June 3, 2019

Donald Rucker, MD
National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. Rucker:

The Health Information Technology Advisory Committee (HITAC) asked the HITAC Notice of Proposed Rulemaking (NPRM) Task Forces to provide recommendations on the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program proposed rule. The recommendations were provided by the following Task Forces: Information Blocking Task Force; the Conditions and Maintenance of Certification Task Force; the Health IT for the Care Continuum Task Force; and the U.S. Core Data for Interoperability (USCDI) Task Force. This transmittal offers these recommendations, which are informed by the deliberations among the Task Force subject matter experts. These recommendations were reviewed, discussed and approved for transmittal by the full HITAC at the March 19, April 10, April 25, May 13, and May 22, 2019 meetings.

Information Blocking Task Force Recommendations

The Health Information Technology Advisory Committee (HITAC) requested that the Information Blocking Task Force (IB TF) provide recommendations to the HITAC regarding the proposals in the Cures Act Notice of Proposed Rulemaking related to information blocking. The Task Force recommendations were reviewed, deliberated, and approved by the full HITAC. This transmittal letter offers these recommendations, which the HITAC wishes to advance to the ONC for consideration.

We believe that there are several aspects of these recommendations which warrant additional exploration to ascertain the impact upon different stakeholder groups, and to provide guidance to them. This is not a suggestion to defer any recommendations, but to provide additional clarity to those stakeholder groups and to assist in the adoption of the 21st Century Cures Act and ensuring the benefits thereof. It is our profound belief that HITAC is best positioned as the agent to assist in this regard.

As co-chairs of the HITAC, we wish to thank ONC for the opportunity to serve in this fundamental role supporting the success of ONC's Proposed Rule and the rulemaking process and promoting improved patient outcomes through information sharing. The discussions of the HITAC have been exhaustive, in no small part due to the diligence and expertise demonstrated by the ONC staff assigned to support this task force. We thank them for their contributions.

Please consider the attached recommendations from the HITAC. Each recommendation is individually numbered, and where recommendations have been removed compared to prior late-stage drafts, we have preserved the original numbering to promote appropriate version control.

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Background

Overarching charge

The Information Blocking Task Force (IB TF or Task Force) was charged with providing recommendations on proposals in the Cures Act Notice of Proposed Rulemaking (ONC's Proposed Rule or Proposed Rule) related to information blocking; the "information blocking," "assurances," and "communications" conditions and maintenance of certification requirements; and the enforcement of all the conditions and maintenance of certification requirements.

Detailed charge

The IB TF was charged with providing recommendations on the following topics:

- Information Blocking:
    - ONC proposed definitions/interpretations of certain statutory terms and provisions, including the price information request for information
    - Seven proposed exceptions to the information blocking definition, and any additional exceptions (request for information)
    - Complaint process
    - Disincentives for health care providers (request for information);
- "Information blocking," "assurances," and "communications" conditions and maintenance of certification requirements; and
- Enforcement of all the conditions and maintenance of certification requirements.

Task Force Approach

In addressing the IB TF's charge, the co-chairs separated the subject matter into three distinct workgroups.

1. The first workgroup considered ONC's proposed definitions and interpretations of certain statutory terms and provisions, including the price information request for information.
2. The second workgroup considered the seven proposed exceptions to the information blocking definition; any additional exceptions (request for information); the complaint process; and disincentives for health care providers (request for information).
3. The third workgroup considered the "information blocking," "assurances," and "communications" conditions and maintenance of certification requirements; and enforcement of all the conditions and maintenance of certification requirements.

During the workgroup deliberations, the co-chairs provided a level of autonomy to each workgroup in order to promote focused review and manage workloads. Once the co-chairs drafted and refined recommendations for each workgroup, the IB TF met multiple times as a whole and together reviewed and finessed the recommendations into the form detailed below.

ONC Definitions/Interpretations of Certain Statutory Terms and Provisions

ONC's definitions and interpretations of statutory terms and provisions provide the bedrock for ONC's information blocking proposals and the scope of actors and actions to be covered by the information blocking provision. The HITAC spent considerable time evaluating, weighing, and measuring the

regulatory text as drafted, and has made thoughtful proposals based upon the members' experiences and input.

1. Health Information Network / Health Information Exchange

We recognize that there are multiple uses of the terms "Health Information Network" (HIN) and "Health Information Exchange" (HIE) across the healthcare ecosystem. Having the terms overlap within the Proposed Rule is likely to cause a degree of confusion. We recommend making the following changes to the definitions of HIN and HIE:

Recommendations 1 (HIE definition) & 2 (HIN definition)

§ 171.102 Definitions of Health Information Exchange and Network		
ORIGINAL	**RECOMMENDED REGULATION TEXT**	**COMPARISON / MARKUP**
Health Information Exchange or HIE means an individual or entity that enables access, exchange, or use of electronic health information primarily between or among a particular class of individuals or entities or for a limited set of purposes. *Health Information Network or HIN* means an individual or entity that satisfies one or both of the following— (1) Determines, oversees, administers, controls, or substantially influences policies or agreements that define business, operational, technical, or other conditions or requirements for enabling or facilitating access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities. (2) Provides, manages, controls, or substantially influences any technology or service that enables or facilitates the access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities.	*Health Information Exchange* or *HIE* means: Any entity who is not considered a Provider, Health Information Network, or Health IT Developer performing the access, exchange, transmittal, processing, handling, or other such use of Electronic Health Information. *Health Information Network* or *HIN* means an individual or entity that satisfies one or several of the following— (1) Determines, oversees, administers, controls, or sets policies or makes agreements that define business, operational, technical, or other conditions or requirements for Health Information Exchange between or among two or more individuals or entities, or (2) Provides, manages, or controls any technology or service that enables or facilitates Health Information Exchange between or among two or more individuals or entities.	*Health Information Exchange or HIE* means: ~~a A~~a~~n~~y ~~individual or~~ entity who is not considered a Provider, Health Information Network, or Health IT Developer performing the ~~that enables~~ access, exchange, transmittal, processing, handling or other such use of ~~e-~~Electronic ~~h~~ Health ~~i-~~Information. ~~primarily between or among a particular class of individuals or entities or for a limited set of purposes.~~ *Health Information Network or HIN* means an individual or entity that satisfies one or ~~both~~ several of the following— (1) Determines, oversees, administers, controls, or sets ~~substantially influences~~ policies or makes agreements that define business, operational, technical, or other conditions or requirements for Health Information Exchange ~~enabling or facilitating access, exchange, or use of electronic health information~~ between or among two or more ~~unaffiliated~~ individuals or entities. (2) Provides, manages, or controls ~~or substantially influences~~ any

		technology or service that enables or facilitates Health Information Exchange ~~the access, exchange, or use of electronic health information~~ between or among two or more ~~unaffiliated~~ individuals or entities.

2. Electronic Health Information (EHI)

The HITAC believes the proposed definition of "electronic health information" (EHI) is a strong definition that covers the breadth of data that should be addressed within the regulation. We recommend a slight modification to the language to address where discrete data may not identify an individual, however, in aggregate it may.

Our intent is that this is a broad definition that embodies a wide range of information concerning patient care. Furthermore, "information" shall be inclusive of all data that can be electronically transmitted or maintained and may include imaging.

Discussion has also looked at whether, in the Cures Act, Congress was seeking to aid transparency across the healthcare ecosystem and whether the definition should be limited to identifiable health information or whether it should include all information within healthcare.

We stress that HITAC is seeking to advance price transparency by augmenting ONC's inclusion of payment information within the definition of EHI and through our recommendation to add (3) to the definition of EHI:"(3) Electronic information which can reasonably be used to inform care decisions, by a provider or patient, including pricing information which can be attributable to an individual patient." This addition would broaden the definition of EHI, and specifically would expand the scope of pricing information covered under the information blocking provision. These recommendations would facilitate price transparency by promoting the availability of information; or if the information is not made available, subjecting the actor in question to the information blocking provision.

An additional minor update would be to clarify that we are not seeking to promote the sharing of information for a specific payment (use of the singular "payment"), but instead are desiring that information for all payments should be covered within this definition. To this end, we recommend pluralizing "payment."

Our recommendation around the sharing of consent information aligns with the anticipated ratification dates for the HL7 FHIR standard for communication of these information types, and the HITAC believes that including consent information is extremely important to meet the intent of the Cures Act.

In addition, we do think that making clear that "information" could be that which is "human readable" (e.g., narrative text captured within clinical notes) and "machine readable" (e.g., codified information using terminologies or classifications such as LOINC, SNOMED CT, CPT, ICD etc.) are specifically covered to prevent ambiguity, and this should be updated within the preamble.

Recommendation 3

§ 171.102 Definition of Electronic Health Information		
ORIGINAL	**RECOMMENDED REGULATION**	**COMPARISON / MARKUP**
Electronic Health Information (EHI) means— (1) Electronic protected health information; and (2) Any other information that identifies the individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the individual and is transmitted by or maintained in electronic media, as defined in 45 CFR 160.103, that relates to the past, present, or future health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.	*Electronic Health Information (EHI)* means— (1) Electronic protected health information (as defined in 45 CFR 160.103); and (2) Electronic Individual Health Information: (i) Any other information that identifies the individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the individual and is transmitted by or maintained in electronic media, as defined in 45 CFR 160.103, that relates to the past, present, or future health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment(s) for the provision of health care to an individual. (ii) On the two-year anniversary of the effective date of the final rule, an individual's consent directives including privacy, medical treatment, research, and advanced care. (3) Electronic information which can reasonably be used to inform care decisions, by a provider or patient, including pricing information which can be attributable to an individual patient.	*Electronic Health Information (EHI)* means— (1) Electronic protected health information (as defined in 45 CFR 160.103); and (2) Electronic Individual Health Information: (i) Any other information that identifies the individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the individual and is transmitted by or maintained in electronic media, as defined in 45 CFR 160.103, that relates to the past, present, or future health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment(s) for the provision of health care to an individual. (ii) On the two-year anniversary of the effective date of the final rule, an individual's consent directives including privacy, medical treatment, research, and advanced care. (3) Electronic information which can reasonably be used to inform care decisions, by a provider or patient, including pricing information which can be attributable to an individual patient.

Recommendation 4

Within the definition of Electronic Health Information, the term "information" shall be read as applying to both "Human Readable" information that can be readily understood by a real person actor without specialized reference (e.g., narrative clinical notes), and also "Machine Readable" information that is interpreted by a computerized actor for use either by computerized processes or a real person actor (e.g., data codified using a terminology or classification).

Minority Opinion**:** Concern has been expressed by a minority of the HITAC that the definition of EHI is overly restrictive in that it demands that information should identify an individual. This minority opinion

suggests that ONC should adopt a revised definition of EHI in the final rule that would remove the requirement that the information be identifiable. The minority opinion believes this change will ensure that information blocking supports patient access to price information to enable shopping for health care services. ONC should also clarify that "future payment" includes price information.

The minority opinion believes that the proposed ONC definition is inconsistent with congressional intent of the Cures Act and definitions in existing law since 1996 (HIPAA).The Cures Act prohibits information blocking of EHI and this term is not defined in the Cures Act. As such, the minority opinion contends that ONC should look to prior definitions in defining this term to effectuate the intent of Congress.

The minority opinion believes that the simplest and most logical interpretation of "electronic health information" is to use the definition of "health information" which is not limited to identifiable information. The minority opinion believes that Congress knew there were different terms for "health information", "individually identified health information", and "protected health information" under HIPAA when it drafted the Cures Act and wished to include all of these within the Cures Act. Congress did not use the term Electronic Individually Identifiable Health Information, which would have limited information blocking to identifiable information.

3. Price Information Request for Comment and Request for Information

Recommendation 5

The HITAC profoundly agrees that price transparency is a desirable goal that is achievable. We further believe that policy levers are required to move the healthcare ecosystem in that direction given the nature of reimbursement.

Our Recommendation 3 specifically supports price transparency by reinforcing ONC's proposed definition of EHI. The proposed definition of EHI (along with our recommendations for amendment detailed in the "Electronic Health information (EHI)" section above) provide for an expansive set of EHI, which could include information on an individual's health insurance eligibility and benefits, billing for health care services, and payment information for services to be provided or already provided, ***which would include price information***. The HITAC strongly supports the inclusion of price information within the definition of EHI.

We emphasize that our recommendation goes one step further than ONC's proposal by recommending the inclusion of "Electronic information which can reasonably be used to inform care decisions" and specifically "pricing information which can be attributable to an individual patient." This addition would broaden the definition of EHI and expand the scope of pricing information covered under information blocking provision. The HITAC stresses that the availability of patient attributable price information (as we recommend) enables a patient to shop for and make informed decisions about their care, and that it should be included in the scope of EHI. These recommendations to support and broaden ONC's proposed definition of EHI would lead to price transparency by making more information available; or if the information is not made available, subjecting the actor in question to the information blocking provision.

The HITAC notes that existing entities within the healthcare ecosystem have access to pricing information which could be utilized by patients to make informed decisions about the nature and location of their care. Those entities should be obliged to share that information, and our recommended amendment to the definition of EHI is designed to promote the sharing of that information by placing non-sharing of attributable pricing information within the boundary of information blocking.

We recommend these measures to promote price transparency are implemented without delay, and urge ONC to not hold back these information blocking proposals (with our recommendations) whilst broader policy considerations for pricing transparency are considered. Our goal with these recommendations is to promote and advance price transparency while not slowing down the finalization of the current ONC rule.

We also recommend that ONC instantiates through HITAC a task force specifically charged with producing recommendations for future rulemaking to address improving price transparency across the healthcare ecosystem.

This newly instantiated task force should consider:

- How the payment and pricing information made available through our Recommendation 3 in addition to generalized price information can be made readily accessible and available to patients, providers, purchasers, payers, employers and any other relevant stakeholders to inform care decisions.
- That the coding for prices can be published simply by using the rate cards between the providers and the payers.
- Whether to get to price transparency, patients need to know the contract negotiated rates.
- How those involved in the financial transactions to support healthcare delivery should provide the real prices - by CPT code or DRGs, bundled and unbundled?
- Whether prices included in the definition of EHI should reflect all services and payment information by all parties (including, but not limited to, health care providers, health plans, insurers, contractors, administrators, pharmacy benefit managers (PBMs), pharmacies, group purchasing organizations (GPOs), technology companies, health IT developers, laboratories, medical devices, brokers and other similar market players).
- The manner in which contract terms, rebates or other forms of incentive payment or other form of remuneration that is or will be directly attributable to a specific service, patient charge or transaction, to a healthcare provider, facility, pharmacy, or medical equipment provider for the health care services, drugs, or equipment delivered is logged and communicated.

4. **Health IT Developer of Certified Health IT**

The HITAC believes clarity is required concerning health IT developers who have at least one product certified under the ONC Health IT Certification Program (Program) and those developers of health IT that do not seek certification under the Program. We believe the number of developers that fall into

the latter category will be ever-increasing over the coming years, for several reasons. New entrants to the health IT market that provide niche services to patients may not seek certification, especially if they are consumer focused instead of clinical. New and existing entrants may not seek certification as they adopt alternative business models which reduce the cost of health IT to end users, and therefore have reduced incentive for certification.

The HITAC wishes to promote innovation and prevent barriers for entry for products that may have important benefits to patients. The HITAC is also mindful that by limiting the applicability of the regulation to only developers of certified health IT there might be the unintended consequence of encouraging developers to not comply with the regulation, which could encourage information blocking practices amongst those non-regulated vendors.

This, coupled with a movement towards self-developers and operators of healthcare-related services could create a "second track" of non-compliant actors being detrimental to the integrated patient care and transparency we desire to foster and promote.

In addition, the HITAC notes that the two following conditions appear to be in error and at odds with the intent of the Cures Act:

- The position that a product developed is "covered" if it is certified, or if the developer also produces a product that is certified, seems not in keeping with the perceived Congressional intent of the Cures Act that if a product is handling EHI then the developer should be covered by the information blocking provision; and
- Depending on what ONC finalizes within the rule process a developer of health IT who may have their products certified, and have that certification terminated or suspended for whatever reason, could potentially find that the regulations no longer apply to them.

Recommendation 6

We recommend clarifying that a developer of health IT is a developer because they create IT designed to perform the access, exchange, or use of EHI whether or not that IT is certified.

The HITAC recognizes that the Cures Act does not provide the necessary statutory powers to promote sanctions against health IT developers who are not producing certified health IT, and that while this may be an enforcement gap, it does not mean that some developers should not be subject to the information blocking provision.

