Comments on:	Notice of Proposed Rule-Making (NPRM) – "21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program"
Source:	US Department of Health and Human Services Office of National Coordinator for Health Information Technology (ONC)
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Thank you for the opportunity to comment on the ONC Notice of Proposed Rule-Making (NPRM) – "21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program".

General Comments

First and foremost we note that objectives of the 21st Century Cures Act are *explicitly stated in individual-centric terms,* emphasizing that *"the vision we seek to achieve is a system where individuals are at the center of their care".*

Key excerpts from the 21st Century Cures Act:

"The 21st Century Cures Act's (Cures Act) focus on trusted exchange is an important next step toward advancing the establishment of an interoperable health system that:

- "Empowers **individuals** to use their Electronic Health Information to the fullest extent;
- "Enables providers and communities to deliver smarter, safer, and more efficient [**individual**] care; and
- "Promotes innovation at all levels." ...

"The vision we seek to achieve is a system where **individuals** are at the center of their care and where providers have the ability to securely access and use health information from different sources. A system where an **individual's** health information is not limited to what is stored in electronic health records (EHRs), but includes information from many different sources (including technologies that **individuals** use every day) and provides a longitudinal picture of their health." ...

[It then lists four important outcomes...]

A. "Providers can access health information about their **patients**, regardless of where the patient received care;
B. "**Patients** can access their health information electronically without any special effort;
C. "Providers and payer organizations accountable for managing benefits and the health of populations can receive necessary and appropriate information on a group of **individuals** without having to access one record at a time (Population Level Data), which would allow them to analyze population health trends, outcomes, and costs; identify at-risk populations [**cohorts of individuals**]; and track progress on quality improvement initiatives; and
D. "The health IT community has open and accessible application programming interfaces (APIs) to encourage entrepreneurial, user-focused innovation to make health information more accessible and to improve electronic health record (EHR) usability."

[Emphasis added]

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1. Trusted Exchange Between Carer and Cared For

This NPRM perpetuates an error common to nearly all strategies in this field. It postulates that multiple (indeed myriad) inter-institutional exchanges will somehow lead to coherent ("integrated") individual patient care that is safe, effective, and efficient across all providers and health plans.

It sets as its objective integrated *individual* care but pursues an approach postulated on integrated *institutional* processes. It equates "integrated institutions" with an "integrated individual".

This strategy is fatally flawed in theory – *it is trying to solve an intrinsically individual-centric problem using an institution-centric approach* – and it has failed in practice consistently and repeatedly over several decades. The result in every case has been (and will continue to be) systems that can babble snippets to each other, but cannot effectively communicate except by building "data dumpsters" which are made available to patients/ providers for each person to decode – assuming they have time to rummage and the ability to create new understanding(s) on their own.

The "trusted exchanges" that are needed are not between institutions, but between the carer and the cared for. There is nothing in the Cures Act that says the goal is to have hospitals integrated with doctors' offices and laboratories *per se*. Yet the NPRM formula for how to achieve these health care objectives is expressed in institution-centric terms. Meanwhile, the individual (and his/her health record) remains scattered – as dissonant and disconnected fragments – across these structures.

We believe this to be a profoundly flawed conception of the problem and its solution. Instead of working to solve fragmentation, this NPRM effectively memorializes its entrenchment. It promotes schemes that have been proven repeatedly not to work at small or large scale. The answer to tackling the complexity is not more of the same. The workings of institutions can no longer act as proxies for the experiences of an individual.

2. Health Information Exchange Strategy – Coherence or Confusion?

The Health Information Exchange (HIE) model requires that every system/device talk to every other system/device and then posits that from those exchanges, coherent individual information and care will somehow emerge. This has not worked (and will not work) in theory or in practice. The reason is simple. Interoperability (in this case dumping data from one system to another) is merely a technical capability. It is not a model for how individual care can be managed – for how the collective "system" is to work to inform, guide, and monitor the overall health and care of each person. Of course, it is better if systems interact in common ways where appropriate, but standards for "data exchange" are not alone sufficient.

Allowing systems to "talk to each other" does not help understand who needs to talk to whom and when, about what they need to talk, and what they mean when they exchange data. It may allow for many snippets of dialogue to be exchanged and even mass data dumps, but it cannot create a single, coherent, shared conversation that ensures each individual's overall health and care is safe, effective, and efficient. Assumptions that this capability will magically appear if only everything is connected to everything else are *prima facie* false and have been proven repeatedly to not work in practice.

3. With not About

The whole aim of the 21st Century Cures Act (and by extension this NPRM) is to ensure individuals get coherent, "joined-up" care. That can only be achieved if the individual is the conceptual design center of the information infrastructure. In this NPRM, as in most other such "standards" proposals, the patient is instead at the periphery – distinguished mostly by their obscurity as a far edge node.

Care is provided to individuals and hence health information and related conversations should align with that care. There must be a unique, shared place that brings together all dialogue and vital information involving the

individual (patient) – *providers can then talk with the patient rather than about the patient*. This allows for a common, shared conversation that can ensure each person's care is coherent across all those participating in their care – including the individual, their family and other care givers – whether or not they are part of the same healthcare practice(s) or use the same institutional or vendor-sourced EHR/HIT system(s).

This requires a new class of infrastructure: an Individual Health Record (IHR) that is uniquely conceived to enable a common, fully-informed conversation about the overall health and care of the individual – across all providers and over extending time. The IHR is a persistent account of an individual's health and care, contributed to and used by all those participating in their care, as part of their duty of care. It works with existing institutional systems such as hospital EHRs that will continue to manage detailed intra-institutional processes.

The IHR is not simply a repository of data, but an active platform that informs, guides, and monitors an individual's overall care. The IHR Model is based on the principle of sharing the "system of the individual" rather than merely the data. Conceptually, an institution's systems talk to the "individual's system" rather than only to other institutions. Providers talk with patients rather than about them.

This reorientation of perspective and design obviates the need to even attempt the technical and organizational complexity of HIEs. **Further, enforcing the HIE model will undermine efforts to create the essential individual-centric infrastructure that is necessary for the health care system we aspire to have.**

Most fundamentally, the solution needs to be designed around the individual and not around the institutions. It ensures individuals fully participate in the conversation about their health and care. Design of the IHR Model asserts that coherent individual care is only possible when there is a "system" that is uniquely associated with the individual.

An individual's IHR is held on their behalf and used under the purview of a health record Custodian (new role), with permissioned access.

