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
Request for Information Regarding Implementation of the 21st Century Cures Act's Trusted Exchange Framework and Common Agreement
(https://oncprojectracking.healthit.gov/wiki/display/INTEROP/Common+Agreement+and+Exchange+Framework**)**

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Introduction and Summary

The Health Record Banking Alliance (HRBA)[*] promotes technology to enable consumer-owned and -controlled accounts held in secure private sector repositories. Repository accounts allow patients to aggregate medical records from a variety of doctors'

[*] 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.

offices, hospitals, and other sources; compile and analyze the consolidated records; control access to them; analyze the compiled data in them; and use the consolidated records in a wide variety of ways, including for treatment and participation in medical research projects.

(Medical offices and hospitals will continue to own and maintain their records with respect to care episodes for their patients.)

Widespread adoption of consumer-controlled health data accounts, holding encrypted "lifetime records," will reduce health care costs overall; enable consumers to be better informed about, and involved in, their health and healthcare; assist consumers in shopping for health care; promote improved care and outcomes; assist emergency responders' timely access to vital patient data that consumers elect in advance to make available; and enable interested patients to be contacted by medical researchers for projects of mutual interest, thus speeding data flows for research and lowering research costs.

In short, adding repositories to the nationwide health IT infrastructure will give consumers sovereignty over their lifetime health records.

Secure private sector health data repositories offer an architectural mechanism for integrating digital health data around the patient. This is an obviously efficient data processing strategy. It is not, however, part of today's health system architecture because of the way U.S. health IT systems began and evolved.

The 21st Century Cures Act amends Title XIII of the American Recovery and Reinvestment Act of 2009 (the Health Information Technology for Economic and Clinical Health Act, or HITECH). Together the two statutes require ONC to establish a trusted exchange framework, including a common agreement among health information networks nationally, within a policy structure that has specific mandates. One of HRBA's purposes in these comments is to explain why repositories are critically important to achieving the policy mandates of the two statutes taken together.

We assert that ONC can most efficiently implement the 21st Century Cures Act by adding secure repositories as pivotal structural components in the systems design for the U.S. health IT system. This change will bring to the trusted exchange framework data processing functions currently unavailable. The repositories will quickly become trusted destinations for patients to send medical records for aggregation, storage, analysis, and access – affordably and easily. Adding repositories to the health IT system architecture thus is key to exchanging the vast stores of patients' disparate digital records now held by medical offices and hospitals in various proprietary data systems that, by and large, cannot exchange medical records with one another.

What is necessary before the private sector can begin offering repositories and secure health data accounts to consumers nationwide? It is ONC's adoption of a nationwide health data exchange standard.

HRBA asserts that the Cures Act, and HITECH as amended by the Cures Act, compel ONC to adopt an exchange standard. It is a systems engineering necessity. The time is right for ONC to do so. Technology for transport and content exists that can be incorporated by regulation into an exchange standard. Doing so will take advantage of the new statutory platform created by the Cures Act, and in a way that complies with and fulfills the Cures Acts' specific mandates and policy goals.

One would be hard-pressed to devise a systems design that complies with the Cures Act and that does not include such repositories and the data exchange standard that will enable them. These comments will explain why that is so. We will also chart how ONC can regularly update the initial exchange standard to keep pace with technology.

This is the path ONC should take to achieve the 21st Century Cures Act's general and specific policy goals and its trusted exchange framework and common agreement.

1. The 21st Century Cures Act Establishes Requisites for the Trusted Exchange Framework

We begin these comments by examining the Cures Act and the HITECH Act as amended and updated by the Cures Act, in order to extract specific systems design mandates imposed by Congress on ONC for the trusted exchange framework. We also want to extract explicit policy prescriptions Congress included in the Cures Act to guide ONC's development of the exchange framework and the common agreement.

Section 4003 of the Cures Act, titled "Interoperability," amends section 3000 of HITECH (itself an amendment of The Public Health Service Act), and redefines "interoperability" in a way that imposes significant new systems design requirements on ONC:

- The secure exchange and use of health information must be enabled in a way that can be done "without special effort on the part of the user." "Exchange," "use," and "without special effort" are not defined for purposes of the statute. Hence ONC must apply the common meaning of each term in implementing and enforcing the Cures Act. Together, these terms in their common meaning encompass, a wide range of system functions and activities. Further, those functions extend to "user, " which also is not defined in the statute. So ONC must give "user" its common meaning. The meaning will include the universe of consumers/patients and clinicians, among others. (HITECH as amended, new §3000(10)(A).)