5. Practices That May Implicate the Information Blocking Provision

Actors vs. Information Type

The HITAC believes that the information blocking provision is designed to ensure that patient information moves without hindrance across the healthcare ecosystem with appropriate authorization to facilitate the provision and reimbursement of care services to patients. These services are likely to be provided by an increasingly broad series of organizations, and these regulations must be structured so that these new entrants to the market are appropriately covered by the conditions herein. It would not

be advantageous to improving patient outcomes if some actors were implicated (through inclusion) and others were not (by the regulations being mute) as the regulations should consider the blocking of information versus the entity performing the blocking.

Recommendation 7

[This recommendation has been removed.]

Pricing Information

The HITAC believes that pricing information is an area that could readily implicate the information blocking provision. This information is not routinely exchanged and will require focus from multiple actors to ensure that the intent of Congress is met. This issue is addressed in more detail in an earlier recommendation.

Recommendation 8

Patient Access - The HITAC believes that "open" patient access to EHI about them is likely to have implications that relate to the information blocking provision. The obligation of actors to provide such access in real-time, and free of charge (beyond approved fee exemptions) is not one that is widely understood or implemented now (even in a "paid" manner). Similarly, providing patients with the tools to appropriately parse EHI to ensure it is understandable to them may potentially have implications that relate to the information blocking provision and ONC should investigate whether this is the case.

6. Parties Affected by the Information Blocking Provision and Exceptions

The HITAC believes that there is opportunity for confusion as to the parties implicated by the information blocking provision and exceptions, and ONC should take steps to remediate this in the final rule.

The HITAC believes that one intention of the Cures Act is for parties who are accessing, exchanging, or otherwise using information about a patient to provide patient care to be implicated by the regulations. The definitions of "actors" within the Cures Act do not have clear boundaries so that organizations can understand whether they are one of the four "actors" defined (provider, health information network, health information exchange, or health information technology developer) to understand whether they are implicated by the information blocking provision.

Recommendation 9

[This recommendation has been removed.]

Recommendation 10

The HITAC recommends that the preamble be updated to give greater specificity as to the real-world organizational types who could fall into the various categories of Actors. For example:

- Retail pharmacies who curate patient information concerning prescriptions, medications, clinical histories, payments etc. This information is considered EHI and should not be blocked. The HITAC believes that Retail Pharmacy would already be considered a Provider through inclusion as a subpart of all Pharmacies. This is desirable to confirm.
- Insurance companies who curate patient information concerning medical histories, payments etc. This information is important to patients as they seek to obtain insurance coverage for care services.
- Retailers who provide patient information services through IoT type devices and services from connected consumer devices. This information is considered EHI and must not be blocked.

We recognize that with the healthcare environment being under constant change, parties may act as one or more than one of the "actor" definitions, and the regulations should recognize that.

Recommendation 11

The HITAC recommends that the preamble should also be updated to give greater specificity as to the real-world organizational types who **would not** fall into these categories and **would not** therefore implicate the information blocking provision. For example:

- Organizations to whom patients have expressed informed **dissent** for information sharing (and this should remain an exception to information blocking under the privacy sub-exception for *respecting an individual's request not to share information*);
- Social media networks who provide access to non-specific patient attributable health information, and
- Analytics companies who provide population health insights based upon non-specific patient data (although a company who provides insights which may be used specific to an identifiable individual **would** implicate the information blocking provision).

The HITAC also recognizes that there are other individual entities who a patient may wish to have access to information about that patient, such as care givers, proxies, etc.

Recommendation 12

The HITAC recommends adopting a position of inclusion for implication based upon an actor's access, exchange, or use of EHI as well as their role in the healthcare ecosystem. We recommend specifically identifying that an entity should not share EHI where a patient has expressly stated their information should not be shared (and this should remain an exception to information blocking under the privacy sub-exception for *respecting an individual's request not to share information*).

Recommendation 13

The HITAC recommends adding the following text to the preamble and ensuring alignment of existing text to it:

> *The healthcare environment is under constant change. A tight definition of the term "Actor" may only be valid on the day it is authored and for a short time afterwards. By focusing the definition of a relevant "Actor" upon the function they undertake and including covered actors*

through their actions as opposed to their inclusion within a group we seek to afford evolutionary coverage through this regulation.

Exceptions

The HITAC has spent considerable time considering the exceptions to the information blocking provision, and the precise meaning of the verbiage expressed. Our recommendations reflect an overwhelming desire to promote clarity and simplicity in the final rule as far as possible, while reflecting the intent of Congress in the Cures Act.

7. **Preventing Harm**

The HITAC applauds ONC for including the provision "Exception – Preventing Harm" in the Proposed Rule. Actors engaged in the access, exchange, and use of EHI must be assured that practices that prevent harm are not an unintended consequence of promoting interoperability. We discussed that the recurring theme of having consistent and non-discriminatory policies are critical as this exception should be rarely applied and when applied should not be a mechanism to selectively block information from specific actors. We also discussed the importance of the inclusion of an exception to prevent the "wrong" data from being shared but focused on ensuring that the focus be on technical data corruption (rather a reluctance to map and interpret EHI) and/or for incorrect patient data when appropriate standards and best practices for patient matching is utilized. That is, an actor's failure to implement appropriate software which prevents the potential of corrupted data or mismatched data should not be used to justify this exception. If data corruption results in the infeasibility or downtime of the system, we would recommend deferring to those exceptions. In addition, language around lack of interpretability of data is not data corruption and may be addressed in another exception. Finally, the inclusion of an opportunity for clinicians to document why information sharing may result in harm is critical in adolescent medicine, behavioral health, infectious diseases, etc. where complexities of local policies, state law and existing federal law about the role of the clinician in determining what information may be withheld in the patient's (or another person's) best interest. The reasons for not sharing information under this exception of harm must be clearly documented within the EHR, the content of which must be made available by the vendor. The documentation must include the reasoning and conditions applied and must be made available for other users of the system and the patient to ensure that this exception does not result in unintended consequences. It is recognized that this will require implementation activities from health IT vendors, and this should be reflected in the enforcement timeline for the final rule.

Recommendation 14

Modify the regulatory text in (a) to read *"…arising from any of the following --"* prior to sub-items (1) – (3).

Recommendation 15

Modify the regulatory text in (a) (1) to read *"Technically corrupt (defined as data that has lost its base integrity and is no longer understandable by the information technology system that created it) or inaccurate data accessed in a patient's electronic health record for intent of access, exchange or use."*

Recommendation 16

Add to the regulatory text a sub-item (d) that the practice should be documented in the electronic health record or system recording the EHI by the appropriate user when the exception arising from using conditions (a) - (c) and must contain the reasoning and criteria used in the judgement of the user who is engaging in the practice under this exception.

Recommendation 17

The regulatory text in (b) is confusing; the word "practice" refers to the information blocking potentially occurring under an exception. Perhaps rephrasing *"If the practice (referring to the permissible information blocking activity) relies on an organizational policy, the policy must be—".*

Recommendation 18

Recommend adding a sub-item to the regulatory text in (b) that existing organizational policies should be reviewed by the organization for consistency with these regulations in order to prevent confusion and undue burden to providers.

Recommendation 19

Recommend adding clear guidance (in preamble) of when this exception should be used versus the exceptions for infeasibility and maintenance.

Recommendation 20

Consider adding examples of where exceptions related to preventing harm from corrupt or inaccurate data or incorrect patient identification may interact with the exception for infeasibility.

8. Promoting the Privacy of EHI

The HITAC believes that legitimate privacy concerns are a sound basis for an exception to the information blocking provision. However, the HITAC, after much discussion, believes that the following recommendations should be incorporated into the final rule:

Recommendation 21

The HITAC recommends adding language indicating that organizational policies must comply with federal, state, and local laws.

Recommendation 22

The HITAC recommends that in section (b)(2) express consent (or dissent) should be documented and recorded.

Recommendation 23

The HITAC recommends that in section (c)(3) the reference to "meaningful" is replaced with "clear and prior notice."

Recommendation 24

The HITAC recommends that organizational practices that are extra to HIPAA or other relevant legislation should clearly be forbidden. For example, policies that restrict transmission to individuals via email where such is the requested form and format of access. In many cases documented organizational policies are used to deny access where access is required.

Recommendation 25

The HITAC recommends that the final rule should specify that organizations should implement policies which ensure compliance with patient consent to information sharing (or lack of information sharing).

Recommendation 26

The HITAC recommends that if an actor functions in multiple states, some of which have more restrictive laws, the actor should implement policies and procedures that accommodate those more restrictive laws only in circumstances where they are required and not extend those greater restrictions to situations where they are not required by law.

9. Promoting the Security of EHI

The HITAC is concerned that actors may leverage this exception to effect information blocking, masquerading as a legitimate concern to protect the integrity of patient information.

Recommendation 27

The HITAC recommends that if the entity requesting patient information can be reasonably considered "legitimate" in that they have passed relevant authentication mechanisms and can reasonably be considered to have appropriate organizational policies in place to protect patient information, then ignorance of that requestor's specific controls is no reason to claim this exception.

Recommendation 28

The HITAC recommends modifying the regulatory text to reflect that if the requestor is the patient (data subject) themselves, and the patient is fully informed to the risks of their information not being appropriately secured, this exception cannot be claimed.

Recommendation 29

The HITAC recommends that actors should not have flexibility to adopt security practices, even when grounded in some standard, that are commercially unreasonable relative to leading practices for sensitive data, in ways that limit and restrict access to data for permissible purposes, unless there is some overriding legal obligation. As an example, although FedRAMP High or SRG High are defined standards, requiring FedRAMP High ATO as a standard for any data requester would serve to limit

interoperability, unless there were some overriding security concern (e.g., MHS or VHA records that contain data relevant to national security).

10. **Recovering Costs Reasonable Incurred**

The HITAC believes there will be a high practical burden to apply the combination of 171.204 and 171.206 to determine appropriate fee structures. By splitting discussion about fees over two exceptions, the proposed regulatory text obscures the critical decision of which fees are permissible and impermissible.

While the HITAC understands the intent of ONC was to address problematic pricing behavior by discouraging rent seeking behavior and extractive pricing, while providing for market-based pricing to allow innovation, the HITAC believes the net force of the proposed rule will be to raise prices (by raising compliance burdens, such as accounting controls, pricing controls, and other pricing compliance activities) and limit the supply for value-added interoperability services.

The combination of the broad definition of EHI, the broad definition of HIN, and the unlimited applicability for 171.204 and 171.206 for all actors and all access, exchange and use, has the effect of putting nearly all interoperability products and services under Federal price controls. This approach lumps all interoperability in the category of problematic rent-seeking behavior requiring regulation. It places, for example, standards-based EHR interoperability interfaces, where high prices disincentive access and discourage an actor from making interfaces self-service; and innovative services, such as patient comparison shopping and bill payment, or AI-based risk scoring on exactly the same footing. The HITAC believes this sets the price for interoperability that should be built-in too high; whereas it discourages value-added services from discovering the appropriate market-based price.

The HITAC finds that pricing related to **access** to what various members term the “legal medical record”, “Designated Record Set” and/or the raw data of the record (and additional data used as part of the legal medical record to provide decision-making) is the most problematic with respect to information blocking. The HITAC also finds that Intellectual Property Rights (IPR) essential to basic access are critical; we accordingly believe that pricing regulation should be targeted to those fees that impede what might be termed “basic” access. The HITAC believes that basic access should be defined as activities essential to represent and interpret clinical, pricing, and related data in certified exchange standards.

Along these lines, the HITAC discussed the term “reasonable” with respect both to IPR (171.206) and cost-based pricing (171.204). The HITAC believes that what is “reasonable” varies according to the type and class of interoperability capability; in particular the HITAC believes that a lower fee (in many cases, a fee of zero) is “reasonable” for essential capabilities that define certified standards-based exchange of the legal medical record held, for example, in an EHR; in other cases, such as for value-added services not essential for basic access, or essential for ordinary exchange and use, what is “reasonable” should be defined by market mechanism.

The HITAC believes the applicability of 171.206 to licensed IPR and 171.204 for all other services creates a market distorting distinction between licensed products (e.g., software supplied on-prem as object

code) and cloud-deployed software-as-a-service, which has a usage fee, but not a licensing fee. As more software moves to a cloud-deployed model, this market distortion is problematic.

In addition, the HITAC found some of the draft language confusing in practice or substantially disagreeing from usual practice.

For example, 171.204 speaks of "cost recovery" but the preamble implies reasonable profits are intended to be allowed. The usual terms for a pricing mechanism based on costs with target margin would be "cost-based pricing" or "cost-plus pricing" or "cost recovery with reasonable margin".

The term "non-standard" (although taken directly from the Cures Act legislative text) creates confusion between "does not conform to standards" and "implemented in a way that creates difficulty to interoperate".

The discussion in 171.204(c)(2) is confusingly worded. The HITAC believes the intent is to count only the direct costs of implementing interoperability.

Recommendation 30

The HITAC recommends that ONC combine the regulatory text currently supplied for 171.204 and 206 into a single allowed fee exception that clearly defines allowed and disallowed fee categories.

Recommendation 31

The HITAC recommends ONC use terminology that distinguishes between pure cost or expense recovery with no provision for margin or profit where this is intended and use terms such as "cost-based pricing" where margin or profit is allowed and "market-based pricing" where no restrictions on pricing are needed.

Recommendation 32

Where cost-based pricing mechanism are required, the HITAC recommends that the method for assessing the cost basis be reasonably associated with the complexity or cost of providing capabilities. Such methods could include reasonable heuristics, estimates or other commonly used methods. For example, size of organization, as measured in revenue or operating expense, is a commonly used heuristic to define pricing for exchange services, because revenue/expense is commonly available and directly correlated with patient flow, which is directly correlated with data volumes. Requiring activity-based accounting mechanism sufficient to account for the direct cost of providing, e.g., access services, is burdensome and is not a common or usual accounting practice. The HITAC believes that reasonable heuristics or estimates are sufficient to avoid arbitrary fees that could constitute information blocking without placing undue burden on actors.

Recommendation 33

The HITAC recommends that ONC distinguish between **Basic Access** and **Value-Added** Access, Exchange, and Use. Within this recommendation references to Designated Record Set and Covered Entity are interpreted in line with 45 CFR 164.501.

The HITAC suggests that ONC consider the following definitions appropriate:

- **Basic Access** where:
    - If an entity is considered a Covered Entity, information that is included within the Designated Record Set as defined in 45 CFR 164.501; or
    - If an entity is a Provider that is not a Covered Entity, the Designated Record Set as defined in 45 CFR 164.501; or
    - If an entity is considered a HIE, HIN, or developer of health information technology, the information that was collected on behalf of a Covered Entity or non-Covered Entity; and
    - Basic transformation of data required to implement standards (from the certified standards list) reasonably required to enable exchange or implement the intended use of a certified technology.
- ***Value-Added Access***, exchange and use not included in Basic Access above.

  For example, infrastructural systems, capabilities that translate, transform, localize, perform decision support, complex transformations, or use artificial intelligence or machine learning, provide novel renderings of data, etc.

The HITAC notes that the emergent definition of USCDI may provide a useful definitional basis for Basic and Value Added access in the future.

Recommendation 34

Notwithstanding the recommended distinction between basic and value-added capabilities, the HITAC recommends that when the output of value-added services are incorporated into, or from, an essential part of the legal medical record, or are routinely used for decision making, they constitute part of the set to which basic access is required (e.g., if a vendor supplies clinical risk scoring services based on the basic record, those services may be offered at market rates; if the risk score is incorporated into or used by clinical staff to make clinical decisions, the individual risk score accordingly becomes part of the record and forms part of basic access to which basic access fee regulation is applied).

Recommendation 35

The HITAC recommends that ONC distinguish between IPR that are ***essential*** to access and IPR that allow for value-added services. The former would include standards-essential IPR or any IPR licensing associated with terminology either defined in certified standards or reasonably required based on regulatory requirements or customary use.

Recommendation 36

The HITAC recommends that allowed fees for basic access be on a pure direct cost recovery basis only. In many cases, where basic access is provided via widely deployed consensus-based certified standards built into health IT, such direct costs would be minimal. The HITAC does **not recommend** that the cost to develop standards be part of the cost basis for fees for basic access; rather any such costs should be a part of the fees for the health IT. The HITAC believes this approach provides a significant incentive to adopt standards; actors who do not provide access through widely deployed consensus-based standards would have an incentive to do so to reduce the total cost structure of access. The HITAC recommends that the cost basis for fees basic access **not** include reasonable mapping to standards (that is, such one-time costs would be a cost of producing Health IT, not a cost of access); such mapping would include

mapping of proprietary terminologies used internally to the standard terminologies used externally (e.g., internal problem list terminologies to SNOMED CT, or proprietary medication databases to RxNorm). Exceptions would include cases where data or terminology sets exist that are not reasonable to include in mapping to standards AND where sufficient mechanisms of basic access exposing the non-standard data exist. In these cases, there are market-based mechanism (e.g., systems integrators) sufficient to set prices for non-standard data mapping.