In effect the individual's system is shared rather than snippets of data exchanged – institutional systems work with the IHR rather than being required to work with each other directly. *This changes an impossible-to-scale, infinitely-faceted, many-to-many connection/conversation/interaction model to a basic and readily implementable series of one-to-IHR connections.*

The IHR Model dramatically simplifies the arrangements. In essence the IHR becomes the point of integration within the whole health system for that individual.

a. The IHR is a persistent account of what matters for an individual and is available for their care across providers and over extended time. The complexities of scattered records, brought together at some unspecified point in the future go away.

b. The individual has a direct, complete way to access their own information and can fully participate in their own care.

c. Through the IHR it is possible to continuously monitor the individual's health and care to help achieve the intended health outcomes, regardless of whether or not a particular institution or care-giver chooses to 'take a look'.

d. The information agreement is between the individual and those providing care at the time of care, managed by a Custodian, and not between a complex of indeterminate and mostly likely unknowable set of institutions.

e. Ensuring individuals have the enforceable right to be given information about the care they receive is essential, but this should be a standard part of clinical practice and the duty of care.

f. As care progresses, institutions can enable their EHR/HIT systems, acting as directed by the individual's right to "transmit" their health information, to push new updates to the IHR as they become available (typically in real-time).

g. The IHR also aligns privacy and confidentiality with the wider responsibilities of clinical practice and duty of care.

h. There is a clear model for managing cohorts of individuals (populations): with appropriate agreements and permissions, a Custodian can provide information on cohorts of individuals without requiring one-at-a-time access.

i. Innovation and access to application programming interfaces (APIs) becomes a much simpler issue: simply interact with the IHR to participate.

All of these capabilities are exactly what the Cures Act set out to achieve. We believe this can only be realized by making individuals 'real' and central in our information infrastructure – thus advancing this approach as an urgent objective – spurring immediate attention and action.

4. The Scatter Model

This NPRM relies substantially on the "Scatter Model" AND the proposition that it may be possible to assemble a patient's health data/records – in real-time – based on a broadcast query mechanism. While it may be possible to broadcast a query for patient information in real-time, it is not feasible to expect that the query will reach – and get – an immediate response across all networks and from all EHR/HIT systems and devices where such information may reside.

For any number of reasons, delays could be measured in minutes, hours or even days. Further, there is a strong likelihood that it will be impossible to identify all possible locations where the data – and types of data – might be found (and ultimately retrieved) based on the query. From a practical standpoint, the requesting entities/clinicians will always be in the position that they don't know what they don't know. They also don't know how long it might be reasonable to wait for query response(s).

See Comment 3. How much better foresight ONC might have to focus on how to engage patients in IHR accounts where all their health data/records can be directed and captured, typically after each encounter, using the Meaningful Use mandate for view/download/transmit. This allows subsequent queries to be directed to one place – an IHR – maintained by a trusted Custodian (such as a health record bank) and controlled by the patient (or their representative). We believe there are obvious and undeniable strengths to this approach versus what the NPRM proposes – typically known as the "Scatter Model". See the following table and in particular the distinguishing advantages shown:

	Scatter Model (what this NPRM and TEFCA propose)	**At the Center – Strengths of the Individual Health Record (IHR) Model**
Basics	Patient data/records are managed across 10s and 100s of HINs and 1000s of systems/devices, each of which maintains/manages: • Trusted software and storage • Accountability, authentication, authorization, consents, access control, audit mechanisms • Some fragment of the patient record	A designated and secure system which is: • Patient-controlled and provider neutral • Maintained by a trusted custodian organization Where the patient or their representative: • Maintains an electronic account and address • Maintains/designates a single place to send/ store their records, e.g., after each encounter • Can direct their individual health data/records after each encounter (using MU provision for view/download/transmit)
Broadcast query	Query goes to 10s or 100s of HINs, then on to 1000s, 10,000s, 100,000s of systems/devices	Query is directed to a single designated IHR custodian and account for each patient
Query response	• Response may be nothing, trickle or deluge • Response content may vary each time • Response may be minutes, hours or days later • You don't know what you don't know • You don't know how long to wait	• Response is immediate • All relevant and permitted records are immediately available • You immediately know what you need to know

	Scatter Model (what this NPRM and TEFCA propose)	At the Center – Strengths of the Individual Health Record (IHR) Model
Confidentiality/ Authorization	Managed within a complex lattice of provider and HIN permissions plus patient consents	Managed at a single point by each patient, patient representative and/or IHR Custodian
Patient consent directives	Managed and kept current across 10s or 100s of HINs and likely dozens of providers	Managed at a single point by each patient, patient representative and/or IHR Custodian
Real-time + Continuous	[Not Applicable]	Sustained (24 x 7) support for individual health and care – monitoring and guidance

5. The HIE Model is the "Spoiler"

See Comments 2 thru 4. The most serious issue is with the underlying HIE model itself and its proven ability to be a "spoiler". The HIE model is all about data massing and myriad exchanges and offers little to the overall process of individual care. The benefits of the IHR in informing, guiding, and monitoring care can only be realized through direct interaction with the full IHR platform and with all of the source data building the IHR record.

The IHR model is to share the platform and not merely exchange subsets of patient data. However, the pursuit of HIEs has for decades prevented the adoption of other models in the belief that all that is needed is stronger enforcement. The two latest (ONC and CMS) NPRMs follow that belief. They are wrong.

While standards may be intended to be a minimum specification, they all too often become a maximum level of achievement in the real world and thus result in an impoverished information environment. *Paradoxically, the HIE model entrenches fragmented systems, data, and care. Patients remain scattered across the institutions with no place that is "theirs" within the overall health care system. This ensures that all of the potential improvements in care efficiency, efficacy and quality can never be achieved.* Giving every patient and physician a "data dumpster" of their information derived from a collage of systems, some well-behaved and others not so much, has been shown to be benefit-free. The new rules are just the latest retreat to the "rigorous standards relentlessly enforced approach". This has been tried over and over and has been shown to fail in every case. It is the wrong approach and cannot be morphed into the right one despite the best intentions. This is why all previous generations of HIEs have failed as soon as stakeholders were asked to pay for them...not because the penalties were not high enough ($1,000,000 anyone?) but because the fundamentals are wrong and cannot be fixed.

6. Coming of Age: The IHR as the Individual's System

See Comments 1-5. It is crucial that the IHR platform is correctly positioned as the individual's system – there to support the overall care of that individual across providers and over extended time. It must not be seen (or positioned) as a "health plan" system, a "provider" system, an "interoperability" system or any other such technical/organizational permutation. That is the IHR's greatest advantage – using a three-legged stool as an analogy – the IHR is the individual/patient "third leg" of the health information "stool", complementing the provider and payment legs. Without the IHR, the stool will forever be leaning over on two legs and impossible to sit upon, no matter how "fat" the provider and payment legs get or how much bracing there is between the two of them. Unfortunately, that is the approach taken by the current ONC/CMS NPRMs as well as the equally flawed TEFCA (Trusted Exchange Framework/Common Agreement), initially proposed in Draft 1 and now offered as Draft 2.

It is also essential that the IHR is not seen as merely another participating source system. It is a different class of platform – an entirely new element of infrastructure. It is the locus of control for an individual's overall health and care. Because this is the only correct approach, it is not surprising that the IHR obviates the need for much of what HIEs aspired and failed (and will continue to aspire and fail) to do.