- Technology that is interoperable under the statute 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).)

- "Complete" and "all electronically accessible health information" are not specially defined for purposes of the statute, and so must be given their common meanings in context. Consider how the common meanings of those terms apply to health information stored in databases in several hospitals and medical offices where a patient has received care. Assume there are different electronic medical record (EMR) systems among those locations, that those systems presently are incompatible in operation, and that therefore they are incapable of exchanging medical record information among them, much less in a manner that needs no special effort. The statutory requirements highlighted here, which pervade the system architecture and system design imposed by Congress in the Cures Act (and HITECH as amended by the Cures Act) thus require innovative additional performance capabilities for the presently installed base of EMR systems and the networks that interconnect them. The architecture of the trusted exchange framework must accommodate these functions.

- In combination, the definitions and system requirements in section 4003(a) and (b) prescribe a high level of system functionality, far beyond present system data exchange capabilities, and impose requirements for pervasive ease of use for the nationwide health IT systems design and the trusted exchange framework.

These provisions require ONC to build a public-private consensus "for the purpose of ensuring full network-to-network exchange of health information." It is a core systems requirement of the Cures Act. The aim is to "build consensus and develop or support a trusted exchange framework, including a common agreement among health information networks nationally." (Cures Act §4003(b).)

The term "health information networks" is not defined for purposes of section 4003(b)) or the Cures Act generally. Its common meaning includes health information networks internal to medical office and hospital systems; local, state or regional networks of limited or substantial capability; and other networks used to exchange health information.

These system specifications are further informed by policy prescriptions set out in reporting requirements for certification in sections 4002 of the Cures Act as it amends HITECH sections 3001(c)(5) and adds section 3009(a), as follows:

- Without special effort, and through the use of application programming interfaces or *successor technology or standards* (emphasis supplied), allow "access *to all data elements* of a patient's electronic health record (emphasis supplied)" permitted by privacy laws (new §3001(c)(5)(D)(iv));

- Include capabilities, among others, for:

    - accessing and exchanging information and data from medical devices

- accessing and exchanging information from other health care providers or applicable users;

- accessing and exchanging patient generated information;

- *providing the patient or an authorized designee with a complete copy of their health information from an electronic record in a computable format* (emphasis supplied).

(HITECH new §§3009A(a)(3)(B)(iv), (vi), (vii), and (viii)). The dual requirements that patients (or their designees) receive a *complete copy* (presumably from an EMR system) of their health information (not simply medical record data) in a *computable format* complement each other. Together they impose a set of specific systems design requirements for the trusted exchange framework. That set also must be set forth explicitly in the common agreement for the exchange framework. "Computable format" is not specifically defined in the statute, and so ONC must give it its common meaning in context. We will consider the significant implications of "computable format" below, in discussing ONC's implementation of the exchange standards mandated by the Cures Act.

- The Cures Act also adds a requirement that the Secretary of HHS, in adopting and implementing standards for the trusted exchange framework under Cures Act section 4003, give "deference to standards published by standards development organizations and voluntary consensus-based standards bodies." Cures Act §4003(d). The Cures Act also sets several ambitious deadlines for ONC to act in implementing the trusted exchange framework (see, e.g., Cures Act §4003(b), adding new HITECH §3001(c)(9)(B)(i) [6 month deadline for date of Cures Act enactment for ONC to convene stakeholders], and new HITECH §3001(c)(9)(C) [deadline of 1 year after convening stakeholders to publish the trusted exchange framework and common agreement]). In light of those deadlines, the requirement for ONC to give deference to published standards assumes signal importance, as we also will explore further below. ONC must perforce rely on existing common standards. It does not have time to wait for new standards to come to the fore, a process that takes years given the need for iterative standards development in order to reach consensus in so complex a commercial sector as health IT. The policy prescription to use industry standards, we believe, adds to the imperative for ONC to adopt a national health data exchange standard, discussed below.

Section 4003(e) of the Cures Act strikes old sections 3002 and 3003 of HITECH and substitutes new, rewritten sections 3002 and 3003. HITECH new section 3002 establishes the Health Information Technology Advisory Committee. The statutory policies the committee is to recommend further inform ONC's design of the trusted framework's systems architecture. These policy specifications include:

- Recommending standards (we note, such as a national health data exchange standard) and implementation specifications for a national and local health information technology infrastructure to advance electronic access, exchange, and use of health information. HITECH new §3002(a). The recommendations are to be consistent with HITECH section 3001(c)(3). That section in HITECH speaks of the "enterprise integration" in exchange and use of health information. HITECH §3001(c)(3)(A)(1). We will later relate the policy commanding enterprise integration to the requirement that EMR systems must supply patients with complete copies of their records in computable formats.