Recommendation 37

The HITAC recommends that allowed fees for access, exchange and use essential IPR be set on a RAND-basis. Such fees would not be "reasonable" if they materially discourage access, exchange or use, or impede the development of competitive markets for value-added exchange and use services. The HITAC recommends that access, exchange and use-essential IPR license grants be sufficient for actors to provide access and/or deliver exchange and use services; for example, IPR grants for terminology sets that are access, exchange and use essential should be sufficient to allow access, exchange and use for permissible purposes. To put this another way, actors would not be able to accept IPR licenses that restrict access only those who also have IPR rights.

Recommendation 38

The HITAC recommends no further restrictions on permitted fees; the HITAC believes that the above restrictions on permitted fees are sufficient to address monopoly rents or gatekeepers and enable market-based pricing for additional services.

11. Responding to Requests that are Infeasible

The HITAC feels that this exception must not be used simply because it would be inconvenient, or have some limited cost, to comply with regulation. The HITAC makes some minor suggestions to aid the drafting of this exception as detailed below.

Recommendation 39

ORIGINAL	RECOMMENDED REGULATION TEXT	COMPARISON / MARKUP
To qualify for this exception, each practice by an actor must meet the following conditions at all relevant times. (a) *Request is infeasible*. (1) The actor must demonstrate, in accordance with paragraph (a)(2) of this section, that complying with the request in the manner requested would impose a substantial burden on the actor that is unreasonable under the	To qualify for this exception, each practice by an actor must meet the following conditions at all relevant times. (a) *Request is infeasible*. (1) The actor must demonstrate, in accordance with paragraph (a)(2) of this section, that complying with the request in the manner requested would impose a substantial burden on the actor that is unreasonable under the	To qualify for this exception, each practice by an actor must meet the following conditions at all relevant times. (a) *Request is infeasible*. (1) The actor must demonstrate, in accordance with paragraph (a)(2) of this section, that complying with the request in the manner requested would impose a substantial burden on the actor that is unreasonable under the

circumstances, taking into consideration— (i) The type of electronic health information and the purposes for which it may be needed; (ii) The cost to the actor of complying with the request in the manner requested; (iii) The financial, technical, and other resources available to the actor; (iv) Whether the actor provides comparable access, exchange, or use to itself or to its customers, suppliers, partners, and other persons with whom it has a business relationship; (v) Whether the actor owns or has control over a predominant technology, platform, health information exchange, or health information network through which electronic health information is accessed or exchanged; (vi) Whether the actor maintains electronic protected health information on behalf of a covered entity, as defined in 45 CFR 160.103, or maintains electronic health information on behalf of the requestor or another person whose access, exchange, or use of electronic health information will be enabled or facilitated by the actor's compliance with the request; (vii) Whether the requestor and other relevant persons can reasonably access, exchange, or use the electronic health information from other sources or through other means; and (viii) The additional cost and burden to the requestor and other relevant persons of relying on alternative means of access, exchange, or use. (2) The following circumstances do not constitute a burden to the actor for purposes of this exception and shall not be considered in	circumstances, taking into consideration— (i) The type of electronic health information and the purposes for which it may be needed; (ii) The cost to the actor of complying with the request in the manner requested; (iii) The financial, technical, and other resources available to the actor; (iv) Whether the actor provides comparable access, exchange, or use to itself or to its customers, suppliers, partners, and other persons with whom it has a business relationship; (v) Whether the actor owns or has control over a predominant technology, platform, health information exchange, or health information network through which electronic health information is accessed or exchanged; (vi) Whether the actor maintains electronic protected health information on behalf of a covered entity, as defined in 45 CFR 160.103, or maintains electronic health information on behalf of the requestor or another person whose access, exchange, or use of electronic health information will be enabled or facilitated by the actor's compliance with the request; (vii) whether similarly situated actors provide similar access, exchange or use; (viii) Whether the requestor and other relevant persons can reasonably access, exchange, or use the electronic health information from other sources or through other means; and (viiii) The additional cost and burden to the requestor and other relevant persons of relying on alternative means of access, exchange, or use.	circumstances, taking into consideration— (i) The type of electronic health information and the purposes for which it may be needed; (ii) The cost to the actor of complying with the request in the manner requested; (iii) The financial, technical, and other resources available to the actor; (iv) Whether the actor provides comparable access, exchange, or use to itself or to its customers, suppliers, partners, and other persons with whom it has a business relationship; (v) Whether the actor owns or has control over a predominant technology, platform, health information exchange, or health information network through which electronic health information is accessed or exchanged; (vi) Whether the actor maintains electronic protected health information on behalf of a covered entity, as defined in 45 CFR 160.103, or maintains electronic health information on behalf of the requestor or another person whose access, exchange, or use of electronic health information will be enabled or facilitated by the actor's compliance with the request; (vii) whether similarly situated actors provide similar access, exchange or use; (viii) ~~(vii)~~Whether the requestor and other relevant persons can reasonably access, exchange, or use the electronic health information from other sources or through other means; and (viiii) ~~(viii)~~ The additional cost and burden to the requestor and other relevant persons of relying on alternative means of access, exchange, or use.

determining whether the actor has demonstrated that complying with a request would have been infeasible. (i) Providing the requested access, exchange, or use in the manner requested would have facilitated competition with the actor. (ii) Providing the requested access, exchange, or use in the manner requested would have prevented the actor from charging a fee. (b) *Responding to requests*. The actor must timely respond to all requests relating to access, exchange, or use of electronic health information, including but not limited to requests to establish connections and to provide interoperability elements. (c) *Written explanation*. The actor must provide the requestor with a detailed written explanation of the reasons why the actor cannot accommodate the request. (d) *Provision of a reasonable alternative*. The actor must work with the requestor to identify and provide a reasonable alternative means of accessing, exchanging, or using the electronic health information.	(2) The following circumstances do not constitute a burden to the actor for purposes of this exception and shall not be considered in determining whether the actor has demonstrated that complying with a request would have been infeasible. (i) Providing the requested access, exchange, or use in the manner requested would have facilitated competition with the actor. (ii) Providing the requested access, exchange, or use in the manner requested would have prevented the actor from charging a fee. (b) *Responding to requests*. The actor must respond to all requests relating to access, exchange, or use of electronic health information, including but not limited to requests to establish connections and to provide interoperability elements in a timely manner under the circumstances which shall not exceed 10 business days. Such response shall include a detailed written explanation of the reasons why the actor cannot accommodate the request. (c) *Provision of a reasonable alternative*. The actor must work with the requestor in a timely manner to identify and provide a reasonable alternative means of accessing, exchanging, or using the electronic health information as applicable.	(2) The following circumstances do not constitute a burden to the actor for purposes of this exception and shall not be considered in determining whether the actor has demonstrated that complying with a request would have been infeasible. (i) Providing the requested access, exchange, or use in the manner requested would have facilitated competition with the actor. (ii) Providing the requested access, exchange, or use in the manner requested would have prevented the actor from charging a fee. (b) *Responding to requests*. The actor must ~~timely~~ respond to all requests relating to access, exchange, or use of electronic health information, including but not limited to requests to establish connections and to provide interoperability elements in a timely manner under the circumstances which shall not exceed 10 business days. Such response shall include ~~(c) *Written explanation*. The actor must provide the requestor with~~ a detailed written explanation of the reasons why the actor cannot accommodate the request. (~~d~~ c) *Provision of a reasonable alternative*. The actor must work with the requestor in a timely manner to identify and provide a reasonable alternative means of accessing, exchanging, or using the electronic health information as applicable.

12. **Licensing of Interoperability Elements on RAND Terms**

The HITAC spent considerable time discussing and expounding the RAND terms as reasons for legitimate exceptions. In conjunction with the preamble, the HITAC felt that the majority of the regulation text as

drafted was appropriate, and had minor recommendations concerning intent and clarity as detailed below.

Recommendation 40

ORIGINAL	RECOMMENDED REGULATION	COMPARISON / MARKUP
To qualify for this exception, each practice by an actor must meet the following conditions at all relevant times. (a) *Responding to requests*. Upon receiving a request to license or use interoperability elements, the actor must respond to the requestor within 10 business days from receipt of the request by: (1) Negotiating with the requestor in a reasonable and non-discriminatory fashion to identify the interoperability elements that are needed; and (2) Offering an appropriate license with reasonable and non-discriminatory terms. (b) *Reasonable and non-discriminatory terms*. The actor must license the interoperability elements described in paragraph (a) of this section on terms that are reasonable and non-discriminatory. (1) *Scope of rights*. The license must provide all rights necessary to access and use the interoperability elements for the following purposes, as applicable. (i) Developing products or services that are interoperable with the actor's health IT, health IT under the actor's control, or any third party who currently uses the actor's	To qualify for this exception, each practice by an actor must meet the following conditions at all relevant times. (a) *Responding to requests*. Upon receiving a request to license or use interoperability elements, the actor must respond to the requestor within 10 business days from receipt of the request by: (1) Negotiating with the requestor in a reasonable and non-discriminatory fashion to identify the interoperability elements that are needed; (2) Offering an appropriate license with reasonable and non-discriminatory terms; and (3) Beginning negotiations with the intent to furnish a quotation for a license (b) *Reasonable and non-discriminatory terms*. The actor must license the interoperability elements described in paragraph (a) of this section on terms that are reasonable and non-discriminatory. (1) *Scope of rights*. The license must provide all rights necessary to access and use the interoperability elements for the following purposes, as applicable. (i) Developing products or services that are interoperable using the licensed interoperability elements	To qualify for this exception, each practice by an actor must meet the following conditions at all relevant times. (a) *Responding to requests*. Upon receiving a request to license or use interoperability elements, the actor must respond to the requestor within 10 business days from receipt of the request by: (1) Negotiating with the requestor in a reasonable and non-discriminatory fashion to identify the interoperability elements that are needed; (2) Offering an appropriate license with reasonable and non-discriminatory terms; and (3) Beginning negotiations with the intent to furnish a quotation for a license (b) *Reasonable and non-discriminatory terms*. The actor must license the interoperability elements described in paragraph (a) of this section on terms that are reasonable and non-discriminatory. (1) *Scope of rights*. The license must provide all rights necessary to access and use the interoperability elements for the following purposes, as applicable. (i) Developing products or services that are interoperable ~~with the actor's health IT, health IT under the actor's control, or~~

	interoperability elements to interoperate with the actor's health IT or health IT under the actor's control. (ii) Marketing, offering, and distributing the interoperable products and/or services to potential customers and users. (iii) Enabling the use of the interoperable products or services in production environments, including accessing and enabling the exchange and use of electronic health information.	(ii) Marketing, offering, and distributing the interoperable products and/or services to potential customers and users. (iii) Enabling the use of the interoperable products or services in production environments, including accessing and enabling the exchange and use of electronic health information.	~~any third party who currently~~ us~~es~~ing the licensed ~~actor's~~ interoperability elements ~~to interoperate with the actor's health IT or health IT under the actor's control~~. (ii) Marketing, offering, and distributing the interoperable products and/or services to potential customers and users. (iii) Enabling the use of the interoperable products or services in production environments, including accessing and enabling the exchange and use of electronic health information.

13. **Maintaining and Improving Health IT Performance**

Recommendation 41

The HITAC recommends that ONC generalize the maintenance exception to cover the following:

- Rate limiting or disabling use of the health IT by user or actors whose use is unusual or would cause degradation of overall performance
- Reasonable and usual practices where SLA or maintenance windows are not named in contract
- Out of SLA performance with reasonable good-faith activity to restore service in a timely matter
- Force majeure or other highly unusual events out of the control of the actor.

Failure to consider these exceptions raises the risk that ordinary failures to achieve good faith service restoration would be adjudicated as information blocking, rather than through normal contractual

resolution processes, and would create a paradoxical incentive for actors to insist on negotiating lower SLA achievement targets.

While we understand that some actors have caused information blocking by abandoning technology, we believe such instances are rare and would not trigger the exceptions noted above.

Recommendation 42

ORIGINAL	RECOMMENDED REGULATION	COMPARISON / MARKUP
To qualify for this exception, each practice by an actor must meet the following conditions at all relevant times. (a) Maintenance and improvements to health IT. An actor may make health IT under its control temporarily unavailable in order to perform maintenance or improvements to the health IT, provided that the actor's practice is— (1) For a period of time no longer than necessary to achieve the maintenance or improvements for which the health IT was made unavailable; (2) Implemented in a consistent and non-discriminatory manner; and (3) If the unavailability is initiated by a health IT developer of certified health IT, HIE, or HIN, agreed to by the individual or entity to whom the health IT developer of certified health IT, HIE, or HIN supplied the health IT. (b) Practices that prevent harm. If the unavailability of health IT for maintenance or improvements is initiated by an actor in response to a risk of harm to a patient or another person, the actor does not need to satisfy the requirements of this section, but must comply with all requirements of § 171.201 at all relevant times to qualify for an exception. (c) Security-related practices. If the unavailability of health IT for maintenance or improvements is	To qualify for this exception, each practice by an actor must meet the following conditions at all relevant times. (a) *Maintenance and improvements to health IT*. An actor may make health IT under its control temporarily unavailable in order to perform maintenance or improvements to the health IT, provided that the actor's practice is— (1) a reasonable, good-faith activity lasting a period of time no longer than necessary to achieve the maintenance or improvements for which the health IT was made unavailable; and (2) Implemented in a consistent and non-discriminatory manner. (b) *Practices that prevent harm.* If the unavailability of health IT for maintenance or improvements is initiated by an actor in response to a risk of harm to a patient or another person, the actor does not need to satisfy the requirements of this section, but must comply with all requirements of § 171.201 at all relevant times to qualify for an exception. (c) *Security-related practices*. If the unavailability of health IT for maintenance or improvements is initiated by an actor in response to a security risk to electronic health information, the actor does not need to satisfy the requirements of this section, but must comply with	To qualify for this exception, each practice by an actor must meet the following conditions at all relevant times. (a) *Maintenance and improvements to health IT*. An actor may make health IT under its control temporarily unavailable in order to perform maintenance or improvements to the health IT, provided that the actor's practice is— (1) a reasonable, good-faith activity lasting ~~For~~ a period of time no longer than necessary to achieve the maintenance or improvements for which the health IT was made unavailable; and (2) Implemented in a consistent and non-discriminatory manner.~~; and~~ ~~(3) If the unavailability is initiated by a health IT developer of certified health IT, HIE, or HIN, agreed to by the individual or entity to whom the health IT developer of certified health IT, HIE, or HIN supplied the health IT.~~ (b) *Practices that prevent harm.* If the unavailability of health IT for maintenance or improvements is initiated by an actor in response to a risk of harm to a patient or another person, the actor does not need to satisfy the requirements of this section, but must comply with all requirements of § 171.201 at all relevant times to qualify for an exception.

initiated by an actor in response to a security risk to electronic health information, the actor does not need to satisfy the requirements of this section, but must comply with all requirements of § 171.203 at all relevant times to qualify for an exception.	all requirements of § 171.203 at all relevant times to qualify for an exception. (d) *Responding to requests that are infeasible.* If the unavailability of health IT is due to highly unusual events out of the control of the actor such as a natural disaster, the actor does not need to satisfy the requirements of this section, if the practice complies with all requirements of §171.205.	(c) *Security-related practices*. If the unavailability of health IT for maintenance or improvements is initiated by an actor in response to a security risk to electronic health information, the actor does not need to satisfy the requirements of this section, but must comply with all requirements of § 171.203 at all relevant times to qualify for an exception. (d) *Responding to requests that are infeasible.* If the unavailability of health IT is due to highly unusual events out of the control of the actor such as a natural disaster, the actor does not need to satisfy the requirements of this section, if the practice complies with all requirements of §171.205.

14. **Additional Exceptions (Request for Information)**

Contractual obligations may and often do conflict with the broad requirements for information blocking. The preamble text discusses multiple situations where contractual terms are used by actors to restrict use of information. The preamble did not address situations where actors are dependent on contractual terms from other parties that may conflict with information blocking provisions.