The role of Custodian is key to making clear that the IHR is the individual's system. Specifically, in relation to the two NPRMs, the IHR should be positioned as the platform with which an individual's smartphone (or PC or tablet or smart watch) needs to interact. It allows individuals to participate together with their providers in a single coherent conversation about their health and care. It gives the individual the means to contribute to that conversation and not be merely the passive listener. This approach not only solves the data fragmentation issue that these rules are attempting to address, but also conforms with the needs of patients and families as set forth in the recent National Academy of Medicine Stakeholder Statement by Patient and Family Leaders. The proposed ONC/CMS NPRMs do not address such needs.

7. System Interactions and Data Flows must be Reflexive and Responsive

As stated in Comments 1-6, this NPRM is oriented to system interactions and data flows and has vanishingly little to say about carer/cared-for interactions, patient flows and clinical work flows. This is a primary (and very real) deficiency. It offers a spinning object without traction on the problem it presumes to solve. If system interactions and data flows are to be effective and efficient (relevant, concise, actionable), they must be optimized to be reflexive and responsive to carer/cared-for interactions, patient flows and clinical work flows. This is where we believe the problem needs serious reorientation.

8. Vital Data Qualities and how Core Datasets/Elements are Expressed

A key provision of the NPRM is adoption of the US Core Data for Interoperability (USCDI). In our review of the USCDI, we find that is far easier to name data sets and elements than it is to operationalize those sets/elements in a form that ensures data integrity, clinical integrity and patient safety.

We know only too well that EHR/HIT systems can capture and propagate mass quantities of data. Claims of "interoperability" are also rampant. Useful, usable, relevant and actionable information (particularly imports from external sources) is still an elusive commodity in the daily practice of most clinicians.

A key point of reference is recent work by the Health Level Seven (HL7) Electronic Health Record Work Group (EHR WG) and their Reducing Clinician Burden (RCB) project. After substantial analysis, the RCB project team established a set of Vital Data Qualities...

Vital Data Qualities	**USCDI must ensure common datasets and elements...**
Data is carried via a verifiable chain of trust from **source to end use**: • Starting as captured at the **source** (point of origination), then • Retained in the source EHR/HIT system, then • Transmitted from the source system, then • Received and retained by the receiving EHR/HIT system, then • Made available to each ultimate **end use and user** (point of access/use).	
• **Is it true and trustworthy?** Accurate, authentic, assured? • **Is it action-able?** Timely, current? Relevant, pertinent? Concise, succinct, to the point? Useful, usable? • **What is immediately *known*** (evident or knowable) regarding its content?	
***Known* and certain as to identity**: patient, provider (individual or organization)	Are associated with the correct identity and subject (of care/treatment)
***Known* to show clear relationship between data and actions taken** (i.e., actions taken to support individual health and to provide healthcare): • **Who did what when, where and why**	Show a clear relationship of datasets/elements with actions taken – who took what action, when, where and why
***Known* to retain clinical context and maintain vital inter-relationships** with/between (as applicable): • Problems, diagnoses, complaints, symptoms, encounters, allergies, medications, vaccinations,	Show a clear relationship between dataset/element and its clinical context and vital inter-relationships (as noted in the ← left-side column ←)

Vital Data Qualities	USCDI must ensure common datasets and elements...
assessments, clinical decisions, orders, results, diagnostic procedures, interventions, observations, treatments/therapies, protocols, transfers, referrals, care plans and status	
***Known* as to source and provenance ("source of truth")**, with traceability to point of origination: human, device, software	Show dataset/element provenance with traceability to source/point of origination
***Known* as to accountable human authorship** (if applicable) with role and credentials	Show dataset/element authorship with role and credentials, as applicable
***Known* as to time orientation** (date/time of occurrence, chronology, sequence), and in terms of: • What has happened: past, retrospective • What is now in progress: present, concurrent • What is anticipated, planned: future, prospective	Show time orientation and chronology/sequence
***Known* to be verified (or not)** with evidence of verification, verifier(s), date(s)/time(s) and method(s)	Show evidence of dataset/element verification, as applicable
***Known* to be updated (or not)** with evidence of prior state(s), effective date(s)/time(s)	Show evidence of dataset/element update, prior state(s), effective date(s)/time(s), as applicable
***Known* to be unaltered** (maintaining fidelity to original/source content) or ***Known* to be altered/transformed** from source content/representation	Show evidence of dataset/element non-alteration or alteration, as applicable
***Known* to be complete** or ***Known* to be partial/pending** or ***Known* to be a snippet/fragment** with other essential details elsewhere	Show evidence of dataset/element completeness (or not), as applicable
***Known* to be comparable** (correlate-able, trend-able) to like data, having same/similar context	Have the same/similar context so as to be comparable, even/especially if sourced by separate EHR/HIT systems
***Known* to be consistent in terms of data definition and with corresponding data**: • Element name(s), data type(s), range, input/display/storage format, unit(s) and scale of measure	Have consistent data naming and definition, even/especially if sourced by separate EHR/HIT systems
***Known* to be sourced as structured (coded) content or not**	Show evidence of data source as structured content or not
***Known*, if coded, to include:** • Coding convention – vocabulary/terminology set or value set – and version	Show evidence, if coded, of coding convention and version
***Known* as to method and purpose of capture**	Show evidence of method and purpose of capture
***Known* as to how external data is integrated** with health data/records in the local EHR/HIT system	Include explicit representation of how external data is integrated with data/records in the local EHR/HIT system
***Known* as to how external data is integrated** among other health/data records from other sources	Include explicit representation of how external data is integrated among data/records from other sources

We believe emphasis on, and incorporation of, these vital Data Qualities is essential to consideration of USCDI as a formal requirement for US-based healthcare providers.

8.1. Immediate context

In conjunction with Comment 8, full context for each USCDI element is essential, first in the initial USCDI set and then as each new dataset and data element is considered for inclusion.

For example, blood pressure should include the following elements of *immediate context*, including provenance:

Who (actor)	Patient or subject of care
	Performer, who measured blood pressure
	Author of health record entry (who may be different than performer)
	Provider: individual practice or organization
What (action taken)	Systolic, diastolic and/or mean measurement
When	Occurred at: date/time/duration
	Recorded at: date/time
Where	Body location, sampling site
	Physical location – e.g., exam room, bedside
	Recorded at: network address and/or device ID
Why	Rationale for, or purpose of, measurement
How	Method – e.g., inflatable cuff with auscultation by stethoscope
Under what circumstance(s) or condition(s)	At rest, pre/post exercise, sitting/standing/lying, or other condition

To be complete and to establish trust (assurance) and truth (authenticity, accuracy), we believe the NPRM must specify that each USCDI element is carried together and tightly coupled with its immediate context.