- Recommending to ONC standards, implementation specifications and certification criteria, in priority, for development and harmonization to include standards, architectures, and software schemes for access to patients' identifiable health information "*across disparate systems* including user vetting, authentication, privilege management, and access control." (Emphasis supplied.) We will relate this policy prescription to the need for ONC to adopt a national health data exchange standard. HITECH new §3002(b)(2)(A).

- Recommending as a priority target area achieving health information exchange nationally and locally in a way that provides accurate patient information and avoids duplication of patient records. HITECH new §3002(b)(2)(B)(i). Below we will relate this policy priority to the unique system architectural advantages of private sector, secure repositories to hold patient-controlled lifetime records and to supply patients with secure tools and secure analytical services. These will aid patients and their health care providers in accessing and using the aggregated records.

- Recommending technologies to make patients' records indecipherable to unauthorized individuals when that information is transported outside secure facilities (such as medical offices and hospitals) where the disclosing entity is responsible for security. HITECH new §3002(b)(2)(B)(i). The addition of secure private sector repositories to the systems architecture for national health data exchange fits well with this policy objective.

New HITECH section 3003, inserted by Cures Act section 4003(e), lays out priorities for ONC when it convenes the newly created HIT Advisory Committee. In addition to emphasizing priority for innovation in health IT, HITECH new §3003(a)(1)(A)(vi), ONC and the Advisory Committee are directed to "identify existing standards and implementation specifications" to support health information exchange. This becomes important when ONC considers a national health data exchange standard, because, as we will discuss below, existing standards and implementation specifications exist, and ONC can select them for the exchange standard to fulfill this policy mandate.

Section 4004 of the Cures Act amends subtitle C of HITECH by adding new HITECH section 3022, prohibiting information blocking. For medical offices, hospitals, and the EMR system vendors that serve them, new sections 3022(a)(2)(B) and(C) set forth important specific prohibitions that ONC must factor into the systems design for the trusted exchange framework.

New section 3022(a)(2)(B) forbids implementing health information technology (which includes EMR systems) "in nonstandard ways that are likely to substantially increase the complexity or burden" of access to, or exchange of, health information.

New section 3022(a)(2)(C)(i) forbids implementing health information technology in ways that restrict "exporting complete information sets" as part of access to, or exchange of, health information.

Taken together, these two provisions impose design requirements that ONC must insist upon for all EMR systems that fall under HITECH and the Cures Act. We will discuss below how these requirements inform, and are informed by, provisions requiring that patients be able to receive complete copies of their health information in computable format for exchange across disparate systems and as a matter of enterprise integration; how those provisions together guide ONC in deciding to mandate a national health data exchange standard, and in selecting the components of that standard from existing, industry-consensus technology.

Cures Act section 4005 imposes two more mandates integral to ONC's architectural planning for the trusted exchange framework. It specifies that EMR systems be capable of transmitting to and receiving from registries. These registries include "clinical-led clinical data registries," in accordance with ONC-recognized standards. Cures Act §4005(a). And it defines "clinical-led clinical data registries" as, among other things, "designed to collect detailed, standardized data . . . for medical procedures, services, or therapies for particular diseases, conditions or exposures," Cures Act §4005(b)(2), and that meet data quality standards including "using standardized data elements . . . to verify the completeness and validity of those data," Cures Act §4005(b)(4).

These specifications are statutory support for architectural, systems design advantages that ONC should incorporate in promulgating a national health data exchange standard. Specifically, they require flexibility so that templates in the exchange standard's content payload can be added, expanded, and refined. That way, new templates can be created and continually refined to meet the needs of clinical-led groups that are developing new data sets and data structures for their specialties.

The practical imperative for ONC to incorporate secure private sector repositories into the systems design for the trusted exchange framework is also apparent from the pivotal policy mandate in section 4006 of the Cures Act. That section seeks to empower patients by improving their access to electronic health information. Among other things, Cures Act section 4006(a) amends HITECH by adding new subsections (c), (d), and (e) to HITECH section 3009. The 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." HITECH new §3009(c)(1) (emphasis supplied).

