopt a nationwide health data exchange standard**

ONC can publish an expedited notice of proposed rule-making (“NPRM”) focused on how best to designate a nationwide health data exchange standard. It can seek expert advice from all sectors of the healthcare and health informatics industries, and from academe, on how to engineer health information data exchange to incorporate all the mandatory functions and features Congress specified the Cures Act.

What do industry and patient groups suggest be mandated in the exchange standard?

A partial list of questions in a new NPRM might include the following:

The Cures Act requires ONC to utilize industry-consensus standards to assemble the data exchange standard. For payload, i.e., content and format, what industry-consensus standards, if any, exist other than C-CDA? C-CDA can be expanded from the current twelve document templates as new data categories and types become available, so proposals that ONC consider using an industry standard other than C-CDA should recommend content and format options that can be expanded in a manner comparable to the C-CDA. (This question is based on the following: Presently, C-CDA templates exist in a single, extra-large implementation guide. It contains 12 documents, 70 sections, and over 120 entry templates. The templates are machine-generated instructions explaining how to apply the base HL7 CDA standard for the specific uses covered by the 12 types of documents. The templates are expressed in a *computable format*. C-CDA document instantiations can thus be tested using new technology developed to make use of the *computable* templates. The recent emergence of more sophisticated testing tools is strengthening the continuous quality improvement efforts for C-CDA.)

What role should FHIR play in the first iteration of the exchange standard? Is FHIR sufficiently mature that it, alone, can function as the nationwide data exchange standard that is required by the Cures Act? Or should ONC wait to include FHIR until a later iteration of the

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<sup>15</sup> *Id.* at 32-33.

<sup>16</sup> 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, available online at: <http://content.healthaffairs.org/content/26/5/w568.full.html>; 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, available at: <http://www.healthit.gov/sites/default/files/summary-report-on-nhin-prototype-architectures-1.pdf> (documents, inadvertently, why health record broadcast query cannot be made to work at scale).

<sup>17</sup> *Id.* note 4 above.

standard, when FHIR is more mature? How many years might that wait be?

In the first iteration of the exchange standard, and if C-CDA is adopted as the content and format part of the standard, should EHR system vendors have the option to instantiate C-CDA in FHIR? Or only in FHIR?

In developing the industry-consensus-based data exchange standard in accordance with statutory requirements, ONC must, among other things, meet the Cures Act's "ease of use," "standardized data elements," "complete record," and "computable" criteria. The most likely (and possibly the only known) engineering approach to this challenge is for ONC to mandate that the standard require certified EHR systems to have the capacities (1) to map health record outputs to the standard and (2), to map received standard inputs to the receiving certified EHR's system, placing standard data elements appropriately in the receiving EHR system. The second criterion is necessary to reduce clinicians' burdens in using their EHR systems and to satisfy data reliability concerns, among other ease-of-use considerations. Given these system engineering requirements, what suggestions do commenters have as ONC develops the rule to specify how the data mapping should be accomplished, including how near-real-time quality control processes should be included in the ONC rule?

As to secure transport, what other industry-consensus standard is available other the Direct Project Applicability Statement for Secure Health Transport Version 1.2 (the "Direct Protocol")?

For transport, and whether or not ONC specifies the Direct Protocol as part of the exchange standard, what identity-proofing and other security considerations should ONC include in the exchange standard? Or should identity-proofing be specified separately from the exchange standard?

What procedures should ONC include in the data exchange standard rule to assure regular updating of its specifications as required by technology and industry process changes?

**5. Absence of a nationwide, digital health data exchange standard will not only delay the goals of the Cures Act, but is susceptible to potential court challenge, further postponing implementation**

The Cures Act was intended, among other specific goals, to benefit patients and clinical providers in accessing and using health information now stored and siloed in EHR systems around the country. If ONC were to adopt the Trusted Framework as proposed, so that health data exchange were again stymied, patients and clinical providers would be harmed. Hence, patients and clinicians, and patient and clinician groups, would have standing to seek review in federal court of any such action by ONC. Other intended beneficiaries of the Cures Act's data exchange provisions would also have standing.

A Trusted Exchange Framework and Common Agreement premised on the mandatory data exchange standard we have outlined in these comments would rationalize and simplify many vexing privacy and security issues, and simplify rather than over-complicate the path to health record interoperability on a national scale. That is so because a mandatory exchange standard

becomes the basis for patient-centric health data and health data systems. That in turn rationalizes the system's functioning. Organizing health records around patients (rather than institutions) is the most efficient health record system there is.

Implicitly, implementing the Cures Act with *a minimum set of mandatory specifications and standards* is a high priority and a virtuous objective. Adopting the data exchange standard suggested here would achieve that goal. It would among other things simplify issues ranging from patient identification and matching (through patient-owned lifetime record accounts in secure repositories) to security and privacy issues and data quality and integrity concerns. A national exchange standard for the U.S. would open the way for private sector innovation. It would spur patient-centered care.

In a world where patients accumulate various providers' encounter records in aggregate lifetime, longitudinal records (many stored in secure, private sector accounts), problems of patient identity and matching, patient consent and authentication, patient-researcher interaction, and patient access to and control of medical record privacy under HIPAA and the Common Rule<sup>18</sup> all would become manageable instead of intractable.

Our society should be wrestling with such problems as data quality issues that still prevent researchers and regulators from being able to access and study real-world data, or software developers from applications of artificial intelligence and machine learning with real patient data. These are the advances that will bring costs down and quality up. The exchange standard we describe here offers the most direct path to these developments.

Liberating patients' health records from the nationwide installed base of proprietary, non-interoperable EHR systems is Congress's stated goal in the Cures Act. ONC should therefore take the opportunity to revise substantially the January 5, 2018 Draft Trusted Exchange Framework and Common Agreement. It must publish a new proposal as we have outlined here, one that complies with the Cures Act's detailed mandates and offers health data exchange standards that can be implemented rapidly and successfully.

Respectfully submitted,

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by

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<sup>18</sup> Federal Policy for the Protection of Human Subjects (the Common Rule), 45 Code of Federal Regulations Part 46 (see <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html> ).