8.2. Extended Context

Following on Comments 8 and 8.1, *extended context* shows key relationships beyond the immediate measurement (for example, extending the context of our blood pressure example):

Context	Blood pressure measurement occurring as:
a) Basic vital signs panel	Part of a vital signs panel (e.g., heart rate, respiratory rate, body temperature, pulse oximeter) as might be captured from the same patient, by the same performer, at the same date/time
b) Inpatient vital sign monitoring	Part of a vital signs panel (as detailed in "a" above), as might be performed hourly in an inpatient setting
c) Outpatient history and physical assessment	Part of a vital signs panel (as detailed in "a" above), performed in an outpatient clinic, in conjunction with a history and physical assessment
d) Weekly monitoring – to rule in/out hypertension	Weekly follow up visits measuring vital signs (as follow up to "c" above) to determine if patient has hypertension (high blood pressure), performed in an outpatient clinic for four successive weeks
e) Weekly monitoring – post hypertension diagnosis	Weekly follow up visits measuring vital signs to assess effectiveness, dosage levels and possible side effects of medication prescribed after patient was diagnosed with hypertension (as follow up to elevated BP levels detected from monitoring described in "d" above)

To be complete and to establish trust (assurance) and truth (authenticity, accuracy), we believe the NPRM must specify that each USCDI element is carried together and tightly coupled with its extended context.

9. Conquest of Information Blocking

This NPRM exposes a cauldron of angst regarding information blocking. We believe there is a much simpler approach. If we bring the patient to the center, as offered by the Individual Health Record (IHR) Model in Comments 1-6, and we ensure required communication of the patient health record updates from the provider to the IHR at every encounter, information blocking becomes something much easier to tame. In the context of treatment, payment and healthcare operations (the HIPAA TPO trio), intentional information blocking is rarely in

the self-interest of the provider unless it involves treatment of a patient by a perceived competitor (another provider) in their community (or service area). For EHR/HIT vendors information blocking may be a temptation as they face off against their technology competitors.

The issue should be removed entirely from the realm of competitive pressure. Using the IHR construct, the obligation of the provider is to the patient and any instance of information blocking (failure to transmit the latest encounter record to the IHR) is easily monitored by the patient, their representative and/or the IHR Custodian.

It is in the patient's self-interest to capture and maintain their health record content – in the IHR – and then to share it with subsequent providers at subsequent encounters. By definition, the patient is in control and information blocking by the patient to their next provider is seldom an issue.

10. Sharing Information with the Patient is a Duty of Care

Taking this a step further, the NPRM should focus and reference requirements that derive from professional conduct, standards of clinical practice and ethics. One should not need a rule to prevent information blocking. Blocking is a point of professional conduct and is not permitted because it constitutes not giving patients information about their health and care. This is already prohibited in every credible set of ethics and codes of practice, including those of the AMA commonly used in the US. Even the exceptions are covered by ethical standards, for example if releasing the information poses a serious risk to the patient or other party (in the judgment of the clinician). The IHR Custodian role (as outlined in previous comments) is the ultimate agent for dealing with these matters. We believe ONC could dispense with much this apparent struggle if it reframed the data exchange issue into a matter of medical ethics and a duty of care. The predicates for this are well understood and would not brook arguments by EHR/HIT vendors and others.

11. Burden Reduction or a Choking Morass of Onerous Regulation?

Promises to reduce burden ring hollow in contemplation of this NPRM with its myriad, very detailed and highly complex set of regulations, full of new and onerous mandates, constraints and penalties. We believe essential objectives of the 21st Century Cures Act can be achieved with a vastly simplified approach, primarily by positioning the individual at the actual center, as described in preceding comments. Such an approach not only unravels many of the complexities found in this NPRM, it also offers a substantial lever to reduce burden.

Specific Comments

FR page 7426, Section I.A, Executive Summary, "In addition to fulfilling the Cures Act's requirements, the proposed rule would contribute to fulfilling Executive Order (E.O.) 13813. The President issued E.O. 13813 on October 12, 2017, to promote health care choice and competition across the United States... Section 1(c) also states that government rules should improve access to and the quality of information that Americans need to make informed health care decisions."

12. Key Objective: Improving Access To and Quality of Information

We agree "that government rules should improve access to and quality of information" and we believe that this can be achieved with specific attention to Vital Data Qualities, as enumerated in Comments 8, 8.1 and 8.2.

FR page 7426, Section I.A, Executive Summary, "The proposed rule focuses on establishing Application Programming Interfaces (APIs) for several interoperability purposes, including patient access to their health information without special effort. The API approach also supports health care providers having the sole authority and autonomy to unilaterally permit connections to their health IT through certified API technology the health care providers have acquired."

13. Trusted Applications for Providers

If “health care providers [have] the sole authority and autonomy to unilaterally permit connections to their health IT through certified API technology”, then it seems obvious that providers must be aware of, and ensure due diligence, with regard to their responsibilities under HIPAA. This suggests that providers must establish a “white list” of software applications to which their APIs may be open for access to patient information. Given that these applications probably number in the 100,000s, this is no small challenge. In fact it is likely to be costly, even onerous, burden on all providers be they small, medium or large.

We believe that in order for these NPRM API provisions to be implemented, it will be necessary for a certification program to be established to build a national reference “white list” of trusted applications to which providers may ensure their permission for API (and thus health information) access.

14. Trusted Applications for Patients

While considering which apps providers can trust, the same situation exists for patients. The NPRM leaves the patient to forage for themselves - remaining silent on if/how they might trust any in a broad array (100,000s) of apps that beckon them. Some are free, some are modestly priced, others are expensive – but that is not a criteria. The question is which apps can be trusted and how does the patient know?

As noted in the previous comment, we believe trusted apps are essential to a healthy and robust health information ecosystem that supports and offers assurance to patients (and providers). This can be accomplished via a formal app certification program and national “white list” of trusted apps.

15. APIs or Bust?

The NPRM follows previous mandates that promote systems “talking to each other” by exchanging patient data in a specified “standard” format. It extends this approach by requiring these systems implement application programming interfaces (APIs) which define how data can be requested and then exchanged between systems point to point or across a network.

The premise is that this will somehow remove obstacles that are preventing health IT from addressing the major challenges facing health care today, in particular the fragmentation of individual care.

The question is not whether there is a shiny new way to exchange data between EHR/HIT systems (as a successor to more traditional message and document exchange), but whether the resulting mélange offers anything better suited than previous incarnations of standards that produce little more (of substance) than mass dumps of often extraneous and inscrutable data (to the clinician who must view/comprehend them)? In other words, do APIs better provision information that is concise, relevant and immediately actionable? If so, how? Or do APIs represent yet another contributor to clinician burden?

We believe APIs, today’s “shiny bauble”, must still prove their worth/benefit as substantively more than the latest fad.

FR page 7426, Section I.B.1, Executive Summary, “In this proposed rule, we also propose potential new deregulatory actions that will reduce burden for health IT developers, providers, and other stakeholders. We propose six deregulatory actions in section III.B: (1) Removal of a threshold requirement related to randomized surveillance which allows ONC-Authorized Certification Bodies (ONC–ACBs) more flexibility to identify the right approach for surveillance actions, (2) removal of the 2014 Edition from the Code of Federal Regulations (CFR), (3) removal of the ONC-Approved Accreditor (ONC–AA) from the Program, (4) removal of certain 2015 Edition certification criteria, (5) removal of certain Program requirements, and (6) recognition of relevant Food and Drug Administration certification processes with a request for comment on the potential development of new processes for the Program.”

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16. Burdens Reduced?