As we propose below, the most efficient, practical way for each patient to compile, control, and use a longitudinal record is through a health record account in a repository. *What other systems design would work?* EMR system portals, after all, restrict patients to using a single hospital system and its affiliated medical offices. Patients, realistically, cannot shop for health services outside that system if they want to preserve the advantages of a consolidated medical record. They cannot coordinate care among other providers outside that portal's system. And of course those outside providers typically will use EMR systems from different EMR system vendors. Patients, thus confined, have no sovereignty over their medical records, and only limited capacity to create a lifetime record they can update and own.

Private sector repositories, in contrast, will offer secure storage and a wide variety of software tools that are not confined as is a provider portal. They will enable account holders to aggregate and update their records automatically; analyze the health information in them; receive alerts based on that information; grant timely access to their treating clinicians remotely or at the point of care; and use their lifetime records to manage their health, healthcare, and interactions with the healthcare system generally.

Thus there is in practical terms under Cures Act section 4006 as it amends HITECH section 3009 this design consequence: the trusted exchange framework must have the systems capability to update patients' longitudinal records *automatically*. Further, this relates directly to the requirement that patient records be in a "*computable format*." See HITECH new §§3009A(a)(3)(B)(viii). The two requirements, combined with the Cures Act's repeated injunctions to use consensus standards, are drivers of ONC's systems design.

Under Cures Act section 4006 as it amends HITECH new §3009(c)(1), the Secretary of HHS is directed to educate providers about health information exchanges "or other relevant platforms" and to clarify providers' misunderstandings about using exchanges or other relevant platforms for patient access to their digital records. HITECH new §3009(c)(2)(A), (B). The systems design significance of this injunction is that other platforms besides "health information exchanges," however that term is defined, are to be included in the trusted exchange framework.

This has two implications for ONC's incorporating secure private sector repositories into the framework architecture. *First, ONC can and should recognize these repositories as health information exchanges in themselves*. After all, standardizing and aggregating heath information inputs from diverse sources and enabling patients to output the compiled information (or selected portions of it) under their control is the repositories' fundamental function. They will quickly become highly efficient health information exchanges in the trusted framework. *Second, and independent of the first factor, secure private sector repositories are "alternate platforms" under the Cures Act, and are eligible for inclusion in the exchange framework on that basis as well*.

Under Cures Act section 4006 as it amends HITECH new §3009(e)(1)(A) and (2)(A)(iii), ONC is directed to promote facilitating communication between researchers and patients, at patients' option with patients' consent. The purpose is to give patients the opportunity to furnish their health record data to researchers in whose work the patients are interested. Secure private sector repositories are ideally suited for this purpose.

Repository architecture does this by enabling re-designed process flow for medical research. Repositories can offer patients the option to be contacted about medical research projects they might care about. Researchers looking for participants (and their medical records) can notify repositories of research opportunities. The repositories then would notify patients who had expressed interest in that kind of research and, at patient request, could put the patients in touch with the researchers. This workflow offers reductions in researchers' costs of acquiring identified patient data, speeds research projects, and offers patients ways to boost research that may benefit them. It is an example of why the secure repository/HRB model is powerful.

Cures Act section 4007 expresses Congress's concern with heretofore vexing problems of patient matching. This section directs the Comptroller General to undertake and publish a study of data matching. For present purposes, we observe that ONC's inclusion of repositories in the framework's architecture will substantially ameliorate the present patient data-matching conundrum to the point where it reduces to a problem set that can be accommodated satisfactorily in the framework.

With repositories added to the national health architecture, patients will direct that records of their encounters be sent to them or their accounts. They ask the sending practice in person, either face to face or via a messaging system with the practice. Either way, the medical office or hospital already knows who they are – they are authenticated to the practice – obviating the need for patient matching (as if there were a reliable matching mechanism available, so far a condition contrary to fact).

We know this systems approach is sufficiently reliable because of experience in the financial system. There customers are credentialed for their various accounts in various financial repositories such as banks and brokerages. Identity proofing and authentication remain essential, and of course all such systems are targets of unremitting attacks by bad actors. But a satisfactory level of security and system performance is attainable. The same will be true for the trusted exchange framework once repositories are included in its systems design.

We conclude this section of HRBA's comments by moving from the Cures Act and HITECH as amended by the Cures Act to a section of HITECH as originally enacted. We focus on an engineering gap that is also a regulatory oversight in ONC's implementation of HITECH section 3000(13)(B)(iv). The Cures Act does not amend this section, so it remains as originally enacted. This gap is a persistent system deficiency. It is the reason why, so far, we have not seen significant progress toward exchanging health information among the existing base of installed EMR systems. It is the engineering reason why health data is not yet "liquid," and health record data exchange remains an elusive goal.