As an example, business associates (BAs) have only the data use rights that are granted under a business associate agreement (BAA); these data use rights may not allow access for all permissible uses. Contractual terms that limit BA data use rights are quite common. Should counterparties not change BAA terms, BAs would be in a difficult position, forced to choose between:

- Cancelling contracts, often subjecting BAs to penalties under contract, and sometimes opening BAs to information blocking enforcement;
- Complying with contractual terms and risking information blocking enforcement;
- Complying with information blocking provisions, while violating contracts and possibly opening HHS OCR enforcement for violating BAA terms.

In other examples, confidentiality provisions of contracts have been used to litigate data use for price transparency, even when such data use is permitted by data use terms in BAAs.

Similar situations would apply for IPR licenses (e.g., terminology sets) that may have provisions preventing information sharing with information requesters who do not have IPR grants.

Recommendation 43

The HITAC recommends that the status of contractual obligations that may be in conflict with information blocking obligations be explicitly clarified by ONC as being void. The simplest solution would be to interpret the intent of Congress to preempt specific contractual terms that are in conflict with the Cures Act.

Recommendation 44

Trusted Exchange Framework and Common Agreement

In ONC's Proposed Rule, ONC noted that they are considering whether they should propose, in a future rulemaking, a narrow exception to the information blocking provision for practices that are necessary to comply with the requirements of the Common Agreement (CA). The release of the second draft of the Trusted Exchange Framework (TEF) late in the public consultation period for the Proposed Rule has given the HITAC the opportunity to comment upon the TEF and the CA.

Considerable discourse has taken place, with two distinct views being articulated:

- That compliance with the TEF should provide a "safe lane" which demonstrates to ONC/HHS Office of Inspector General (OIG) that information blocking is not taking place; and
- That providing a "safe lane" is a protectionist approach which should not be adopted and the TEF should be a series of good practice guidelines.

We urge ONC during the rulemaking process to consider carefully the enduring demand of the Cures Act to promote information sharing and prohibit information blocking amongst all actors involved in the provision and administration of care. We believe that a careful balance needs to be struck to encourage compliance to the information blocking provision, potentially through adoption of the TEF, and the need to investigate information blocking activities where warranted – and not inadvertently provide bad actors with an opportunity to circumvent regulation compliance.

Recommendation 44.1

The HITAC recommends that an exception be included to cover organizations engaged in legitimate research, biosurveillance, or epidemiological activities.

We recommend the following exception be included:

> The following activities are specifically excluded from implicating the rule:
>
> - Non-direct clinical care being conducted by public health authorities;
> - Research as defined by 45 CFR 164.501.

15. **Complaint Process**

The HITAC supports ONC's proposal on the information blocking complaint process as it is written in the Proposed Rule with no further edits or comments.

16. **Disincentives for Health Care Providers (Request for Information)**

The HITAC believes that, while some types of problematic activities relating to information blocking are more typical of health IT developers or other similar actors, other refusals to share data, including using over interpretation of HIPAA and other privacy laws, stricter than necessary organizational policies, or concerns of patient "leakage" to competitive institutions, are more typical of provider organizations. The HITAC believes that disincentives must be sufficient to discourage problematic behavior, encourage compliance, and incent providers to work with OIG and others to address and remediate problematic behavior.

Recommendation 45

The HITAC recommends that ONC work with CMS to build information blocking disincentives into a broad range of CMS programs, and that ONC work with other Federal departments and agencies that contract with providers (e.g., VHA, DoD MHS, IHS, CDC, etc.) to similarly build information blocking disincentives into contracting and other programs.

Recommendation 46

The HITAC recommends that providers attest to comply with information blocking requirements as a part of Conditions of Participation, Conditions for Coverage, contracts, and other similar relationships, covering both FFS, value-based care, and direct payment relationships, and that findings of information blocking by OIG, findings violations relating to information blocking attestations of the False Claims Act by FTC, or other similar enforcement actions trigger disincentives up to and including removing organizations from participation or coverage.

Conditions and Maintenance of Certification and Enforcement

17. **170.401 Information Blocking**

The HITAC supports ONC's proposal on the Information Blocking Condition of Certification as it is written in the Proposed Rule with no further edits or comments.

18. **170.402 Assurances**

The HITAC considered this Condition of Certification and Maintenance of Certification for certified health IT at length. Discussions focused upon the transparency of the certification process, recommendations concerning "honesty" in communications by a vendor, and mandating the Certified Health IT Product List (CHPL) for publishing product certification periods have been made. In addition, setting a minimum retention period for record keeping in the event that an IT vendor removes a product from market was felt to be appropriate to ensure that potentially short lived products would inadvertently not have their documentation maintained.

Recommendation 47

ORIGINAL	RECOMMENDED REGULATION	COMPARISON / MARKUP
(a) *Condition of Certification.* (1) A health IT developer must provide assurances satisfactory to the Secretary that the health IT developer will not take any action that constitutes information blocking as defined in 42 U.S.C. 300jj-52 and § 171.103, unless for legitimate purposes specified by the Secretary; or any other action that may inhibit the appropriate exchange, access, and use of electronic health information. (2) A health IT developer must ensure that its health IT certified under the ONC Health IT Certification Program conforms to the full scope of the certification criteria. (3) A health IT developer must not take any action that could interfere with a user's ability to access or use certified capabilities for any purpose within the scope of the technology's certification. (4) A health IT developer that manages electronic health information must certify health IT to the certification criterion in § 170.315(b)(10). (b) *Maintenance of Certification*. (1) A health IT developer must retain all records and information necessary to demonstrate initial and ongoing compliance with the requirements of the ONC Health IT Certification Program for: (i) A period of 10 years beginning from the date each of a developer's health IT is first certified under the Program; or (ii) If for a shorter period of time, a period of 3 years from the effective date that	(a) *Condition of Certification.* (1) A health IT developer must provide assurances satisfactory to the Secretary that the health IT developer will not take any action that constitutes information blocking as defined in 42 U.S.C. 300jj-52 and § 171.103, unless for legitimate purposes specified by the Secretary; or any other action that may inhibit the appropriate exchange, access, and use of electronic health information. (2) A health IT developer must ensure that its health IT certified under the ONC Health IT Certification Program conforms to the full scope of the certification criteria. (3) A health IT developer must not take any action that could interfere with a user's ability to access or use certified capabilities for any purpose within the scope of the technology's certification, and the health IT developer shall provide honest communication and expert advice as required by a user. (4) A health IT developer that manages electronic health information must certify health IT to the certification criterion in § 170.315(b)(10). (b) *Maintenance of Certification*. (1) A health IT developer must retain all records and information necessary to demonstrate initial and ongoing compliance with the requirements of the ONC Health IT Certification Program for:	(a) *Condition of Certification.* (1) A health IT developer must provide assurances satisfactory to the Secretary that the health IT developer will not take any action that constitutes information blocking as defined in 42 U.S.C. 300jj-52 and § 171.103, unless for legitimate purposes specified by the Secretary; or any other action that may inhibit the appropriate exchange, access, and use of electronic health information. (2) A health IT developer must ensure that its health IT certified under the ONC Health IT Certification Program conforms to the full scope of the certification criteria. (3) A health IT developer must not take any action that could interfere with a user's ability to access or use certified capabilities for any purpose within the scope of the technology's certification~~.~~, and the health IT developer shall provide honest communication and expert advice as required by a user. (4) A health IT developer that manages electronic health information must certify health IT to the certification criterion in § 170.315(b)(10). (b) *Maintenance of Certification*. (1) A health IT developer must retain all records and information necessary to demonstrate initial and ongoing compliance with the requirements of the ONC Health IT Certification Program for: (i) A period of 10 years beginning from the date each of a

removes all of the certification criteria to which the developer's health IT is certified from the Code of Federal Regulations. (2) A health IT developer that must comply with the requirements of paragraph (a)(4) of this section must provide all of its customers of certified health IT with the health IT certified to the certification criterion in § 170.315(b)(10) within 24 months of this final rule's effective date or within 12 months of certification for a health IT developer that never previously certified health IT to the 2015 Edition, whichever is longer.	(i) A period of 10 years beginning from the date each of a developer's health IT is first certified under the Program; or (ii) If for a shorter period of time, a period of 3 years from the effective date that removes all of the certification criteria to which the developer's health IT is certified from the Code of Federal Regulations. (iii) If for a shorter period of time, a period of 3 years from the date of withdrawal by the health IT developer of a certified health IT product from certification. (2) A health IT developer that must comply with the requirements of paragraph (a)(4) of this section must provide all of its customers of certified health IT with the health IT certified to the certification criterion in § 170.315(b)(10) within: (i) 24 months of this final rule's effective date, or (ii) 12 months of certification for a health IT developer that never previously certified health IT to the 2015 Edition. (3) ONC will preserve on the CHPL (or in another format) a list of the start and end dates of each previously certified health IT product.	developer's health IT is first certified under the Program; or (ii) If for a shorter period of time, a period of 3 years from the effective date that removes all of the certification criteria to which the developer's health IT is certified from the Code of Federal Regulations. (iii) If for a shorter period of time, a period of 3 years from the date of withdrawal by the health IT developer of a certified health IT product from certification. (2) A health IT developer that must comply with the requirements of paragraph (a)(4) of this section must provide all of its customers of certified health IT with the health IT certified to the certification criterion in § 170.315(b)(10) within: (i) 24 months of this final rule's effective date, or (ii) ~~within~~ 12 months of certification for a health IT developer that never previously certified health IT to the 2015 Edition. ~~, whichever is longer.~~ (3) ONC will preserve on the CHPL (or in another format) a list of the start and end dates of each previously certified health IT product.

19. 170.402 Assurances – Request for Information Regarding the Trusted Exchange Framework and the Common Agreement

Recommendation 48

[This recommendation has been removed.]

20. **170.403 Communications**

Recommendation 49

There was concern in the HITAC that ONC's timeline for updates to contracts was insufficient and that the work was significantly underestimated by ONC's regulatory impact analysis. There was an example raised from a member of the group of needing to hire four additional lawyers to complete the work in that timeframe. The intent was to instead have health IT developers propose a plan for contract updates in 2 years, and update contracts at next renewal or within 5 years.

The HITAC recommends the following revisions to the regulatory text:

> (2) Contracts and agreements.
>
> > (i) A health IT developer must not establish, renew, or enforce any contract or agreement that contravenes paragraph (a) of this section.
> >
> > (ii) If a health IT developer has a contract or agreement in existence at the time of the effective date of this final rule that contravenes paragraph (a) of this section, then the developer must in a reasonable period of time, but not later than two years from the effective date of this rule, ~~amend the contract or~~ agree with the relevant client on a plan to amend the contract or an agreement to remove or void the contractual provision that contravenes paragraph (a) of this section.
> >
> > (iii) The plan required by paragraph (ii) of this section must be completed within five years of the effective date of this rule.

Recommendation 50

It was discussed that attempting to enumerate on a screen what might be third-party content that was the intellectual property of a third party was infeasible. Instead, health IT developers could provide a list of third-party content that might be present.

The HITAC recommends the following revisions to the regulatory text:

> (iii) The developer has put all potential communicators on sufficient written notice of a list of third-party content included in the health IT ~~each aspect of its screen display that contains third-party content~~ that cannot be communicated because the reproduction would infringe the third-party's intellectual property rights;

Recommendation 51

There was discussion of whether administrative functions of health IT could unintentionally reveal significant intellectual property of health IT developers. For example, the security configuration of health IT is less important in meeting the needs of communications protected under the Cures Act.

The HITAC recommends clarifying in the preamble that appropriate administrative functions of health IT could be included as "non-user facing aspects" based on the assessment that those communications are not matching the purpose required by the Cures Act and that also affect a limited set of users.

Recommendation 52

There was discussion of concerns of sharing screenshots, the value that health IT developers put on time spent designing and improving screens and user interfaces, and that there are valid reasons why screenshots are both required to be shared and could also be considered "fair use." The goal was that the communications protected under the Cures Act should not permit unintended use, such as using screenshots to attempt to copy screen designs from a competitor. Some members of the HITAC felt that the "fair use" provisions of the preamble already prohibited copying for competitive reasons. However, the restriction that screenshots be permitted to be communicated under fair use principles is not in the regulatory text and the group felt that it deserved further consideration. The intent of the HITAC was that the actor disclosing a screenshot is responsible for determining that the disclosure's purpose does meet the "fair use" expectations and that further redisclosures would have to similarly meet the fair use expectations, and in doing so appropriately protect from potential intellectual property infringements.

The HITAC recommends the following revisions to the regulatory text:

> (2) A health IT developer does not prohibit the fair use communication of screenshots of the developer's health IT, subject to the limited restrictions described in paragraph (a)(2)(ii)(D) of this section, and with the understanding that any actor disclosing the screenshots is responsible for communicating to the actor they disclose to that subsequent use is to be "fair use."

Recommendation 53

In (2)(i)(A), the group felt that it was reasonable for health IT developers to request that they be notified when a disclosure required by law takes place, and that this was accommodated in the current regulatory text.

Recommendation 54

In (2)(i)(C), the group felt that notification to health IT developers prior to (or simultaneous with, if prior was not possible) public reporting would be beneficial for resolving security vulnerabilities prior to the knowledge being widespread.

Recommendation 55

In (2)(i) the group felt that a specific protection might be called for those individuals who highlight information blocking practices and identify them to the appropriate authorities so that the individual is not subject to retaliatory action by the actor identified by the whistleblower. Obviously ONC would need to phrase it so that a whistleblower would not be able to leverage this as mechanism to avoid sanctions for other activities (e.g. performance etc.).

The HITAC recommends the following addition to regulatory text:

> (E) Communicating information about a health IT developer's failure to comply with a Condition of Certification, or with any other requirement of this part, to ONC or an ONC-ACB. Any person who makes a communication covered by (2)(i) to an appropriate entity must not be subject to retaliatory action which could reasonably be considered due to their whistleblowing activity.

Recommendation 56

The HITAC recommends an additional category of communications that would not be protected (neither receiving unqualified protection nor their restriction necessitating a permitted restriction). The intent was that this category would include communications such as false communications, things protected by attorney-client privilege, and so forth. The HITAC did not intend for false communications such as libel to be protected as an unintended consequence. Other examples of unprotected communications might include communications sent by a person who improperly obtained the information or received it from somebody who did not have the right to provide the information, such as a hacker.

The HITAC recommends clarifying in preamble that the goal of the unprotected communications provision is to not extend protections of necessitate permitted restrictions for this category of communications. Specifically, where a communication is unlawful (such as violations of securities law or court orders); the content is false, deceptive, or likely to cause confusion (such as trade libel or trademark infringement); the content is protected by law from disclosure (such as attorney-client privileged communications); the content is subject to a lawful obligation on the health IT developer to prohibit or restrict such communication (such as third party intellectual property); or the content was obtained without authorization (such as by a hacker).

The HITAC recommends the following addition to regulatory text:

> (a)(3) Unprotected Communications. Specific communications are not extended the protections or restrictions in this section, where those communications are considered unprotected in that they are either:
>
> (i) protected by other legislation or regulation; or
>
> (ii) false or unlawful.