See comment 11. While we appreciate and applaud the intent of this proposal for "new deregulatory actions that will reduce burden for health IT developers, providers, and other stakeholders", we believe that the crush (and curse) of "burden" is felt most acutely by front-line clinicians at the point of care/point of service. We believe this NPRM offers vanishingly little to those clinicians already severely impacted by regulatory burden. Many comments were offered in January 2019 on the ONC Strategy for Burden Reduction and we believe that the writers of this NPRM should go back and review those comments and make a serious attempt to recast this NPRM in light of industry input and advice regarding burden reduction.

FR page 7426, Section I.B.1.d, Executive Summary, Electronic Health Information Export, "Specifically, this criterion would... Enable the export of EHI for a single patient upon a valid request from that patient or a user on the patient's behalf... This criterion provides developers with the ability to create innovative export capabilities according to their systems and data practices. We do not propose that the export must be executed according to any particular standard, but propose to require that the export must be accompanied by the data format, including its structure and syntax, to facilitate interpretation of the EHI therein. Overall, this new criterion is intended to provide patients and health IT users, including providers, a means to efficiently export the entire electronic health record for a single patient or all patients in a computable, electronic format."

FR Page 7446, Section 4, "Electronic Health Information Export: We propose to adopt a new 2015 Edition certification criterion for EHI export in § 170.315(b)(10). This criterion is intended to provide patients and health IT users with a means to efficiently export the entire electronic health record for a single patient or all patients in a computable, electronic format, and facilitate the receiving health IT system's interpretation and use of the EHI, to the extent reasonably practicable using the developer's existing technology..."

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17. EHI Export Guidelines

While we appreciate and applaud the intent of this proposal to "enable the export of [Electronic Health Information] for a single patient upon a valid request from that patient or a user on the patient's behalf", we also note that the NPRM does "not propose that the export... be executed according to any particular standard". This leaves the required export capability open to broad interpretation, potential inadequacy and dereliction of the duty and "means to efficiently export the entire individual electronic health record for a single patient or all patients in a computable, electronic format".

There is a strong need to ensure that the EHI export serves as something more than a "garbage out" data dump. We believe it is imperative to establish that the export is designed to ensure health record quality and integrity. Following are rules that should guide any export.

a. All individuals must be identified along with their identifying characteristics, including the subject of care, each individual who is involved in provision of health and care services, each individual who is the author or verifier of health record entry content.
b. The health record export should be organized to reflect discrete record entries, chronological over time, including the date/time of health and care services rendered, along with the date/time of corresponding health record entries. This reflects that health and care activities may be documented in real-time (as they occur) or may be documented at a later time.
c. Record entries contain discrete events (actions or activities) to support health or provide care, along with related information, and include patient registration events, encounter/admission check-in, orders, results, assessments, clinician decisions, care plans and actions, vital sign measurement, treatments/therapies, diagnostic procedures, medication or vaccination administration, interventions, observations, transfers, referrals, pre-authorization events, clinical/health status, etc.
d. Record entries should be organized with clarity as to historical health and care activities (past), health and care activities currently underway (present/in progress), and health and care activities anticipated (future).
e. Record entries should reflect the fact that they have been updated, after creation of the initial entry, and show the progression of updates over time – with the date/time of each update.
f. Record entries should reflect that they were signed or attested (or not), for example, by the originating author or someone else.

g. Record entries should reflect that they have been verified (or not), for example, in the case where the original entry was entered by one person and verified by another (such as a supervisor or preceptor), or where the original entry contains input captured from an automated device (such as monitor or instrument).
h. Record entries should reflect whether content is transformed (or not) from source representation, for example, translated from one coding system to another or translated from one human language to another. In other words, has the content been transformed (in any way) from what the original author saw?
i. Record entries should reflect the clinical context of their content, so that the receiving system (and ultimate user) is able to see/understand vital relationships between, for example: problems, diagnoses, complaints, symptoms, encounters, allergies, medications, vaccinations, assessments, clinical decisions, orders, results, diagnostic procedures, interventions, observations, treatments/therapies, protocols, care plans and status.

18. EHI Export – Efficient and Reasonably Practical?

While we understand the need for for this proposal "to efficiently export the entire electronic health record for a single patient and all patients", there is a serious requirement to ensure that such export is both "efficient" and "reasonably practicable". To understand this better, we consulted a handy dictionary for these key terms, "efficient", "reasonable" and "practicable".

Efficient
- achieving maximum productivity with minimum wasted effort or expense
- working in a well-organized and competent way
- preventing the wasteful use of a particular resource
- synonyms: organized, methodical, systematic, logical, orderly, businesslike, streamlined, productive, effective, cost-effective, labor-saving, competent, capable, able, proficient, adept, skillful, skilled, effective, productive, organized, businesslike, nimble

Reasonable
- as much as is appropriate or fair; moderate
- fairly good; average
- synonyms: sensible, rational, logical, fair, fair-minded, just, equitable; intelligent, wise, levelheaded, practical, realistic; sound, reasoned, well-reasoned, valid, commonsensical; tenable, plausible, credible, believable; within reason, practicable, sensible; appropriate, suitable; fairly good, acceptable, satisfactory, average, adequate, fair, all right, tolerable, passable

Practicable
- able to be done or put into practice successfully
- able to be used; useful
- synonyms: realistic, feasible, possible, within the bounds/realms of possibility, viable, reasonable, sensible, workable, achievable

Now that didn't really help, did it? We believe for this NPRM to offer useful guidance, there must be a serious attempt to make clear what is meant by these terms. Please use very crisp and definitive language.

18.1 EHI Export – What are the Challenges?

Let's explore this further. Clearly that which is efficient, reasonable, practical is going to be different – a difference potentially measured in light years – depending on whether you are the patient, the provider organization, the end user clinician, payer, the IHR custodian, the EHR/HIT system developer (either as source/sender, as receiver, or both), a mobile app developer.

Is it efficient or reasonably practical to... (Or actually, is it scalable and sustainable to...)	**If so, to whom?**
a) Allow broadcast queries across all providers, all networks, all systems, all devices – effectively to "query the world"?	?
b) Allow individual providers and their production EHR/HIT systems/devices to be hit with a constant barrage of broadcast queries (potentially thousands to millions of hits per day)	?

	particularly when they have nothing to report? Or when the requester lacks authorization (permission/consent) for what they requested?	
c)	Have no throttle on repeated inquiries from the same requester to send the entire patient record x1, x2, x3, x4, x5... possibly occurring over and over within the same minute, same hour or same day? Possibly jamming out next request before the last is completely processed? Possibly because the requester isn't satisfied with the latency of response? Possibly because the requester isn't satisfied that they got what they expected?	?
d)	Allow broadcast or directed queries where the norm is to always ask for everything? When the requester doesn't know specifically what to ask for, so the default is to ask for everything?	?
e)	Allow repeated broadcast or directed queries where the requester doesn't know what has changed since the last query (1 hour ago, 1 day ago, 1 week ago, 1 month ago...), so the default is to ask for everything again?	?
f)	Allow repeated broadcast or directed queries when the requester finds that the record (assembled from multiple sources) appears to be incomplete, inconsistent or inconclusive (e.g., showing orders without result or subsequent activity, showing referrals "lost to follow up")?	?
g)	Allow broadcast or directed queries when the requester finds that key elements of context are missing? So the query is repeated?	?