What is this gap? It is that ONC did not implement a design feature specified in HITECH as originally enacted. HITECH, section 3000(13)(B)(iv), specifies the core criterion for a "Qualified Electronic Health Record" to achieve a minimum level of health data exchange:

> The term 'qualified electronic health record' means an electronic record of health-related information on [*sic*] an individual that –
>
> (B) has the capacity–
>
> . . . .
>
> (iv) to exchange electronic health information with, and integrate such information from [*sic*] other sources.

If an EMR system can exchange and integrate health information, it can, perforce, meet subsection 3000(13)(B)'s three other criteria: facilitating clinical decision support, physician order entry, and capture and query relevant to health care quality.

ONC's existing regulations do not require vendors' systems to comply with HITECH section 3000(13)(B)(iv) in order for records in them to be considered "Qualified Electronic Health Records." So a Qualified Electronic Health Record need not be one that can be exchanged with other EMR systems in medical offices or hospitals.

The consequence of this omission is that an EMR system that lacks the capacity for digital record exchange can still be considered Certified EHR Technology under HITECH section 3000(1). This qualifies the system for federal incentive payments even though, in HITECH, those payments are only supposed to go to EMR systems with the capacity for digital record exchange. So ONC's current regulations, unaccountably and inexplicably, omit considering the core functional criterion be used under HITECH in the test for certifying EHR technology.

As ONC implements the Cures Act, the exchange framework, and the common agreement, isolating this critical systems design gap is helpful, because ONC must be sure to close it. When combined with consumer health record accounts held in secure private sector repositories, a national data exchange standard is the mechanism for doing so.

We turn to HRBA's recommendations for those tasks.

2. Implementing the Trusted Exchange Framework Requires Secure Private Sector Repositories for Patient-Owned Longitudinal Records and a National Health Data Exchange Standard

The Cures Act and HITECH supply ONC with an innovative systems design platform – the Trusted Exchange Framework at its core – as well as the policy framework to support

it. As ONC considers systems designs to integrate health information around the patient, the statutory platform enables it to liberate siloed medical records, use repositories as the key mechanism to integrate records around each patient, create longitudinal lifetime records, and give patients reliable access, control, and ownership of them.

An architecture powered by private sector repositories to exchange data with hospital and medical office EMR systems will transform the health IT system nationally. It will enable patients to make all or relevant portions of their aggregated records available to clinicians at the point of care, whenever and wherever the care episode occurs. The records will be in standard, searchable formats. They will speed the treating clinician's task of locating the most relevant and timely data and isolating it from the whole longitudinal record.

These system features will revolutionize data exchange for care transitions. They will open exchange standards to innovative, new clinician-led data sets and templates. They also will substantially mitigate problems of patient matching, because – as with banks – each account holder will have a unique identifier at each repository where the patient maintains an aggregated record. Consequently, positive patient identification will be part and parcel of access that patients grant to treating providers, as well as to researchers and others for whom full or partial access is appropriate as patients elect.

If repositories are key for ONC to implement the trusted exchange framework efficiently, then promulgating a national health data exchange standard is essential to making repositories feasible and to enabling routine, secure data exchange among EMR systems in hospitals and medical offices.

A. Industry Already Has Developed Components Necessary for an Initial Digital Health Information Data Exchange Standard.

What is necessary for ONC to develop a national exchange standard?

As the discussion in the previous section establishes, the Cures Act directs ONC to look to industry-consensus standards. The Act's tight time frames require that ONC select standards based on already developed technology. There is insufficient time for nascent standards to mature.

The Direct protocol for secure transport and the Consolidated Clinical Document Architecture (C-CDA) for content payload are industry-consensus standards. While both technologies continue in development, current versions of each are available today. The current versions are sufficiently mature and functional to be selected by ONC now for the initial, baseline iteration of the national health data exchange standard.

Direct Protocol

ONC can, with confidence borne of thoroughgoing knowledge, adopt the Direct Project Applicability Statement for Secure Health Transport Version 1.2 (the "Direct Protocol") as the transport mechanism for the health data exchange standard.

From a systems operating perspective, ONC will be concerned with credentialing and identity proofing for consumers and other users of the trusted exchange framework. These processes will be expanded to scale through the Direct Trust's or other private sector entities' taking on the necessary range of credentialing tasks. Those functions are independent from a systems design perspective. They can be separated from ONC's adoption of a framework architecture that relies on secure repositories for data exchange to and from consumers' longitudinal records. They are similarly independent of the need for ONC to adopt a national health data exchange standard.