Corresponding Suggested Regulatory Text Changes for the Above Recommendations

ORIGINAL	RECOMMENDED REGULATION	COMPARISON / MARKUP
(a) *Condition of Certification*. (1) A health IT developer may not prohibit or restrict the communication regarding— (i) The usability of its health IT; (ii) The interoperability of its health IT; (iii) The security of its health IT; (iv) Relevant information regarding users' experiences when using its health IT; (v) The business practices of developers of health IT related to exchanging electronic health information; and	(a) *Condition of Certification*. (1) A health IT developer may not prohibit or restrict the communication regarding— (i) The usability of its health IT; (ii) The interoperability of its health IT; (iii) The security of its health IT; (iv) Relevant information regarding users' experiences when using its health IT; (v) The business practices of developers of health IT related to exchanging electronic health information; and	(a) *Condition of Certification*. (1) A health IT developer may not prohibit or restrict the communication regarding— (i) The usability of its health IT; (ii) The interoperability of its health IT; (iii) The security of its health IT; (iv) Relevant information regarding users' experiences when using its health IT; (v) The business practices of developers of health IT related to exchanging electronic health information; and

(vi) The manner in which a user of the health IT has used such technology.	(vi) The manner in which a user of the health IT has used such technology.	(vi) The manner in which a user of the health IT has used such technology.
(2) A health IT developer must not engage in any practice that prohibits or restricts a communication regarding the subject matters enumerated in paragraph (a)(1) of this section, unless the practice is specifically permitted by this paragraph and complies with all applicable requirements of this paragraph.	(2) A health IT developer must not engage in any practice that prohibits or restricts a communication regarding the subject matters enumerated in paragraph (a)(1) of this section, unless the practice is specifically permitted by this paragraph and complies with all applicable requirements of this paragraph.	(2) A health IT developer must not engage in any practice that prohibits or restricts a communication regarding the subject matters enumerated in paragraph (a)(1) of this section, unless the practice is specifically permitted by this paragraph and complies with all applicable requirements of this paragraph.
(i) *Unqualified protection for certain communications.* A health IT developer must not prohibit or restrict any person or entity from communicating any information or materials whatsoever (including proprietary information, confidential information, and intellectual property) when the communication is about one or more of the subject matters enumerated in paragraph (a)(1) of this section and is made for any of the following purposes—	(i) *Unqualified protection for certain communications.* A health IT developer must not prohibit or restrict any person or entity from communicating any information or materials whatsoever (including proprietary information, confidential information, and intellectual property) when the communication is about one or more of the subject matters enumerated in paragraph (a)(1) of this section and is made for any of the following purposes—	(i) *Unqualified protection for certain communications.* A health IT developer must not prohibit or restrict any person or entity from communicating any information or materials whatsoever (including proprietary information, confidential information, and intellectual property) when the communication is about one or more of the subject matters enumerated in paragraph (a)(1) of this section and is made for any of the following purposes—
(A) Making a disclosure required by law;	(A) Making a disclosure required by law;	(A) Making a disclosure required by law;
(B) Communicating information about adverse events, hazards, and other unsafe conditions to government agencies, health care accreditation organizations, and patient safety organizations;	(B) Communicating information about adverse events, hazards, and other unsafe conditions to government agencies, health care accreditation organizations, and patient safety organizations;	(B) Communicating information about adverse events, hazards, and other unsafe conditions to government agencies, health care accreditation organizations, and patient safety organizations;
(C) Communicating information about cybersecurity threats and incidents to government agencies;	(C) Communicating information about cybersecurity threats and incidents to government agencies;	(C) Communicating information about cybersecurity threats and incidents to government agencies;
(D) Communicating information about information blocking and other unlawful practices to government agencies; or	(D) Communicating information about information blocking and other unlawful practices to government agencies; or	(D) Communicating information about information blocking and other unlawful practices to government agencies; or
(E) Communicating information about a health IT developer's failure to comply with a Condition	(E) Communicating information about a health IT developer's failure to comply with a Condition	(E) Communicating information about a health IT developer's failure to comply with a Condition

of Certification, or with any other requirement of this part, to ONC or an ONC-ACB. (ii) *Permitted prohibitions and restrictions.* For communications about one or more of the subject matters enumerated in paragraph (a)(1) of this section that is not entitled to unqualified protection under paragraph (a)(2)(i) of this section, a health IT developer may prohibit or restrict communications only as expressly permitted by paragraphs (a)(2)(ii)(A) through (F) of this section. (A) *Developer employees and contractors*. A health IT developer may prohibit or restrict the communications of the developer's employees or contractors. (B) *Non-user-facing aspects of healthIT*. A health IT developer may prohibit or restrict communications that disclose information about non-user-facing aspects of the developer's health IT. (C) *Intellectual property.* A health IT developer may prohibit or restrict communications that would infringe the intellectual property rights existing in the developer's health IT (including third-party rights), provided that— (1) A health IT developer does not prohibit or restrict, or purport to prohibit or restrict, communications that would be a fair use of a copyright work; and (2) A health IT developer does not prohibit the communication of screenshots of the developer's health IT, subject to the limited restrictions described in paragraph (a)(2)(ii)(D) of this section.	of Certification, or with any other requirement of this part, to ONC or an ONC-ACB. Any person who makes a communication covered by (2)(i) to an appropriate entity must not be subject to retaliatory action which could reasonably be considered due to their whistleblowing activity. (ii) *Permitted prohibitions and restrictions.* For communications about one or more of the subject matters enumerated in paragraph (a)(1) of this section that is not entitled to unqualified protection under paragraph (a)(2)(i) of this section, a health IT developer may prohibit or restrict communications only as expressly permitted by paragraphs (a)(2)(ii)(A) through (F) of this section. (A) *Developer employees and contractors*. A health IT developer may prohibit or restrict the communications of the developer's employees or contractors. (B) *Non-user-facing aspects of healthIT*. A health IT developer may prohibit or restrict communications that disclose information about non-user-facing aspects of the developer's health IT. (C) *Intellectual property.* A health IT developer may prohibit or restrict communications that would infringe the intellectual property rights existing in the developer's health IT (including third-party rights), provided that— (1) A health IT developer does not prohibit or restrict, or purport to prohibit or restrict, communications that would be a fair use of a copyright work; and	of Certification, or with any other requirement of this part, to ONC or an ONC-ACB. Any person who makes a communication covered by (2)(i) to an appropriate entity must not be subject to retaliatory action which could reasonably be considered due to their whistleblowing activity. (ii) *Permitted prohibitions and restrictions.* For communications about one or more of the subject matters enumerated in paragraph (a)(1) of this section that is not entitled to unqualified protection under paragraph (a)(2)(i) of this section, a health IT developer may prohibit or restrict communications only as expressly permitted by paragraphs (a)(2)(ii)(A) through (F) of this section. (A) *Developer employees and contractors*. A health IT developer may prohibit or restrict the communications of the developer's employees or contractors. (B) *Non-user-facing aspects of healthIT*. A health IT developer may prohibit or restrict communications that disclose information about non-user-facing aspects of the developer's health IT. (C) *Intellectual property.* A health IT developer may prohibit or restrict communications that would infringe the intellectual property rights existing in the developer's health IT (including third-party rights), provided that— (1) A health IT developer does not prohibit or restrict, or purport to prohibit or restrict, communications that would be a fair use of a copyright work; and

(D) *Screenshots*. A health IT developer may require persons who communicate screenshots to— (1) Not alter screenshots, except to annotate the screenshot, resize it, or to redact the screenshot in accordance with § 170.403(a)(2)(ii)(D)(3) or to conceal protected health information; (2) Not infringe the intellectual property rights of any third parties, provided that — (i) The developer has used all reasonable endeavors to secure a license (including the right to sublicense) in respect to the use of the third-party rights by communicators for purposes of the communications protected by this Condition of Certification; (ii) The developer does not prohibit or restrict, or purport to prohibit or restrict, communications that would be a fair use of a copyright work; (iii) The developer has put all potential communicators on sufficient written notice of each aspect of its screen display that contains third-party content that cannot be communicated because the reproduction would infringe the third-party's intellectual property rights; and (iv) Communicators are permitted to communicate screenshots that have been redacted to not disclose third-party content; and (3) Redact protected health information, unless the individual has provided all necessary consents or authorizations or the communicator is otherwise authorized, permitted, or	(2) A health IT developer does not prohibit the fair use communication of screenshots of the developer's health IT, subject to the limited restrictions described in paragraph (a)(2)(ii)(D) of this section, and with the understanding that any actor disclosing the screenshots are responsible for ensuring that each use is being put to "fair use." (D) *Screenshots*. A health IT developer may require persons who communicate screenshots to— (1) Not alter screenshots, except to annotate the screenshot, resize it, or to redact the screenshot in accordance with § 170.403(a)(2)(ii)(D)(3) or to conceal protected health information; (2) Not infringe the intellectual property rights of any third parties, provided that — (i) The developer has used all reasonable endeavors to secure a license (including the right to sublicense) in respect to the use of the third-party rights by communicators for purposes of the communications protected by this Condition of Certification; (ii) The developer does not prohibit or restrict, or purport to prohibit or restrict, communications that would be a fair use of a copyright work; (iii) The developer has put all potential communicators on sufficient written notice of a list of third-party content included in the health IT that cannot be communicated because the reproduction would infringe the third-party's intellectual property rights; and	(2) A health IT developer does not prohibit the fair use communication of screenshots of the developer's health IT, subject to the limited restrictions described in paragraph (a)(2)(ii)(D) of this section, and with the understanding that any actor disclosing the screenshots are responsible for ensuring that each use is being put to "fair use." (D) *Screenshots*. A health IT developer may require persons who communicate screenshots to— (1) Not alter screenshots, except to annotate the screenshot, resize it, or to redact the screenshot in accordance with § 170.403(a)(2)(ii)(D)(3) or to conceal protected health information; (2) Not infringe the intellectual property rights of any third parties, provided that — (i) The developer has used all reasonable endeavors to secure a license (including the right to sublicense) in respect to the use of the third-party rights by communicators for purposes of the communications protected by this Condition of Certification; (ii) The developer does not prohibit or restrict, or purport to prohibit or restrict, communications that would be a fair use of a copyright work; (iii) The developer has put all potential communicators on sufficient written notice of a list of third-party content included in the health IT ~~each aspect of its screen display that contains third-party content~~ that cannot be communicated because the reproduction would infringe the

required by law to disclose the protected health information. (E) Pre-market testing and development. A health IT developer may prohibit or restrict communications that disclose information or knowledge solely acquired in the course of participating in pre-market product development and testing activities carried out for the benefit of the developer or for the joint benefit of the developer and communicator. A developer must not, once the subject health IT is released or marketed for purposes other than product development and testing, and subject to the permitted prohibitions and restrictions described in paragraph (a)(2)(ii) of this section, prohibit or restrict communications about matters enumerated in paragraph (a)(1) of this section. (b) *Maintenance of Certification* (1) Notice. Health IT developers must issue a written notice to all customers and those with which it has agreements containing provisions that contravene paragraph (a) of this section: (i) Within six months of the effective date of the final rule that any communication or contract provision that contravenes paragraph (a) of this section will not be enforced by the health IT developer. (ii) Within one year of the final rule, and annually thereafter until paragraph (b)(2)(ii) of this section is fulfilled, that any communication or contract provision that contravenes paragraph (a) of this section will not be enforced by the health IT developer.	(iv) Communicators are permitted to communicate screenshots that have been redacted to not disclose third-party content; and (3) Redact protected health information, unless the individual has provided all necessary consents or authorizations or the communicator is otherwise authorized, permitted, or required by law to disclose the protected health information. (E) Pre-market testing and development. A health IT developer may prohibit or restrict communications that disclose information or knowledge solely acquired in the course of participating in pre-market product development and testing activities carried out for the benefit of the developer or for the joint benefit of the developer and communicator. A developer must not, once the subject health IT is released or marketed for purposes other than product development and testing, and subject to the permitted prohibitions and restrictions described in paragraph (a)(2)(ii) of this section, prohibit or restrict communications about matters enumerated in paragraph (a)(1) of this section. (3) Unprotected Communications. Specific communications are not extended the protections or restrictions in this section, where those communications are considered unprotected in that they are either: (i) protected by other legislation or regulation; or (ii) false or unlawful. (b) *Maintenance of Certification*	third-party's intellectual property rights; and (iv) Communicators are permitted to communicate screenshots that have been redacted to not disclose third-party content; and (3) Redact protected health information, unless the individual has provided all necessary consents or authorizations or the communicator is otherwise authorized, permitted, or required by law to disclose the protected health information. (E) Pre-market testing and development. A health IT developer may prohibit or restrict communications that disclose information or knowledge solely acquired in the course of participating in pre-market product development and testing activities carried out for the benefit of the developer or for the joint benefit of the developer and communicator. A developer must not, once the subject health IT is released or marketed for purposes other than product development and testing, and subject to the permitted prohibitions and restrictions described in paragraph (a)(2)(ii) of this section, prohibit or restrict communications about matters enumerated in paragraph (a)(1) of this section. (3) Unprotected Communications. Specific communications are not extended the protections or restrictions in this section, where those communications are considered unprotected in that they are either: (i) protected by other legislation or regulation; or (ii) false or unlawful.

(2) Contracts and agreements. (i) A health IT developer must not establish or enforce any contract or agreement that contravenes paragraph (a) of this section. (ii) If a health IT developer has a contract or agreement in existence at the time of the effective date of this final rule that contravenes paragraph (a) of this section, then the developer must in a reasonable period of time, but not later than two years from the effective date of this rule, amend the contract or agreement to remove or void the contractual provision that contravenes paragraph (a) of this section.	(1) Notice. Health IT developers must issue a written notice to all customers and those with which it has agreements containing provisions that contravene paragraph (a) of this section: (i) Within six months of the effective date of the final rule that any communication or contract provision that contravenes paragraph (a) of this section will not be enforced by the health IT developer. (ii) Within one year of the final rule, and annually thereafter until paragraph (b)(2)(ii) of this section is fulfilled, that any communication or contract provision that contravenes paragraph (a) of this section will not be enforced by the health IT developer. (2) Contracts and agreements. (i) A health IT developer must not establish, renew, or enforce any contract or agreement that contravenes paragraph (a) of this section. (ii) If a health IT developer has a contract or agreement in existence at the time of the effective date of this final rule that contravenes paragraph (a) of this section, then the developer must in a reasonable period of time, but not later than two years from the effective date of this rule, agree with the relevant client on a plan to amend the contract or an agreement to remove or void the contractual provision that contravenes paragraph (a) of this section. (iii) The plan required by paragraph (ii) of this section must be	(b) *Maintenance of Certification* (1) Notice. Health IT developers must issue a written notice to all customers and those with which it has agreements containing provisions that contravene paragraph (a) of this section: (i) Within six months of the effective date of the final rule that any communication or contract provision that contravenes paragraph (a) of this section will not be enforced by the health IT developer. (ii) Within one year of the final rule, and annually thereafter until paragraph (b)(2)(ii) of this section is fulfilled, that any communication or contract provision that contravenes paragraph (a) of this section will not be enforced by the health IT developer. (2) Contracts and agreements. (i) A health IT developer must not establish, renew, or enforce any contract or agreement that contravenes paragraph (a) of this section. (ii) If a health IT developer has a contract or agreement in existence at the time of the effective date of this final rule that contravenes paragraph (a) of this section, then the developer must in a reasonable period of time, but not later than two years from the effective date of this rule, ~~amend the contract or~~ agree with the relevant client on a plan to amend the contract or an agreement to remove or void the contractual provision that contravenes paragraph (a) of this section.

	completed within five years of the effective date of this rule.	(iii) The plan required by paragraph (ii) of this section must be completed within five years of the effective date of this rule.

21. 170.580 ONC Review of Certified Health IT or a Health IT Developer's Actions

The HITAC was concerned with the idea that direct review communications could be serious in consequence. Specifically, relying on email could be problematic if the respondent is on vacation, out of office, or had left the company.

Recommendation 57

ORIGINAL	RECOMMENDED REGULATION	COMPARISON / MARKUP
§ 170.505 Correspondence. (a) Correspondence and communication with ONC or the National Coordinator shall be conducted by email, unless otherwise necessary or specified. The official date of receipt of any email between ONC or the National Coordinator and an applicant for ONC-ACB status, an applicant for ONC-ATL status, an ONC-ACB, an ONC-ATL, health IT developer, or a party to any proceeding under this subpart is the date on which the email was sent. (b) In circumstances where it is necessary for an applicant for ONC-ACB status, an applicant for ONC-ATL status, an ONC-ACB, an ONC-ATL, health IT developer, or a party to any proceeding under this subpart to correspond or communicate with ONC or the National Coordinator by regular, express, or certified mail, the official date of receipt for all parties will be the date of the delivery confirmation to the address on record.	§ 170.505 Correspondence. (a) Correspondence and communication with ONC or the National Coordinator shall be conducted by email, unless otherwise necessary or specified. The official date of receipt of any email between ONC or the National Coordinator and an applicant for ONC-ACB status, an applicant for ONC-ATL status, an ONC-ACB, an ONC-ATL, health IT developer, or a party to any proceeding under this subpart is the date on which the email was sent. (b) In circumstances where it is necessary for an applicant for ONC-ACB status, an applicant for ONC-ATL status, an ONC-ACB, an ONC-ATL, health IT developer, or a party to any proceeding under this subpart to correspond or communicate with ONC or the National Coordinator by regular, express, or certified mail, the official date of receipt for all parties will be the date of the delivery confirmation to the address on record. (c) Notices initiating direct review, of potential non-conformity, of non-conformity, of suspension, of proposed termination, of termination, of ban, or concerning the appeals process will be issued	§ 170.505 Correspondence. (a) Correspondence and communication with ONC or the National Coordinator shall be conducted by email, unless otherwise necessary or specified. The official date of receipt of any email between ONC or the National Coordinator and an applicant for ONC-ACB status, an applicant for ONC-ATL status, an ONC-ACB, an ONC-ATL, health IT developer, or a party to any proceeding under this subpart is the date on which the email was sent. (b) In circumstances where it is necessary for an applicant for ONC-ACB status, an applicant for ONC-ATL status, an ONC-ACB, an ONC-ATL, health IT developer, or a party to any proceeding under this subpart to correspond or communicate with ONC or the National Coordinator by regular, express, or certified mail, the official date of receipt for all parties will be the date of the delivery confirmation to the address on record. (c) Notices initiating direct review, of potential non-conformity, of non-conformity, of suspension, of proposed termination, of termination, of ban, or concerning the appeals process will be issued

	simultaneously via certified mail and email.	simultaneously via certified mail and email.