(Broadcast and directed queries are standard – and presumed to be routine – ways to gather scattered health information as proposed in ONC's TEFCA.)

19. A Boon to Medical Malpractice Attorneys?

With the NPRM proposal to "enable the export of [Electronic Health Information] for a single patient upon a valid request from that patient or a user on the patient's behalf", this will become the obvious way for patients and their advisers/lawyers to produce a "complete" copy of the health record for purposes of making claims against providers, in malpractice or other actions. There are many instances in recent case law where judgments have been found in favor of the plaintiff after the electronic health record rendering – as produced from an EHR or other HIT system – is excluded from evidence. This is often because, in the process of discovery, the author of health record content is unable to authenticate items ascribed to them or which are misattributed by audit functions of the EHR/HIT system or which are rendered in a form that is so different from the format of the entry screen (or other input device) that such content is beyond recognition (when viewed by the attributed author).

(We harken back to dark ages of the paper world, when health record copies were reproduced by photo copiers and/or fax machines – yet the copy was produced as an identical rendering of the original – in original handwriting with signatures even!)

Also, what are the legal risks if the EHI export renders health record content in a form/format that is different than what a provider produces as output from their EHR/HIT system for purposes of discovery in a legal case? All HIE/Standard approaches that "transform" or "normalize" exchanged data create an easily exploitable dissonance.

20. What the Author Sees versus What the EHI Export Produces

Given the legal risks outlined in Comment 19 it seems obvious that that the time has come to ensure what the author sees at the point of care/point of record entry origination is identical to what is rendered by the EHI export function. This should remain true whether the rendering comes from the EHR/HIT system that is the actual source of health record content or at some point downstream after that content has been exchanged – maybe one or even many hops away.

The common practice of content transformation from source representation to exchange artifact to receiver representation must (at minimum) be accompanied by the original source representation (what the author saw) as health record content moves downstream from the source – hop by hop.

We believe that before this NPRM is finalized it is crucial for ONC to convene the brain trust of healthcare providers, payers, clinical professional societies, the legal community, medical malpractice carriers, EHR/HIT developers, standards developers and others to address and fully resolve this serious issue.

FR page 7429, Section I.B.5, Executive Summary, Communication, "As a Condition and Maintenance of Certification under the Program, the Cures Act requires that health IT developers do not prohibit or restrict communications about certain aspects of the performance of health IT and the developers' related business practices."

FR Page 7467, Section VII.A.3, Communications: "The Cures Act requires that a health IT developer, as a Condition and Maintenance of Certification under the Program, does not prohibit or restrict communication regarding the following subjects:
• "The usability of the health information technology;
• "The interoperability of the health information technology;
• "The security of the health information technology;
• "Relevant information regarding users' experiences when using the health information technology;
• "The business practices of developers of health information technology related to exchanging electronic health information; and
• "The manner in which a user of the health information technology has used such technology."

FR Page 7467, Section VII.A.3.a, Background and Purpose: "This Condition of Certification addresses industry practices that severely limit the ability and willingness of health IT customers, users, researchers, and other stakeholders who use and work with health IT to openly discuss and share their experiences and other relevant information about the performance of health IT, including the ability of health IT to exchange health information electronically. These practices result in a lack of transparency around health IT that can contribute to and exacerbate patient safety risks, system security vulnerabilities, and product performance issues."

21. No "Privileged Communications" Regarding Performance of EHR/HIT Systems

We appreciate and applaud the removal of restrictions on "communications about certain aspects of the performance of health IT and the developers' related business practices". Commonly known as "gag clauses" these restrictions have long inhibited free discourse and dissemination of crucial issues regarding the performance, usability and safety of EHR/HIT systems. This is a welcome and long-awaited reform of onerous and stifling practices to hide and obfuscate serious deficiencies with technology "solutions".

22. Performance of EHR/HIT Systems Must Include Data Quality

Following on the previous comment, we agree with the listed communications "that a health IT developer... does not prohibit or restrict" but we believe the enumeration should also include no prohibition or restriction regarding the "quality and usability of health information" captured, managed, rendered and/or exchanged by the health information technology provided by that EHR/HIT developer.

FR Pages 7432 through 7454, Section III, Deregulatory Actions for Previous Rulemakings AND Section IV, Updates to the 2015 Edition Certification Criteria

23. Deregulation Yet Not Impactful Burden Reduction (to the Front-line Clinician)

In the NPRM Sections cited above, ONC is offering a seemingly beneficent bounty of deregulatory actions to reduce burden, yet from our reading, many of these actions merely remove obsolete requirements or obvious functionality that any credible EHR/HIT system would never be offered without. Few of the deleted items will actually have any impact on the heavy burden placed on front-line clinicians in their daily practice. In balance against the mountain of new requirements, reporting and accounting rules and huge penalties, these deregulatory actions seem very paltry – removing a few pebbles while adding many boulders to the saddle of burdens that must be carried.

FR Page 7441, Section 3.B.1.b.i, "Updated Versions of Vocabulary Standard Code Sets: We [ONC] propose that the USCDI Version 1 (USCDI v1) include the newest versions of the 'minimum standard' code sets included in the CCDS available at publication of a subsequent final rule. We request comment on this proposal and on whether this could result in any interoperability concerns."

24. Interoperability Concerns Regarding "Minimum Standard" Code Sets

Obvious interoperability concerns regarding USCDI v1 and related "minimum standard" code sets are as outlined in Comments 8, 8.1 and 8.2 and 12, ensuring Vital Data Qualities for USCDI.

FR Page 7441, Section 3.B.1.b.ii, "Address and Phone Number: The USCDI v1 includes new data elements for 'address' and 'phone number.' The inclusion of 'address' (to represent the postal location for the patient) and 'phone number' (to represent the patient's telephone number) would improve the comprehensiveness of health information for patient care. The inclusion of these data elements is also consistent with the list of patient matching data elements already specified in the 2015 Edition 'transitions of care' certification criterion (§ 170.315(b)(1)(iii)(G)), which supports the exchange of patient health information between providers of patient care."

25. Address

Since key components of Address are Street Address (often SA1 and SA2) and City/Town which are typically free-text, it is unclear as to how reliable Address may be for algorithmic matching. Often addresses are equivalent but not necessarily identical character for character. May be easy for a human to assimilate and determine a match but may be much more difficult for a software algorithm to determine the same match.

Note that address(es) may be from outside the US and include a variant postal code format.

It is critical to include date/time provenance for address to allow (at least tentative) determination of which address(es) might be most current.

26. Phone Number

Note that phone number may be different than XXX-XXX-XXXX and may include a country code and/or variant format (not all subjects are US citizens), and/or may include a phone extension of 1-6 digits.

It is critical to include date/time provenance for phone number to allow (at least tentative) determination of which phone number(s) might be most current.