Consolidated Clinical Document Architecture

The C-CDA is an existing industry-consensus standard. Its development, the result of time and great effort, is continuing. It is, by no means, a standard that meets all current needs of clinicians, patients, researchers, or officials with oversight responsibility; it is not presented that way. Indeed, the C-CDA is designed to evolve, adding capacity and functionality. It is also the best industry consensus standard available today. It can be integrated into a national data exchange standard to enable the trusted exchange framework for the near- and mid-term.

We propose that ONC adopt all 12 current C-CDA templates as part of the exchange standard. ONC knows that many clinicians and clinician groups have more specific needs than the higher level of document defined by C-CDA's 12 document templates. But current (R2.1) collection of C-CDA templates should not be viewed as a closed and final set. Rather, the C-CDA at present is a starter set with some of the most basic building blocks included.

For ONC to integrate the C-CDA as the payload element of a national exchange standard, a basic systems design strategy is to avoid corrupting the basics that C-CDA has put in place. The strategy is to use an existing C-CDA template if it is appropriate to a particular clinical use or application. If a system, say a clinical-led clinical data registry as defined in Cures Act §4005, develops, collects, or organizes more specific information, then the clinical registry can use more specific templates to add categories and slots for additional data elements.

Meanwhile, for purposes of developing a highly usable payload component for the national exchange standard, ONC can be confident that the base C-CDA is not difficult to use, even though, early on in its development, many aspects of templates were not well defined. Today and for the past 24 months, projects are underway to improve the C-CDA. For example, value sets are getting a quality assurance overhaul. They will be accessible at the National Library of Medicine's Value Set Authority Center.

New mechanisms are also being developed to expand the C-CDA. They will allow more templates to be defined; and new versions of existing C-CDA templates are beginning to be balloted. Thus, what some have criticized as rigidity in the C-CDA is being addressed. C-CDA is becoming suppler and nimbler, and the continuous improvement process will gain

momentum for the foreseeable future.

There will be requirements in terms of technical criteria for each new template to prove it is a suitable extension for C-CDA. This ongoing template development and quality control process will make it practical for clinical-led groups to create new and more specific templates. Creating other document types will also become a standardized process. Thus ONC can be confident that there will be accessible processes to augment the starting point established by C-CDA.

For all these reasons, C-CDA can and should be the basis for ONC's creating a digital content standard to support the trusted exchange framework. C-CDA is capable now of exchanging much basic medical record data. No other consensus standard will become available in the time frame set by the Cures Act deadlines for establishing the trusted exchange framework and common agreement. Selecting C-CDA now also will hasten progress on the C-CDA's overall further development. Conversely, failure to use C-CDA for the national data exchange standard would hamper progress.

In the vernacular, C-CDA has shortcomings, but it is the best option open to ONC for an exchange payload standard. It is highly suitable as a point of departure for further systems development, and the process of its improvement will only accelerate once it is incorporated into the exchange standard.

This perspective highlights policy advantages of accelerating the basic transition from *not* transmitting *all data elements* in a digital structure to transmitting *all data element*s in a standard digital structure. It is consistent with the ambitious Cures Act deadlines for promulgating the trusted exchange framework.

Once EMR system vendors write mapping application programming interfaces (APIs) to publish and accept *all data elements* in standard digital form, they will meet Cures Act requirements for the *enterprise integration* of C-CDA in *computable formats*. Receiving EMR systems with this mapping capacity must populate *all data elements* reliably. The clinicians using those systems will enjoy rapid access to the precise clinical data they need for particular care episodes.

Thus the trusted exchange framework will usher in the critical benefit for clinicians of system "bi-directionality." Clinicians receiving records from patient accounts in a secure private sector repository, or from a sending medical office or hospital, will know that *all data elements* in the incoming transmission have been mapped to, and will be available in, predictable locations in their own enterprise EMR system. The data exchange between systems will be lossless. Clinicians will be able to search, graph, and isolate the health data they seek.

The implications are profound for episodic care, particularly care transitions, and for reducing burdens on clinicians. *Enterprise integration* supporting reliable bi-directional health data exchange based on mapping via standard *computable formats* exponentially increases the capacity of the receiving EMR to create a patient's story for the treating

physician or care team. It enables the care team to go directly to relevant medical information. It creates a clinical narrative with context and nuance. It speeds any examination and allows faster and more reliable identification of the subjective and objective elements necessary to develop an assessment and plan. This level of "machine processing" is what the Cures Act requires of the trusted exchange framework.