The HITAC recommends that ONC clarify in preamble that ONC should use both email and certified mail for notices of initiating direct review, potential non-conformity, non-conformity, suspension, proposed termination, termination and ban. Notices regarding appeals would be the same.

22. 170.581 Certification Ban

The sense of the HITAC was that knowledge of past bans was important for stakeholders and therefore indefinite communication of past records (ban with start and end date, if lifted) seems appropriate.

Recommendation 58

Indefinite communication of past records (ban with start and end date, if lifted) seems appropriate.

Recommendation 59

We do not recommend establishing a minimum time period over which a ban must last, even if the health IT developer is a repeat offender. The sense of the HITAC was that a minimum ban time period could have unintended consequences.

23. Request for Comment on Application of Conditions and Maintenance of Certification to Self-Developers

The provisions of information blocking and the Assurances Condition of Certification would apply to self-developers also. Most of the provisions of the Communications Condition of Certification would also apply to self-developers. The HITAC identified one area that would require modification for self-developers, which was in (a)(2)(ii)(A) where the HITAC noticed that employees of a developer can have their communications restricted, but that this could have the consequence of limiting communications of users of the self-developed health IT for the reasons identified under Cures.

Recommendation 60

The HITAC recommends that ONC call out an exception to (a)(2)(ii)(A) for self-developed systems, so that communications by health IT users aren't restricted by being employees of the same company doing the development.

ORIGINAL	RECOMMENDED REGULATION	COMPARISON / MARKUP
§ 170.403 Communications. (a)(2)(ii)(A) *Developer employees and contractors*. A health IT developer may prohibit or restrict the communications of the	§ 170.403 Communications. (a)(2)(ii)(A) *Developer employees and contractors*. A health IT developer may prohibit or restrict the communications of the	§ 170.403 Communications. (a)(2)(ii)(A) *Developer employees and contractors*. A health IT developer may prohibit or restrict the communications of the

developer's employees or contractors.	developer's employees or contractors. Healthcare organizations self-developing certified systems are not permitted to restrict the communications of their user employees with respect to these provisions.	developer's employees or contractors. Healthcare organizations self-developing certified systems are not permitted to restrict the communications of their user employees with respect to these provisions.

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Conditions and Maintenance of Certification Task Force Recommendations

1. Background

1.1. Overarching charge

The Conditions and Maintenance of Certification Task Force will develop and advance recommendations on the "application programming interfaces (API)," "real world testing," and "attestations" Conditions and Maintenance of Certification requirements; updates to most 2015 Edition health IT certification criteria; changes to the ONC Health IT Certification Program; and deregulatory actions.

1.2. Detailed charge

Make specific recommendations on:

1.2.1. Conditions and Maintenance of Certification Requirements

Recommendations on the following Conditions and Maintenance of Certification requirements: "API," "real world testing," and "attestations."

1.2.2. Updates to 2015 Edition Certification Criteria

Recommendations on most proposed updates to the 2015 Edition certification criteria including: "standardized API for patient and population services," "electronic health information export," "electronic prescribing," "clinical quality measures – export," and privacy and security-related *attestation* criteria ("encrypt authentication credentials" and "multi-factor authentication").

1.2.3. Modifications to the ONC Health IT Certification Program

Recommendations on proposed modifications to the ONC Health IT Certification Program (Program).

1.2.4. Deregulatory Actions

Recommendations on proposed deregulatory actions related to certification criteria and Program requirements including: (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.

2. Recommendations

2.1. Overarching Recommendations

As part of our deliberations, the HITAC discussed a number of topics relating to the proposed rule. Given the overarching nature of these topics, we felt it helpful to provide a set of general recommendations to ONC.

2.1.1. Clarity on Rationale for Maintaining a "2015" Edition

In review of the records retention requirements for ONC-ACBs, but applicable to many sections of the proposed rule, the HITAC questioned *why* ONC proposed to modify the 2015 Edition as opposed to creating a *new* edition. There are broad-sweeping changes to the 2015 Edition as a result of this proposed rule. By not updating to a new edition, users of the CHPL would be confused about which version of 2015 Edition is being referenced. Also, there are records retention implications for ONC-ACBs and Health IT developers when an edition is continually modified rather than retired and replaced by a new edition that may require retention for an inordinate amount of time that would not otherwise be required if a new edition is established instead when there are significant modifications to an Edition by rulemaking.

Recommendation 1: The HITAC recommends ONC introduce a new edition of certification rather than propose changes to the 2015 Edition.

2.2 Conditions and Maintenance of Certification Requirements

2.2.1 Real World Testing

2.2.1.1 Timing of submission of real world testing plan

ONC proposes that a health IT developer must submit an annual real world testing plan to its ONC-ACB via a publicly accessible hyperlink no later than December 15, of each calendar year for each of its certified 2015 Edition Health IT Modules that include certification criteria specified for this Condition of Certification. Prior to submission to the ONC-ACB, the plan would need to be approved by a health IT developer authorized representative capable of binding the health IT developer for execution of the plan and include the representative's contact information. The plan would need to include all health IT certified to the 2015 Edition through August 31 of the preceding year.

Recommendation 2: The HITAC recommends ONC reconsider the due date for real world testing plans and provide more flexibility for the deadline to avoid holidays and avoid overloading the ONC-ACBs/federal government. The HITAC recommends an alternative for 170.405(b)(1): instead of requiring submission of an annual real world testing plan to the ONC-ACB via a publicly accessible hyperlink no later December 15 of each year, require submission no later than the latest certification anniversary date each year for the health IT developers' applicable certified 2015 Edition Health IT Modules.

2.2.1.2 Certification Criteria Plan Must Address:

Recommendation 3: The HITAC recommends ONC provide more clarity in the final rule preamble in section VII.B.5 around the care settings/venues the test plan must cover with the goal of making minimum expectations clear and establishing which settings and the number of settings for the applicable certified Health IT Modules.

Recommendation 4: The HITAC recommends ONC provide guidelines in the final rule preamble for a test plan. The HITAC supports the proposed pilot year and recommends including the pilot year in the final rule. After the pilot year, the HITAC suggests creation of a standardized template incorporating the elements of an acceptable test plan.

Recommendation 5: The HITAC recommends ONC provide clarity in the final rule preamble on how successful real world testing is met for the following: (1) continued compliance with certification criteria (including standards and code sets), (2) exchange in intended use settings, and (3) receipt and use of

electronic health information in the certified EHR. The HITAC reviewed and determined not all three elements are possible for *all* certification criteria proposed for real world testing.

2.2.1.3 Scenario and Use Case Focused Testing

The HITAC had significant discussion on the definition of scenario testing versus use case testing and whether or not they were essentially the same.

Recommendation 6: The HITAC recommends ONC clarify and define the terms, "scenario" and "use case" (§ 170.405(b)(1)(iii)(A)). If these terms mean the same thing, choose and use just one of these terms in the final rule regulatory text and in the preamble. In the final rule preamble, the HITAC also recommends ONC clarify the term "workflow" as it is used in section VII.B.5 of the proposed rule preamble regarding real world testing. The HITAC acknowledges the variability that exists in provider workflows and is concerned this could require an infinite number of test cases for a health IT developer's customer base. The HITAC recommends the final rule preamble be clear and reasonable with what is intended where the preamble states "...developers can and should design scenario-based test cases that incorporate multiple functionalities as appropriate for the real world workflow and setting."

The HITAC recommends ONC clarify in the final rule preamble where existing interoperability testing (such as that performed by The Sequoia Project or other existing networks) can satisfy expectations for real world testing.

Recommendation 7: The HITAC recommends modifying § 170.405(b)(1)(iii)(A) to also include as permissible testing approaches automated testing and regression testing:

> (A) The testing method(s)/methodology(ies) that will be used to demonstrate real world interoperability and conformance to the certification criteria's requirements, including scenario, use case-focused, automated, or regression testing;

Recommendation 8: ONC states that successful real world testing means: "Electronic health information is received by and used in the certified health IT." The HITAC recommends ONC provide clarification in the final rule preamble in section VII.B.5 around testing the "receipt and use" of information received through exchange versus testing the exchange of information (sending and receiving). When the health IT being tested does not receive data in the criterion being tested, end user-based testing would not be pertinent.

The HITAC recommends ONC expect that if health IT developers are testing the use of data received through exchange, the health IT vendors should have intended users involved in usability testing.

Users (including providers) were not considered in the cost estimates for real world testing in the proposed rule preamble. Therefore, the HITAC recommends ONC revise real world testing cost estimates in the final rule preamble section XIV.C.2.a.3.6 to incorporate this.

To reduce cost, the HITAC further recommends ONC prioritize real world testing criteria based on risk.

Discussion
The HITAC thinks testing the use of information is important to usability of interoperability. Testing the use of information received through exchange requires consideration of human factors and usability to understand whether the intended users can efficiently and effectively use the presented information.

Use of data testing would be pertinent to the receipt of data in the EHR. If health IT developers are testing the use of data received through exchange, the health IT vendors should have users involved in the testing to validate that users can process and use that information. When certified health IT products receive "foreign" data, we have heard user feedback desiring it be viewable, actionable, and reportable alongside the user's "native" data to be useful and reduce burden on providers using the technology. The intent of the HITAC is not to prescribe certain design approaches but to encourage user-centered design.

The HITAC recognizes that the expense of use-based testing is significant for both health IT developers and users of health IT. The HITAC significantly discussed the costs of this proposal for multiple players: vendors, the other interoperability partners who would be involved, provider organizations and users. The concern was how to prioritize where testing is helpful without unnecessarily increasing cost or burden.

Recommendation 9: The HITAC recommends ONC clarify in the final rule preamble the expected involvement of providers and third parties to support the "real world" nature of the testing.

The HITAC recommends ONC provide guidance in the final rule preamble on testing options that address the use of simulated data and address requirements for unidirectional versus bidirectional test cases. For example, the final rule should clarify whether the health IT developer is required to provide testing for both endpoints/sides in a bi-directional testing scenario.

2.2.1.4 Methodology

Recommendation 10: The HITAC recommends ONC allow in the final rule preamble for flexibility for vendors with regard to real world testing where there is no difference in the testing approach, result or capability. The HITAC suggests the preamble address the following:

- Common capability – test once across all settings and test cases if truly the same capability for the same requirement
- Unchanged capability – allow the vendor to attest to capabilities that remain unchanged from prior year
- Common requirement – test once if the requirement does not vary across all settings and test cases for requirements such as secure communication
- Production experience – clarify whether real world testing is required for what already has long-standing evidence and history of operating in real world production environments
- Clarify applicability of requirement for various practice and care settings. For example, clarify whether all of the named CDA/document types apply to every venue
- Attestation – allow for attestation instead of retesting

2.2.1.5 Measurement/metrics

Recommendation 11: The HITAC recommends ONC include in the final rule preamble section VII.B.5 a description of "measurement" and provide clarity on the role of measurement and specificity for what kinds and for what purposes or proof points. The HITAC recommends ONC consider including updated metric expectations after the pilot year. Where the real world testing is for both interoperability and use of received data, the HITAC recommends ONC consider specifying in the final rule preamble section that there be at least one metric for interoperability and one metric for use, which might correspond with metrics of use used in safety enhanced design testing.

2.2.1.6 Standards Version Advancement Process

Recommendation 12: [This recommendation has been removed.]

2.2.1.7 Other Considerations

Recommendation 13: The HITAC recommends ONC clarify in the final rule preamble the role and expectations of testing partners (who may or may not be subject to contractual requirements) over which the health IT developers have no control or authority over. For example, some testing partners (for example: immunization registries, other EHR developers and providers) are likely to receive many requests to participate in other parties' real world testing. While these testing partners can try to be helpful, they will have limited resources to assist other groups.

The HITAC further recommends ONC clarify whether declining to participate as a testing partner (who may or may not be subject to contractual requirements) in real world testing is considered to be information blocking. The HITAC recommends ONC consider and clarify in the final rule preamble how reasonable protections can be provided for testing partners who have limited resources and, therefore, are unable to participate in an unlimited set of tests. The final rule preamble should provide reasonable assurances for health IT developers who have tried to engage testing partners in testing yet were not successful in getting their commitment to participate.

Recommendation 14: The HITAC recommends ONC review and revise the Regulatory Impact Analysis time estimates that would be required to ensure they accurately reflect and align with the clarified understanding of the real world testing expectations in the final rule.

2.2.2 Attestations

Recommendation 15: The HITAC recommends ONC include a specific deadline at the middle of the year and the end of year/ beginning of year for attestations in the final rule preamble section VII.B.6. This would provide flexibility for the ONC-ACBs to work with developers to get the attestations in rather than specifying a predefined 14-day window of time which seems too prescriptive and subject to problems should the period of time fall during a holiday or government closures, etc. The HITAC recommends ONC consider, for example, setting the deadline for the health IT developers to submit their semi-annual attestations to the ONC-ACB to the last Friday of January and July (this avoids holidays).

2.2.3 Application Programming Interfaces

2.2.3.1 Key Terms

Recommendation 16: The HITAC recommends ONC clarify in the final rule preamble section VII.B.4.b what is considered an acceptable relationship between the API Technology Supplier and the API User, or clarify what activities are expected or permitted to occur between the API Technology Suppliers and API Users. There are multiple relationships supported in this environment and this particular relationship is not sufficiently addressed in the proposed rule preamble. Relationships prior to the involvement of an API Data Provider are of particular interest.

2.2.3.2 Proposed API Standards, Implementation Specifications, and Certification Criterion

Recommendation 17: The HITAC recommends ONC solely adopt FHIR Release 4 (or a subsequent 4.x version if one is created with errata) in the final rule for reference in proposed § 170.315(g)(10) (Option 4) and in the preamble section VII.B.4.c and VII.B.4.c.i. The HITAC is making this recommendation because FHIR Release 4 provides the first normative version, will support enhanced capabilities (such as bulk data), and will focus and unify the industry on a single release of the standard versus multiple releases of the standard.

Recommendation 18: The HITAC recommends ONC move forward in the final rule with implementation specifications and implementation guides to ensure everyone is working from the same set of specifications as this would enhance interoperability and reduce implementation complexity and potentially cost. The HITAC sees value in health IT developers harmonizing to a specified version/release.

Recommendation 19: The HITAC recommends ONC require compliance with HL7 US Core FHIR Implementation Guides (IGs) rather than specifying the Argonaut implementation guides in the final rule regulatory text § 170.215(a)(3) and (4) and preamble section VII.B.4.c.ii. Where HL7 IGs are not available for the corresponding and required Argonaut functionality, the HITAC recommends ONC assist in facilitating their inclusion in the HL7 US Core FHIR IGs.

2.2.3.3 Proposed Adoption of Standards and Implementation Specifications to Support Persistent User Authentication and App Authorization

Recommendation 20: The HITAC recommends ONC address the legitimate and expected activity for SMART Guide to protect patient data with respect to providing persistent tokens to applications and the applications' ability to keep the token confidential. Someone will need to ascertain that API Users provided a persistent token are developing products that secure the token appropriately, but it is not clear who plays that role. The HITAC recommends the ONC clarify who it is and how the determination is made in the final rule preamble section VII.4.c.iii.

Recommendation 21: The HITAC recommends ONC work with OCR and other responsible agencies to provide formal guidance on current uses of FHIR APIs, such as in SMART on FHIR applications or CDS Hooks services, with respect to compliance with relevant privacy and security regulations, such as HIPAA (e.g., the inappropriate sending of full patient demographic details, the inappropriate use of broadly-scoped data access tokens). This deliberation can leverage the work and recommendations of the prior HIT Policy Committee and HIT Standards Committee Joint API Task Force as a starting point

(https://www.healthit.gov/sites/default/files/facas/APITF_Links_to_API_comments_and_recommendations_from_HITSC_and_HITPC_2015-11-30.docx).