Page 7442, Section 3.B.1.b.v, "Provenance: The USCDI v1 also includes a new data class, titled 'provenance'. 'Provenance' has been identified by stakeholders as valuable for interoperable exchange. The provenance of data was also referenced by stakeholders as a fundamental need to improve the trustworthiness and reliability of the data being exchanged. Provenance describes the metadata, or extra information about data, that can help answer questions such as when and who created the data."

FR Page 7480, Section VII.B.4.c.ii, Proposed Adoption of Associated FHIR... Implementation Specifications [including Provenance]: "...it is equally important over the long-term that the industry not lose sight of the metadata (i.e., the who, what, when, where, why, and how) behind the data that was created. As a result, we believe that this early stage of FHIR deployment is the best time for the industry to build in support for the Provenance resource. Otherwise, if we were to expand the ARCH in future years to include this FHIR resource, we estimate that the developer burden and overall industry impact would be greater than building this support in 'from the start.' Specifically, and to remain consistent with the USCDI, we propose to require that the 'Provenance.recorded' (for the author's time stamp) and 'Provenance.agent.actor' (for the author and author's organization) elements be supported as part of the Provenance resource."

27. Provenance

We strongly agree "that this early stage of FHIR deployment is the best time for the industry to build in support for the Provenance resource". Provenance is a vital part of ensuring health data/records, as captured, updated,

exchanged and rendered, are not just a collection of fragmented elements but include context and relationships. This cannot be stressed enough. "When and who created the data" is important but is not nearly enough.

"Who did what when where why and how" within a chronology of health history and healthcare tells a story. Odd fragments of data without contextualization, without sequence, known timeliness, or actionability are often found irrelevant by clinicians who are often resentful of substantial time taken to try to make sense of the amorphous collage of loosely coupled data dumped (often repeatedly and voluminously) into the patient record from some external source.

This is why it is so important to focus on the Vital Data Qualities, as enumerated in Comments 8, 8.1 and 8.2 and 12, to achieve what "interoperability solutions" have thus far lacked.

This NPRM Provenance Proposal runs along the lines of "we don't want to burden developers of EHR/HIT systems" by specifying more than a smidgen of provenance ("when and who created the data"). Instead the burden is placed on clinicians who have no way to make sense of the data, to make a trust decision, lacking many of the most important facts. This is not good patient care under any rubric.

The balance: offering fleeting benefit to a relatively small number of EHR/HIT developers vs. offering an enduring benefit to potentially millions of clinicians. We believe there is no valid reason not to require full provenance (who, what, when, where, why and how) at each point where health information is captured, changed or exchanged.

FR Page 7459, Section VI.A.2, Recommendations for the Voluntary Certification of Health IT for Use in Pediatric Care: "To support the first part of Section 4001(b) of the Cures Act, ONC considered the historical efforts on the Children's Model EHR Format, the input from stakeholders, and our own technical analysis and review of health IT capabilities and standards to develop a set of recommendations for voluntary certification for health IT for pediatric care."

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28. Voluntary Certification for Pediatric EHR Functionality

While we appreciate and applaud ONC's recognition of the need for a voluntary certification program for EHR/HIT system functionality supporting pediatric practice, we believe this approach should also be based on formal consensus balloted and approved standards, particularly ISO/HL7 10781 EHR System Functional Model Release 2 (or Release 2.1 which has passed HL7 ballot and is planned for publication Summer of 2019). The EHR-S FM is an international standard and in conjunction with the HL7 Child Health Functional Profile Release 1 offers a broad range of functions and conformance criteria specifically targeted toward EHR/HIT system functionality to support pediatric practice.

FR Page 7459, Section VI.A.2a, ''API functionality'' Criteria: "which addresses many of the challenges currently faced by patients and by caregivers such as parents or guardians accessing child's health information, including the 'multiple portal' problem, by potentially allowing individuals to aggregate health information from multiple sources in a web or mobile application of their choice."

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29. Aggregation of Health Information from Multiple Sources

We commend this NPRM provision (and subsequent bulleted criteria) as they support exactly the Individual Health Record Model we've promoted in Comments 1-6.

FR Page 7467, Section VII.A.2.d, Trusted Exchange Framework and the Common Agreement—Request for Information: "We request comment as to whether certain health IT developers should be required to participate in the TEFCA as a means of providing assurances to their customers and ONC that they are not taking actions that constitute information blocking or any other action that may inhibit the appropriate exchange, access, and use of EHI."

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30. TEFCA Requirement

Much of what is proposed in TEFCA Draft 1 (2018) is both unscalable (i.e., broadcast query – query the world – all providers, all networks, all systems, all devices) and unsustainable. TEFCA Draft 2 (2019) seems to offer only more of the same. We believe that if TEFCA participation becomes a requirement of this NPRM (when finalized), everything will cascade into failure.

There are NO other examples – across all industries, across all electronic computing schemes, across all nations – where success can be claimed with any similar approach.

FR Page 7477, Section VII.B.4.c.i, Proposed Adoption of FHIR DSTU2 Standard: "...we propose to adopt the HL7® Fast Healthcare Interoperability Resources (FHIR®) standard as a foundational standard within our suite of proposals. Specifically, we propose to adopt FHIR Draft Standard for Trial Use (DSTU) 2... as a baseline standard conformance requirement."

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31. FHIR DSTU2 (2015) → FHIR Release 4 (2019)

As it stands Release 4 is the current (and only) normative version of FHIR (published in January 2019). FHIR DSTU2 is over four years old and is specifically designated a draft standard for trial use (DSTU). Many, many changes have been applied to FHIR between DSTU2 and the Release 4 Normative edition. A large portion of these changes are not backward compatible and thus implementations based on DSTU2 will have to be revised (likely ripped and replaced) to be brought forward. Since this is the first NPRM to require FHIR APIs it seems only appropriate to designate the normative (and one hopes best) release, particularly since the NPRM will not become a final rule until 2020 at the soonest.

It will be hard enough to keep Federal rules up-to-date with current Standards without specifying a DSTU which will be 5 years old when the final rule is published. Unlike certain distilled and fermented beverages, draft standards don't improve with age and are designed with training wheels which are intended to be cast off when their normative successors are ready.

We support Option 4 (solely FHIR Normative Release 4), as designated by ONC.

FR Page 7478, Section VII.B.4.c.i, Proposed Adoption of FHIR DSTU2 Standard: "In the years since the 2015 Edition final rule, industry stakeholders have made rapid progress to advance the FHIR standard. This includes substantial investments in industry pilots, specification development led through the Argonaut Project 82 production deployment of APIs conformant to FHIR Release 2 following the Argonaut specifications, and the support for FHIR Release 2 in Apple's iOS 11.3, which includes a new 'health records' app for the iPhone based on these specifications.83 Therefore, the industry is well prepared and ready to adopt the FHIR standard."