While C-CDA is being implemented and before clinician groups begin significant expansion, data that cannot be mapped into existing C-CDA templates still will be captured as clinical narrative and will be available as narrative for the receiving clinician or care team. As C-CDA document templates and extensions are added and mapped for enterprise EMR integration, the volume of data available for clinical use in standard *computable formats* will expand in coverage and sophistication.

Emphasis on enterprise bi-directionality for EMR systems will yield another benefit: faster transitions to newer technologies. For example, simultaneous mapping from C-CDA entry templates to FHIR Resources is underway. Soon it may be commonplace to define *computable formats* in C-CDA entries and FHIR resources at the same time. So ONC can envision lossless information exchange between C-CDA (or newer CDA templates not yet incorporated into C-CDA) and FHIR.

All this power and progress available with C-CDA is reason for ONC not to succumb to the allure of other possible content standards that may be in early conceptual or developmental stages but will not be available in Cures Act time frames. ONC cannot abide that delay.

Implementation Guides

The aim, as noted earlier, is that implementation of C-CDA document templates in EMRs will be bi-directional. For patient records to be populated efficiently and effectively, each EMR system must both create and consume information exchanged in C-CDA documents. Put in terms of Cures Act requirements, the receiving EMR must perform these functions as a matter of *enterprise integration.* In turn, *all data elements* must be in a *computable format* so they can be mapped in order to permit reliable, i.e., lossless, exchange *across disparate systems*.

These are not optional systems design features. Only by meeting these functional standards can EMR systems satisfy the Cures Act mandate – a requirement imposed by Congress – of offering patients access to their electronic health information *in a single, longitudinal format that is easy to understand, secure, and may be updated automatically.* As a consequence of ONC's meeting these statutory mandates, patient records will also be far easier and less burdensome for clinicians to use and manage.

Implementation guides are crucial to EMR system vendors and their customers (medical practices, hospitals, pharmacies, others) to enhance workflow and lossless information flow between sending and receiving systems. They define the computable formats used to exchange the information.

Presently, C-CDA templates exist in a single, extra-large implementation guide. It contains 12 document, 70 section, 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.

In the future, as more C-CDA templates are needed to update and extend information exchange capabilities, more mature implementation guide production and management processes will be needed. Strict quality criteria for the creation of implementation guides will need to be enforced. This may require additional tooling to support computer-aided analysis so new templates developed in additional implementation guides are consistent and fully complementary to existing C-CDA templates

A searchable repository also will be necessary so all organizations exchanging health data can easily find the implementation guides they need to encode and decode the information being shared. Managing multiple implementation guides will play a critical role in speeding and scaling *enterprise integration* of the trusted exchange framework. Speeding this engineering of *computable formats* for bi-directional reliability will be fundamentally important to ONC, so the value of implementation guides, and the need to develop more of them, is apparent. Experience with, for example, the indispensable role of implementation guides in the introduction of HIPAA standard transactions, lends force to this recommendation.

Procedure for Updating the Standard

Rapid technical development is ongoing, and ONC is well aware of much of it. For example, FHIR or Fast Healthcare Interoperability Resources, holds great promise for health data interchange. FHIR is being used for health data exchange now in an increasing number of applications. But waiting for the next technology to mature is a prescription for unending delay. It would stall regulatory adoption of an exchange standard, which is the key to achieving an initial capability for system-wide data liquidity.

ONC should instead update and evolve the baseline standard on a scheduled basis to enable progressively more capable digital health information exchange. Availability of an update to the base HL7 CDA standard (from R2.0 to R2.1) addresses limitations discovered in CDA R2.0 and expands the expressivity of C-CDA. This will create the opportunity for new implementation guides to be developed, and additional templates to be created, building upon the strong foundation of C-CDA.

ONC can announce subsequent rule making proceedings at regular intervals, perhaps annually, amending the exchange standard to keep current with technological developments and phasing in new technology to maintain the system's nationwide operations without undue disruption. ONC's focus on maintaining alignment between present operational uses

of C-CDA and emerging new data exchange capabilities developing in FHIR will facilitate a smooth path forward without unwanted delays.

Thus, a national health data exchange standard established upon the present use of C-CDA is a pragmatic, progressive strategy for reaching the Cures Act's initial mandates and policy goals.

B. ONC Should Enforce HITECH's Data Exchange and Integration Requirement Using a Round Trip Interoperability Assessment Protocol.