2.2.3.4 Search Support

Recommendation 22: The HITAC recognizes additional standards and piloting work of bulk API queries is important, and to allow for that work, the HITAC recommends ONC require this functionality 12 months after other API updates are expected.

2.2.3.5 Transparency Conditions

Recommendation 23: The HITAC recommends ONC clarify what happens at 6 months and what happens at 24 months concerning publication of API documentation by revising the preamble text as specified below. The HITAC was puzzled by requirements to update API documentation (6 months) prior to the requirement to update API capabilities (24 months).

Revise preamble text in section VII.B.4.d.iii to read: "For the purposes of the specific transparency conditions proposed in § 170.404(a)(2) and their relationship and applicability to API Technology Suppliers with products already certified to § 170.315(g)(7), (8), or (9), we propose to establish a compliance date of six months from the final rule's effective date (which would give developers approximately eight months from the final rule's publication date) to revise their existing API documentation to come into compliance with the final rule for these criteria."

2.2.3.6 App Registration/ Condition of Certification Requirements

Recommendation 24: The HITAC recommends ONC further clarify the requirements and expectations around the app registration condition of certification based on a number of issues the HITAC identified regarding app registration. The HITAC recommends clarification in the final rule preamble that would address the following:

- What the practice of "registration' consists of and does not consist of and who is the party responsible for keeping a list of registered apps.
- What "verifying the identity" of an API user consists of and does not consist of and who is the party responsible for performing this. If this is optional, specify that those who haven't performed it are clearly excused from possible cases where API users misrepresent themselves.
- What "vetting" an app (in contrast to verifying identity of a user) consists of and what falls outside the definition of vetting and who is the party responsible for vetting and who is prohibited from vetting. If vetting is optional and not performed, specify that those who haven't performed it are clearly excused from any possible consequences attributable to poorly designed or malicious apps.
- Identifying any tasks (such as an API Data Provider whitelisting a particular app for the first time or an API Data Provider endorsing particular apps) that fall outside of "registration," "identity verification," and "vetting." Describe the tasks, and identify the parties that can and cannot perform them. If they aren't performed, provide clarity that the party is not liable.

2.2.4 Applicability of Conditions and Maintenance of Certification Requirements for Self-Developers

Recommendation 25: The HITAC recommends ONC evaluate the appropriateness of requiring self-developers seeking and maintaining certification to meet all the requirements as proposed in the rule for the real world testing, APIs, and attestations to conditions of maintenance and certification for certified health IT modules that are not offered for commercial resale but must be certified in order for the providers using the modules to participate in certain federal programs. The HITAC recommends ONC specifically address the following in its evaluation and update the final rule preamble Section VII and regulatory text where appropriate:

Real world testing: Permitting self-developers seeking and maintaining certification to use their production experience for the venues where they have deployed their software and their actual trading partner experience to meet the real world testing requirements (for capabilities relevant to a limited set of trading partners) assuming the certified capabilities otherwise meet the other criteria required for certification. Additionally, allowing self-developers of certified Health IT Modules to meet the requirements for Maintenance of Certification in subsequent years with results of the initial real world testing if nothing has changed in the way their self-developed certified product functions and operates.

APIs: CMC requirements applicable to fees as these requirements may not apply to self-developers seeking and maintaining certification. If the self-developer is selling its API technology or charging for its use, the self-developer seeking and maintaining certification of its API technology would be subject to the CMC requirements related to *API fees* and *permitted fee conditions* in § 170.404.

Attestations: None

2.3 Updates to the 2015 Edition Certification Criteria

2.3.1 Electronic Health Information Export

Recommendation 26: The HITAC recommends ONC provide clarity in the final rule preamble around the scope of the EHI export in the 2015 Edition certification criteria. The HITAC recommends the EHI Export scope be limited to EHI collected and retained by the certified EHR technology and apply only to the EHI that is commonly understood to be part of the legal medical record. The HITAC further recommends that health IT developers be required to provide a plain language definition of EHI typically included in the legal medical record held by their certified Health IT Module as part of their export documentation.

Discussion:

The HITAC thinks narrowing the EHI export scope/certification criteria to the legal medical record is important in particular for research data stored in an EHR. The HITAC discussed other challenges with exporting data outside the legal medical record, including incomplete information such as a half-finished note.

The HITAC also acknowledged in its discussion that non-certified health IT might need similar EHI export capability to support a patient's access to his/her EHI and/or a provider's transition of its information/data to another health IT system, but the HITAC concluded that the information blocking provisions were sufficient to ensure health IT developers met the EHI export needs of patients and users

in a similar manner and those systems should not be included in the scope of the 2015 Edition certification criteria for EHI export.

Recommendation 27: The HITAC recommends ONC clarify in the final rule preamble section IV.B.4 that the export process must accommodate manual review by the API Data Provider to comply with state/local laws prior to being released. A state may have laws prohibiting release of certain EHI to a patient and the EHI export process would need to accommodate compliance.

Recommendation 28: The HITAC recommends ONC include audit log data for the EHI Export transitions between health IT systems use case (but not for the EHI Export patient use case due to privacy of health system staff) in the final rule preamble section IV.B.4.

Recommendation 29: The HITAC recommends ONC not require in the final rule preamble section IV.B.4 that the EHI export criterion include capabilities to permit health care providers to set date ranges/specific time period for EHI export due to the complexity experienced by health IT developers in complying with date range/time period flexibility in the View, Download, Transmit certification criterion. Additionally, patients should have access to all of their data regardless of time period.

2.3.2 Electronic Prescribing

Recommendation 30: The HITAC recommends ONC make in the final rule regulatory text § 170.315(b)(11) and preamble section IV.B.2 e-Rx transactions optional that are not applicable to all settings and/or need piloting. If all transactions are required, this could jeopardize the timeline specified for availability/production use. The HITAC recommends the revisions below:

Prescriber applicable:

- NewRxRequest
- NewRxResponseDenied
- RxFillIndicatorChange
- RxChangeRequest, RxChangeResponse
- RxRenewalRequest, RxRenewalResponse (note this is also new, and could be implemented after 1/1/2020 without loss of current functionality)

Optional prescriber applicable:

- REMSInitiationRequest
- REMSInitiationResponse
- REMSRequest
- REMSResponse

LTC only:

- Resupply
- DrugAdministration
- Recertification

Pharmacy only:

- RxTransferRequest
- RxTransferResponse
- RxTransferConfirm

Not applicable:

- GetMessage. Get Message is an obsolete method of message retrieval that essentially is unused since intermediated electronic transacting came into being through RxHub and SureScripts back about 2007 or 2008.

2.3.3 Clinical Quality Measures – Export

Recommendation 31: The HITAC recommends ONC update the clinical quality measurement proposal in the final rule regulatory text § 170.315(c)(3) and preamble section IV.B.3 per the table below. ONC proposes that all products adopt both the CMS ambulatory IG for QRDA III and CMS inpatient IG for QRDA I. If this change is not made, developers will not know how to comply with requirements for QRDA in domains that are not relevant to the care settings supported by their products. Inpatient Implementation Guides include hospital information (for example, hospital identifiers) that would not be relevant to an ambulatory setting and vice versa. We see this as an important technical correction for quality reporting use cases.

	All Products
QRDA I Export	Inpatient CMS IG

Instead, the HITAC recommends the adoption requirements look like:

	Products for Ambulatory Settings	**Products for Inpatient Settings**
QRDA I Import	Generic	Generic
QRDA I Export	Generic	Inpatient CMS IG

Recommendation 32: The HITAC agrees quality reporting using FHIR-enabled APIs is a good aspirational direction for ONC to take and include in future rulemaking, but they are not ready today to replace or complement QRDA reports for quality reporting and improvement.

2.3.4 Privacy and Security Transparency Attestations Criteria (Encrypt Authentication Credentials and Multi-factor Authentication)

Recommendation 33: The HITAC recommends ONC apply privacy and security attestations only to new certifications/new products after this rule is finalized (preamble section IV.B.6), not to products already in widespread use, where the widespread publication of the attestation on these criteria might create a

vulnerability and unintended consequences if malicious actors had this information about existing production systems.

Recommendation 34: The HITAC recommends ONC add a text box for developers to describe their yes/no attestations in certification (modify final rule regulatory text in § 170.315(d)(12)(i) and (ii) and § 170.315(d)(13)(i) and (ii), and preamble section IV.B.6). This would also help with clarity for use cases (login, signing EPCS, etc.). This will allow developers to provide clarity to stakeholders as to what use cases, third party considerations, workflows, etc., that they considered when attesting yes or no. The information provided will also be useful to ONC.

2.4. Modifications to the ONC Health IT Certification Program (No Recommendations)

2.4.1 Principles of Proper Conduct

2.5 Deregulatory Actions for Previous Rulemakings

2.5.1. Removal of Randomized Surveillance Requirements

Recommendation 35: The HITAC recommends ONC not remove the prohibition on consecutive selection of one Health IT Module in the final rule regulatory text (preserve § 170.556(c)(6)) and preamble section III.B.1. The goal is that if the proposed deregulation is implemented to remove the requirement on ONC-ACBs to conduct random surveillance, ONC-ACBs may still randomly surveil but cannot consecutively select the same Health IT Module for random surveillance more than once in a 12-month period. If through random surveillance, an ONC-ACB discovers non-conformance in a Health IT Module, they would still be able to follow up on the same Health IT Module within the 12-month period through its reactive surveillance authority.

2.5.2 Removal of Certain 2015 Edition Certification Criteria

Recommendation 36: The HITAC recommends ONC adopt a general principle in the final rule preamble section III.B.4 of not duplicating data-capture criteria within the certification criteria (such as demographics) for data classes included in USCDI and based on this principle, the HITAC recommends ONC consider other criteria, such as demographics, that could also be removed and do so in the final rule.

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Health IT for the Care Continuum Task Force Recommendations

The Health Information Technology Advisory Committee (HITAC) has provided recommendations on health IT supporting pediatric care and practice settings; data segmentation for privacy; and, input on a request for information on how health IT can support the treatment and prevention of opioid use disorder (OUD). This transmittal offers these recommendations, as informed by the deliberations among the Task Force and the full HITAC. We appreciate the opportunity to work on these issues and hope that the results will be of value to ONC.

1. Background

1.1 Overarching charge

With this letter, the Health Information Technology Advisory Committee provides recommendations on ONC's approach, recommendations, and identified 2015 Edition certification criteria to support pediatric care and practice settings; related criteria to support multiple care and practice settings; and a request for information on how health IT can support the treatment and prevention of opioid use disorder.

1.2 Detailed charge

Make specific recommendations on:

- The 10 ONC recommendations to support the voluntary certification of health IT for pediatric care, including whether to remove a recommendation;
- Identified 2015 Edition certification criteria for supporting the certification of health IT for pediatric care and practice settings and the pediatric technical worksheets *(which outlines existing, new or proposed certification criteria as correlated for the voluntary certification of health IT for pediatric care as well as correlated supplemental Children's EHR Format Requirements to specific ONC pediatric health IT recommendations);*
- 2015 Edition "DS4P" and "consent management for APIs" proposed certification criteria;
- How health IT can support the treatment and prevention of opioid use disorder in alignment with the HHS strategy to address the opioid crisis

2. Health IT for Pediatrics

The HITAC recommends to retain the ten ONC Pediatric Health IT Recommendations for the voluntary certification of health IT for pediatric care and to affirm the proposed rule identified existing and proposed certification criteria as relevant for the voluntary certification of health IT for pediatric care.

The HITAC also provides recommendations for the development of non-regulatory informational resources that can provide additional technical support for pediatric health IT implementation focused on the ten ONC Pediatric Health IT Recommendations and that this resource may be informed by the implementation considerations as identified by the HITAC.

The HITAC expressed great enthusiasm for the planned voluntary pediatric certification of EHRs as the vast majority of EHRs used by pediatricians lack pediatric functionality resulting in unsafe practices.[1] The members expect significant improvements in the care of children and a reduction in burden for providers caring for children. The HITAC further notes that these implementation considerations should be regarded as a starting point to achieving full pediatric functionality, and that future work is needed to improve and advance pediatric EHR functionality beyond these first requirements as identified by the Pediatric EHR Format and AHRQ research.[2]

Below is a table referencing all the ONC Pediatric Health IT Recommendations with the aligned 2015 Edition Certification Criteria along with the aligned proposed new or updated certification criteria, as well as the HITAC recommendations and implementation considerations to inform future (potential) non-regulatory information resources such (e.g., implementation guides).

ONC Pediatric Health IT Recommendations HITAC Crosswalk			
ONC Pediatric Health IT Recommendation and Supplemental Children's EHR Format Requirements	**Alignment with 2015 Edition Certification Criteria**	**Alignment with Proposed New or Updated Certification Criteria**	**HITAC Recommendations and Implementation Considerations to Inform Future (Potential) Non-Regulatory Informational Resource (e.g., Implementation Guide)**

Recommendation 1: Use biometric-specific norms for growth curves and support growth charts for children
 	
Supplemental Children's Format Requirements for Recommendation 1:
1. Allow unknown patient sex
2. Record Gestational Age Assessment and Persist in the EHR
3. Support growth charts for children
	• Common Clinical Data Set* (CCDS)
	• Demographic
	• Clinical Decision Support (CDS)
	• Application Programming Interfaces
		• United States Core Data for Interoperability (USCDI)
		• Application Programming Interfaces (APIs)
			• **Recommendation:** All functional criteria under the "Alignment with 2015 Edition Certification Criteria" and the "Alignment with Proposed New or Updated Certification" should be retained as listed
			• **Additional Implementation Considerations:**
			  ○ Should include a visual display (plotting data) to serve as an alert
			  ○ Displayed value must be able to reference correct data sets (limit to data that are in the public domain and evidence based)
			• **Recommendation for Supplemental Requirements:** Retain all supplemental requirements as is for Recommendation 1

[1] Temple MW, Sisk B, Krams LA, Schneider JH, Kirkendall ES, Lehmann CU. Trends in Use of Electronic Health Records in Pediatric Office Settings. J Pediatr. 2019 Mar;206:164-171.e2. doi: 10.1016/j.jpeds.2018.10.039. Epub 2018 Dec 5. PubMed PMID: 30527749.

[2] Wald JS, Haque SN, Rizk S, Webb JR, Brown S, Ebron S, Lehmann CU, Frisse M, Shorte VA, Lomotan EA, Dailey BA, Johnson KB. Enhancing Health IT Functionality for Children: The 2015 Children's EHR Format. Pediatrics. 2018 Apr;141(4). pii: e20163894. doi: 10.1542/peds.2016-3894. Epub 2018 Mar 8. PubMed PMID: 29519956.