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32. Justification for FHIR DSTU2 not Withstanding

While we recognize that the current Argonaut specification is based in FHIR DSTU2, it is far from a worthy example of best practice in FHIR implementation. It uses <25 of the now total 148 FHIR resources and DOES NOT specify/include either the Provenance or AuditEvent resources, making it impossible to ensure basic evidence of authorship, context, timeframe, timeliness, traceability to source and thus confirm accuracy and trustworthiness of health information content. When we have raised concerns regarding this deficiency with the Argonaut Team and their response is basically along the lines of "it's all we care to do right now". This is bad for patients and bad for the country.

FR Page 7495, Section VII.A.5, Real World Testing: "The Cures Act requires, as a Condition and Maintenance of Certification under the Program, that health IT developers have successfully tested the real world use of the technology for interoperability in the type of setting in which such technology would be marketed..."

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33. Real World Testing?

Testing is a relative term. In all work done over the past 30 years, testing mostly required the provider of data to demonstrate that all fields in a message or document are populated to the specified format. Testing is very unlikely to check the faithfulness to care or source of the content including:

- Validity of data (authentication/verification)
- Provenance of each contributing element (a real problem for patient summaries where data elements are amalgamated from multiple sources and points in time)
- Amendments (updated/corrected from its initial instance)
- Completeness with respect to expectation of care
- Context of care including the care coordination process

All these are necessary to create a record that is useful and useable for care. Most are substantially beyond the capabilities of data exchanges (or dumps) across HIEs.

We believe it is crucial to test Vital Data Qualities (see Comments 8, 8.1 and 8.2) not as the static output of a source system but rather in real world scenarios from source to use – point of data/record origination to point of data/record access/use (across one or more points of exchange). This ensures that fidelity to source can be tested (and ensured), not at a single point or within a single system, but rather end-to-end.

FR Page 7524, Section VIII.D.1, Preventing Harm – Risk of Corrupt or Inaccurate Data Being Recorded or Incorporated in a Patient's Electronic Health Record, "[This information blocking] exception may apply to practices that prevent harm arising from corrupted or inaccurate EHI being recorded or incorporated in a patient's electronic health record. Users of health IT systems strive to maintain accurate electronic health records by carefully inputting EHI and verifying existing EHI. Occasionally a clinician or other user of health IT is presented with EHI that, due to a failure of the technology, is either entirely incorrect or contains inaccurate information. At other times, EHI could become corrupted. In these cases, the sharing or integration of such EHI could lead to inaccuracies in the patient's electronic health record that then run the risk of being propagated further. We note, however, that known inaccuracies in some data within a record may not be sufficient justification to withhold the entire record if the remainder of the patient's EHI could be effectively shared without also presenting the known incorrect or corrupted information as if it were trustworthy. Also, we would expect that once information is known to be inaccurate or corrupted, a health care provider holding that record would, for example, take action to cure the inaccuracy or corruption. We understand that in the ordinary course of practice, and consistent with professional and legal standards for clinical record keeping, health care providers take appropriate action to remediate known problems with EHI and restore a record as a whole to be safely usable, and therefore safely sharable.

"This recognized risk is limited to corruption and inaccuracies caused by performance and technical issues affecting health IT. For example, this exception may be relevant if certified health IT were to incorrectly present an old and superseded version of a medication list, or when only partial copies of laboratory tests are being linked to a patient when the patient's record is exchanged. However, this recognized risk does not extend to purported accuracy issues arising from the incompleteness of a patient's electronic health record generally. Electronic health records, like the paper charts they replaced, are inevitably imperfect records. Many patients see multiple health care providers and so it is unlikely that any single health care provider's record will provide a complete picture of a patient's health. Some patients intentionally keep certain information secret even from their health care providers, and others fail to share potentially critical information with their health care providers because they forget to, or simply do not understand its clinical significance.

"While the access, exchange, or use of EHI in these situations could give rise to the risk of harm if the EHI was relied on without qualification, such reliance does not accord with our understanding of clinical practice, as the risk of incompleteness resulting from patients having multiple providers, or from errors of omission by patients and their care providers, is not unique to electronic health records or their interoperable exchange. Therefore, the risk that the EHI a given health care provider holds for a given patient may not be a perfectly complete record of that patient's health or care will not be recognized as being sufficient to support an actor qualifying for this exception in the face of a claim of information blocking."

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34. Risk of Corruption and Inaccuracy

It is reasonable to assume that most all exchanged health information is subject to loss, alteration or error in the course of transmission from point of origination (source of truth) to each ultimate point of use, and may include misidentification, loss of accuracy, loss of clinical context and more. This is inherent in the double transformation of health information content typically occurring in one hop: source representation to exchange

artifact (message, document or resource) to receiver representation. (Each additional hop only multiplies this deleterious effect.)

There are exchange schemes which ensure that what the author saw (at the point of origination), is what is exchanged, is what is retained by the receiver, is what is presented to the ultimate user, but these are a rarity in the real world, where derivative health information is the norm, in fact encouraged by SDO "experts" and the government agencies that foster and promulgate their work into regulatory requirements.

(We do not cherish old technology like faxes and photocopiers but note that at least they reliably reproduce an exact copy of the original.)

Seems like most healthcare providers could only deliver EHI that they can vouch as trustworthy, thus only EHI which is sourced firsthand within their organization and by EHR/HIT systems and other technology that they directly manage, maintain and thus can both safeguard and ensure. Second/thirdhand EHI – sourced elsewhere by/in external entities and systems) could and should thus be "blocked" from further dissemination.

This is the sad but factual state of our health information ecosystem – a situation that this NPRM does not address.

FR Page 7555, Section X, Patient Matching Request for Information: "It is a common misconception that technology alone can solve the problem of poor data quality, but even the most advanced, innovative technical approaches are unable to overcome data quality issues. Thus, we seek input on the potential effect that data collection standards may have on the quality of health data that is captured and stored and the impact that such standards may have on accurate patient matching. We also seek input on other solutions that may increase the likelihood of accurate data capture, including the implementation of technology that supports the verification and authentication of certain demographic data elements such as mailing address, as well as other efforts that support ongoing data quality improvement efforts."

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35. Poor Data Quality is a Constant Risk

As noted in this NPRM language, there is ample and continuing evidence that poor data quality is the endemic state of most electronic health information. There are plenty of reasons for this, many of which have been cited in previous comments. Often what the author saw, is not precisely retained in the source EHR/HIT system, is not what is conveyed in the course of exchange, is not what is retained in the receiving EHR/HIT system, and is not what is displayed to the end user (e.g., clinician). Data is transformed in the course of exchange, from source representation, to/from the exchange artifact (message, document, resource), to the receiver representation. Data is lost, altered or in error. Key elements of (clinical) context are lost. Patients, providers and others are mis-identified. The list goes on and on...

Many have implored ONC and SDO "experts" again and again, to make sure that health information is unaltered from source to use – in all cases and regardless of the path of transit from end to end. "Normalization" predicates facts that are not in evidence about what the source/sending system is transmitting and what the receiving system needs. It is always a reflection of the "normalizer's" world view. **Each receiving environment needs to have unmodified source data so that whatever treatment will be locally given relies on the source – and the unmodified source data should always be easily available to the end user if a question arises.**

Clinical integrity and patient safety are at risk – every day and at every moment – so long as we fail to address this critical requirement.