The Trusted Exchange Framework contemplated in these comments would result in an enhanced, reconfigured system architecture for nationwide health information exchange. A virtue of this design is that it focuses on the core engineering task of EMR vendors' writing application program interfaces for their systems to create reliable bi-directional data processing capability as follows:

- to enable publishing from their proprietary EMR systems *all data elements* in standard C-CDA document templates (12 as of this writing) *in computable formats* as a matter of *enterprise integration*, and

- to enable receipt by their proprietary EMR systems of standard C-CDA document templates in *computable formats* and populating the receiving EMR system with *all data elements* so received as a matter of *enterprise integration*.

The Appendix to these comments contains a schematic of how this focused engineering requirement will enable simplified, faster, more understandable, less burdensome enforcement of health data exchange standards under the trusted exchange framework that we suggest ONC adopt. This focused enforcement test can be applied to all providers' EMR systems subject to jurisdiction under the Cures Act and HITECH. It can also be applied to all other APIs for systems and devices that claim to exchange health information according to the framework and the common agreement.

This is a round-trip interoperability test. It could be administered on testing websites. The test involves an EMR system's publishing, i.e., outputting *all data elements* in a health record *in computable format* to another EMR system. The receiving EMR system would, as a matter of *enterprise integration*, process *all data elements* in the data received and, because the payload is *computable*, populate it in the appropriate data locations in that EMR system.

Then the process would be reversed, with the receiving EMR system extracting *all data elements* in that data set *in computable format* and sending the payload back to the first EMR system. A successful test will result in the data's being received back by the first system with no data corruption, loss of content, or loss of fidelity.

The same kind of test can be performed between EMR systems and devices using APIs that comport with the trusted exchange framework and specifications spelled out in the common agreement.

ONC can, on a principled basis under the Cures Act and HITECH as amended by the Cures Act, simplify its enforcement and mitigate the enforcement burden on the health care industry, all to great benefit. ONC can do this by using the specific, straightforward Round Trip Interoperability Assessment as the test *to replace over 900 pages of Meaningful Use regulations*.

Doing so combines ONC's old authority under HITECH with its new authority under the Cures Act. It directly implements HHS's and ONC's mandate for significant regulatory simplification. It lifts a much-criticized regulatory burden from providers and EMR system vendors. It is practical because it relies on industry consensus around existing technology (the C-CDA and the Direct Protocol) to move data out of and into the diverse base of installed EMR systems. It accommodates new APIs, devices, and systems based on them. Thus a practical protocol for maintaining the integrity and lossless capacity of the trusted exchange framework will be integral to its success.

EHR system vendors will be particular beneficiaries, because this systems design offers an immediate path to meeting their obligations under the Cures Act. Providers will be beneficiaries as well, because medical offices and hospitals cannot afford to pay for multiple trust frameworks. They also should not have to confront unnecessary complexity and added risk of losing data integrity from attempting to operate across multiple trust frameworks or trying to integrate with multiple frameworks.

Conclusion

There is private sector enthusiasm for new business models using a repository network architecture. The efficiency of integrating longitudinal records around the patient is magnetic. Cybersecurity benefits are real.

Private sector repositories will offer patients valuable analytical services to enhance use of their health data. With patient authorization, clinicians will access all or part of patients' compiled records at the point of care. They will go directly to relevant data, to create a narrative story in context for assessment and treatment. Burdens on clinicians will be substantially reduced because of improved system usability.

Experience shows, however, that the private sector secure repository model cannot enable the trusted exchange framework unless ONC, using the policy platform and mandates of the Cures Act, adopts a national standard for health data exchange. Once promulgated, that exchange standard would become the ultimate application programming interface for new health systems and devices.

With these changes, data in existing EMR systems nationwide will flow freely and securely under patient control. Data will follow patients. Patients will use their aggregate, compiled records to manage their health and to shop for healthcare services. Patients will have sovereignty over their lifetime health information.

Respectfully submitted,
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Appendix

The Test: Round Trip Exchange Interoperability Assessment

System A	Exchange	System B
1. Extracting from source record entries, sends a clinical payload using any single or combination of exchange artifact(s)	→ → →	**2.** Instantiates payload in health record entries
4. Instantiates payload in a new set of health record entries	← ← ←	**3.** Extracting directly from those health record entries, sends the same clinical payload back using any single or combination of exchange artifact(s)
Basis for Assessment: Is there any loss of content, context or fidelity when comparing original System A record entries to System A record entries resulting from the round-trip?		

Other Patterns: 1) Reverse Roles of Systems A & B 2) System A → System B → System C → System A
Exchange Artifact(s): e.g., HL7 or NCPDP messages, HL7 CDA/C-CDA documents, HL7 FHIR resources