Recommendation 2: Compute weight-based drug dosage
 	
Supplemental Children's Format Requirements for Recommendation 2:
1. Rounding for administrable doses
2. Alert based on age-specific norms
	• Electronic Prescribing	• United States Core Data for Interoperability (USCDI)
		• Electronic Prescribing
			• **Recommendation**: All functional criteria under the "Alignment with 2015 Edition Certification Criteria" and the "Alignment with Proposed New or Updated Certification" should be retained as listed
			• **Additional Implementation Considerations:**
			  ○ Minimum standard is limited to liquid, enteral medications that are dosed based on weight
			  ○ Dispensed and administered doses should be displayed in mL
			  ○ Calculators should not round more than what is measureable using a syringe
			  ○ Prescription final dose should be transmitted with metadata – additional information in text on how dose was derived (show your work)
			  ○ Include original weight for calculation
			• **Recommendation for Supplemental Requirements:** Retain "Rounding for administrable doses" and remove "Alert based on age-specific norms" (pertains to medication dosing only due to the lack of availability of age specific dose ranges for pediatric medication in the public domain)

Recommendation 3: Ability to document all guardians and caregivers
 	
Supplemental Children's Format Requirements for Recommendation 3:
1. Ability to document parental (guardian) notification or permission
2. Record parental notification of newborn screening diagnosis
	• Care Plan
	• Transitions of Care
	• Application Programming Interfaces
	• Transitions of Care
	• Demographic
		• Unites States Core Data for Interoperability (USCDI)
		• Data Segmentation for Privacy
		• Application Programming Interfaces
			• **Recommendation:** All functional criteria under the "Alignment with 2015 Edition Certification Criteria" and the "Alignment with Proposed New or Updated Certification" should be retained as listed
			• **Additional Implementation Considerations:**
			  ○ Guardian and caregiver information should be documented in a structured way (including role)
			  ○ Encourage more robust nomenclature development towards a standard in the future to reference (e.g., through various paths including Standards Development

3. Authorized non-clinician viewers of EHR data 4. Document decision-making authority of patient representative			Organizations, Interoperability Standards Advisory, USCDI) ○ Should have infinite ability to add list for all relevant contacts of the family (no limited fixed number) ○ Ability to manage list of active and historical participants (remove, archive, or start/end date) ● **Recommendation for Supplemental Requirements:** Retain all supplemental requirements for Recommendation 3 (with additional implementation consideration that the "Authorized non-clinician viewers of EHR data" requirements should not be provided as free text (The EHR should allow users to choose from a vendor provided terminology of authorized non-clinician viewers))
Recommendation 4: Segmented access to information **Supplemental Children's Format Requirements for Recommendation 4:** 1. Problem-specific age of consent	● Data Segmentation for Privacy ● Transitions of Care	● United States Core Data for Interoperability (USCDI) ● Data Segmentation for Privacy ● Application Programming Interfaces (APIs)	● **Recommendation:** All functional criteria under the "Alignment with 2015 Edition Certification Criteria" and the "Alignment with Proposed New or Updated Certification" should be retained as listed ● **Additional Implementation Considerations:** ○ Limit the information sent out relevant to dependents on family based insurance (e.g., billing information) ○ A user should be able to identify items that they want protected ○ Prevent tagged data from showing in CDA, portal, or exit note given to another provider ● **Future work considerations**: improvement in the transmission and sharing of data, and level of granularity involved with tagging ● **Recommendation for Supplemental Requirements:** ○ Remove "Problem-specific age of consent" requirement (due to challenges of varying state and local laws)

Recommendation 5: Synchronize immunization histories with registries
 	
Supplemental Children's Format Requirements for Recommendation 5:
1. Produce completed forms from EHR data
	• Transmission to Immunization Registries
	• View, Download, and Transmit to Third Party (VDT)
		• United States Core Data for Interoperability (USCDI)
		• Application Programming Interfaces (APIs)
			• **Recommendation:** All functional criteria under the "Alignment with 2015 Edition Certification Criteria" and the "Alignment with Proposed New or Updated Certification" should be retained as listed
			• **Additional Implementation Considerations:**
			  ○ Needs future work into consolidating state immunization forecasting model into single resource
			  ○ Reduce amount of time to update forecasting
			  ○ Look into onboarding practices (time delays) and resources for immunization forecasting
			  ○ Clinicians should be able to verify source origins
			  ○ The HITAC supports existing resources and investments by CDC and stakeholders for improving standards and interoperability of the Immunization Information Systems (IIS) including the voluntary testing and recognition program for EHRs and other clinical software, and the Immunization Collaborative convened by the Healthcare Information and Management Systems Society (HIMSS) and the American Immunization Registry Association (AIRA)
			• **Recommendation for Supplemental Requirements:**
			  ○ Retain supplemental requirements as is for Recommendation 5

Recommendation 6: Age and weight-specific single-dose range checking	• Clinical Decision Support (CDS) • Application Programming Interfaces (API)	• United States Core Data for Interoperability (USCDI) • Application Programming Interfaces (API)	• **Recommendation:** All functional criteria under the "Alignment with 2015 Edition Certification Criteria" and the "Alignment with Proposed New or Updated Certification" should be retained as listed • **Additional Implementation Considerations:** ○ Consider similar limitations on dose calculations as seen in

			Recommendation 2 (Compute weight-based drug dosage) ○ Existing sources for dose range recommendations should be integrated into workflow ○ Allow user access to best practices or standards (demonstrating correct information source + element of shown work for clinician to verify) ○ Ability to test EHR accuracy ○ Include in QA/QI testing process
Recommendation 7: Transferrable access authority **Supplemental Children's Format Requirements for Recommendation 7:** 1. Age of emancipation	● View, Download, and Transmit to Third Party (VDT) ● Application Programming Interfaces	● Data Segmentation for Privacy ● Application Programming Interfaces (APIs)	● **Recommendation:** All functional criteria under the "Alignment with 2015 Edition Certification Criteria" and the "Alignment with Proposed New or Updated Certification" should be retained as listed ● **Additional Implementation Considerations:** ○ More control needs to be at the end user (e.g., mark individuals with specific privileges until standard nomenclature can be developed) ○ Distinguish authority to access, exchange, or use patient data from medical decision making authority ○ Recommend an ad hoc limited standard or best practice paper to be developed in the meantime ○ Need for nomenclature to be developed based on state/local laws ○ Contradictory access – broad and vague at moment (EHR should be able to document via text field) ● **Recommendation for Supplemental Requirements:** ○ Retain supplemental requirements as is for Recommendation 7
Recommendation 8: Associate maternal health information and demographics with newborn	● Care Plan ● Transitions of Care ● Demographics ● Family Health History	● United States Core Data for Interoperability (USCDI) ● Application Programming	● **Recommendation:** All functional criteria under the "Alignment with 2015 Edition Certification Criteria" and the "Alignment with Proposed New or Updated Certification" should be retained as listed ● **Additional Implementation Considerations:**

	• Social, Psychological, and Behavioral Data	Interfaces (APIs)	○ Information should be available in a format that can be exported and easily digested by pediatric EHR ○ Further integrate records between maternal and child (e.g., capability exists but mainly as text info such as family health history) ○ Further research is needed on existing transmission of this type of data
Recommendation 9: Track incomplete preventative care opportunities	• Clinical Decision Support (CDS) • Clinical Quality Measures • Application Programming Interfaces	• Application Programming Interfaces (APIs)	• **Recommendation:** All functional criteria under the "Alignment with 2015 Edition Certification Criteria" and the "Alignment with Proposed New or Updated Certification" should be retained as listed • **Additional Implementation Considerations:** ○ Generate lists for recall purposes ○ Flag patients – create alert for when patient falls outside expected values
Recommendation 10: Flag special health care needs	• Problem List • Clinical Decision Support (CDS) • Clinical Quality Measures	• United States Core Data for Interoperability (USCDI) • Application Programming Interfaces (APIs)	• **Recommendation:** All functional criteria under the "Alignment with 2015 Edition Certification Criteria" and the "Alignment with Proposed New or Updated Certification" should be retained as listed • **Additional Implementation Considerations:** ○ Ability to determine generic flags ○ Ability to transmit in coded way from system to system ○ Ability to track mental health for children ○ Would like to see incorporated into SNOMED or ICD

The last column as noted includes implementation considerations to inform future (potential) non-regulatory informational resource as identified by the HITAC. In addition to these considerations for specific pediatric recommendations, the HITAC members identified considerations that cut across these recommendations and, they believe, should help inform the future development of any implementation guide. This includes the importance of accounting for setting specific implementation guidance as pertains to both ambulatory and inpatient settings; and, it also includes the importance of identifying

priority use cases to inform any future implementation resource. One such priority use case involves support for the long-term needs of pediatric survivors of complex conditions. The HITAC notes the value of a pediatric record that supports the needs of children with complex conditions through childhood and the transition to care in adult settings and can provide guidance on appropriate follow-up and preventive actions for this vulnerable population.

3. Opioid Use Disorder (OUD) Request for Information (RFI)

The HITAC recommends that ONC consider the following for any future activities related to the Opioid Use Disorder Request for Information.

3.1 Request for Information on Health IT and Opioid Use Disorder Prevention and Treatment

As part of our deliberations, the HITAC discussed various topics around how health IT can support the treatment and prevention of opioid use disorder in alignment with the HHS strategy to address the opioid crisis. Therefore we would like to provide feedback as per ONC's request for information.

We believe health IT can further clinical priorities, as well as public health goals, while offering more systematic coordinated approaches for OUD prevention and treatment. For example, health IT can support a clinician's ability to access and use community resource information and to make referrals for individuals with or at risk for OUD. We also believe that ideally the medication history in Prescription Drug Monitoring Programs (PDMPs) should be available "as a single point of entry" for clinicians to access without burden of having to log in to and use multiple portals. Having explored efforts to improve standards and interoperability involving the Immunization Information Systems (IIS) as pertains to the ONC Pediatric Health IT Recommendation on immunizations, the HITAC identified that in the context of PDMP interoperability- any national efforts to harmonize PDMP data could make state variations less likely to impede interoperability and integration efforts.

As a general sense and value, existing and new criteria can support clinical priorities and advance interoperability for OUD. The successful implementation of health IT can help support OUD and aid in the achievement of national and programmatic goals, especially where they may align with initiatives across the Department of Health and Human Services (HHS) and with stakeholder and industry led efforts.

The HITAC also discussed topics around health IT solutions and effective approaches to improve opioid prescription practices and clinical decision support (CDS) for OUD. We explored issues of burden, usability, and "trigger" for CDS Hooks from a clinician's perspective as pertains to workflow considerations and acknowledge the value of CDS tools, including CDS Hooks for the OUD use care, and recognize the importance of having underlying data available and of the United States Core Data for Interoperability (USCDI). We note that implementation should be made as simple as possible (possibly one click) to ease tracking and monitoring the desirable outcome. In addition, the HITAC recommends that these CDS Hooks should be functional at point of care, especially for rural areas where internet connection can be unreliable.

The HITAC also recommends the creation of a standardization order sets to more effectively and quickly bring decision support into the treatment of this disorder.

3.1.1 Data Segmentation for Privacy (DS4P) and Consent Management for APIs Certification Criteria

ONC proposes to remove the current 2015 Edition DS4P-send and receive certification criteria and replace them with three new DS4P criteria (two for C-CDA and one for FHIR). HITAC acknowledges that DS4P would help for opioid management and provide greater confidence in sharing OUD information. The HITAC also recognizes that the "consent management for APIs" proposal would also aid in furthering the exchange of information. The HITAC notes that, with appropriate protections in place, health IT can help providers electronically use and share data allowing providers to appropriately share health information while both complying with laws/legal requirements[3] and respecting/honoring patient privacy preferences, often referred to as consent requirements.[4,5,6]

Encouraging stakeholders to collaborate to create viable solutions for the implementation of DS4P is crucial for improving interoperability while protecting patient privacy. Motivations for completing this work include: (1) a patient's privacy must be maintained wherever information flows in the health care continuum, and (2) accurate and complete health information must be shared to enable providers to make appropriate decisions at the point of care. Without solving this problem, patient care and safe transfer of information are compromised.

The HITAC acknowledges barriers to optimal implementation of DS4P such as: safety implications; medicolegal recordkeeping requirements; "leakage" or the concern that segmentation will not meet user expectations (particularly regarding narrative content); and, the significant scope of development efforts to implement DS4P in health information technology systems. The HITAC recognizes that governance will be necessary to prioritize use cases for industry consideration, address barriers, and facilitate consistent implementation. However, the HITAC agrees that it is crucial to initiate future work to advance DS4P now including efforts on both technical and policy components. Failure to do so at this junction would be a great opportunity loss and hamper future interoperability efforts. The work could be accomplished in part through multi-stakeholder collaborative work and testing of the DS4P standard to enable priority use cases.

The HITAC recognizes that patients do have the right to choose to restrict information. At this time, stakeholder consensus regarding what data may be restricted by the patient and what data must be transmitted to support safe coordinated care is lacking. The HITAC is concerned that the health IT community currently lacks the policy recommendations to move forward with DS4P.

The HITAC recommends that ONC stand up a multi-stakeholder workgroup to identify and define policy needs and functional requirements to address patient privacy and provider needs.

The HITAC identifies published resources to help inform on the development of these privacy practices as referenced below:

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[3]*See HIPAA FAQs* https://www.hhs.gov/hipaa/for-professionals/faq/index.html*with noted specific example FAQs in subsequent footnotes*

[4]https://www.hhs.gov/hipaa/for-professionals/faq/264/what-is-the-difference-between-consent-and-authorization/index.html

[5]https://www.hhs.gov/hipaa/for-professionals/faq/488/does-hipaa-permit-a-doctor-to-discuss-a-patients-health-status-with-the-patients-family-and-friends/index.html

[6]https://www.hhs.gov/hipaa/for-professionals/faq/personal-representatives-and-minors/index.htm

- Carequality Principles of Trust. Ratified Jan 2015. The Sequoia Project, 2017.https://sequoiaproject.org/wp-content/uploads/2017/08/Carequality_Principles-of-Trust_Final.pdf
- Carr JM., Chairperson, National Committee on Vital and Health Statistics. Letter to Secretary of Health and Human Services Kathleen Sebelius. 10 November 2010.https://www.ncvhs.hhs.gov/wp-content/uploads/2014/05/101110lt.pdf
- CommonWell Health Alliance Member Services Agreement. 28 December 2018.https://www.commonwellalliance.org/wp-content/uploads/2019/01/CommonWell-MSA-28Dec2018-1.pdf
- Cuevas AG, O'Brien K, Saha S. Can patient-centered communication reduce the effects of medical mistrust on patients' decision making? *Health Psychol.* 2019 Apr;38(4):325-333.
- Hazin R, Brothers KB, Malin BA, *et al*. Ethical, legal, and social implications of incorporating genomic information into electronic health records. *Genet Med* 2013 Oct 15(10):810-816.
- Kilbride MK and Joffe S. The New Age of Patient Autonomy: Implications for the Patient-Physician Relationship. *JAMA* 2018 Nov 20;320(19):1973-1974.
- Minari J, Brothers KB, Morrison M. Tensions in ethics and policy created by National Precision Medicine Programs. *Hum Genomics* 2018 Apr 17;12(1):22. doi: 10.1186/s40246-018-0151-9.
- "Protecting Sensitive Health Information in the Context of Health Information Technology." Consumer Partnership for eHealth. June 2010.http://go.nationalpartnership.org/site/DocServer/Sensitive-Data-Final_070710_2.pdf?docID=7041
- Santana MJ, Manalili K, Jolley RJ, *et al.* How to practice person-centered care: a conceptual framework. *Health Expect*. 2018 Apr; 21(2): 429–440.
- The Office of the National Coordinator for Health Information Technology. Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap. Final Version 1.0. October 2015.https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf
- The Office of the National Coordinator for Health Information Technology. Trusted Framework and Common Agreement Draft 2. April 2019.https://www.healthit.gov/sites/default/files/page/2019-04/FINALTEFCAQTF41719508version.pdf

Additional resources for historical purposes:

- The Office of the National Coordinator for Health Information Technology. Patient Consent for Electronic Health Information Exchange and Interoperability. https://www.healthit.gov/topic/interoperability/patient-consent-electronic-health-information-exchange-and-interoperability
- The Office of the National Coordinator for Health Information Technology. Health Information Privacy Law and Policy. https://www.healthit.gov/topic/health-information-privacy-law-and-policy
- The Office of the National Coordinator for Health Information Technology. Health Information Technology. https://www.healthit.gov/topic/health-information-technology

3.1.2 Health IT and Neonatal Abstinence Syndrome (NAS)

In its September 2018 report, *Facing Addiction in America: The Surgeon General's Spotlight on Opioids*, the HHS Office of the Surgeon General describes how the incidence of Neonatal Abstinence Syndrome (NAS), has increased dramatically in the last decade along with increased opioid misuse. ONC has requested public comment on these health IT policies, functionalities and standards to support providers engaged in the treatment and prevention of OUD including for the NAS use case.

The HITAC supports the idea of health IT policies, functionalities and standards to support providers engaged in the treatment and prevention of OUD. Specifically for the NAS use case, the HITAC recommends exploring broader ways to begin standardizing definitions with order sets. These order sets must be computable and identify specific language for EHRs to implement more accurately. In addition, we recommend that when such data sets around OUD are created, the data sets should not be used for punitive measures as it may discourage patients from receiving care when needed (e.g., child protection services and prosecution).

[Continued on Next Page]

U.S. Core Data for Interoperability (USCDI) Task Force Recommendations

The Health Information Technology Advisory Committee (HITAC) asked the U.S. Core Data for Interoperability Task Force (USCDI TF) to provide recommendations around the proposed Data Elements in USCDI v1. The Task Force recommendations were reviewed, deliberated, and approved by the full HITAC. This transmittal letter offers these HITAC recommendations, which are informed by deliberations among the Task Force subject matter experts and the full HITAC.

USCDI Task Force Charge

The USCDI TF was charged with reviewing the newly specified Data Elements proposed in the USCDI v1. The specific charge was to provide recommendations on the following:

- Inclusion of New Patient Demographics Data Elements
  - Address; Phone Number
- Inclusion of Provenance Data Elements
  - Author; Author's Time Stamp; Author's Organization
- Inclusion of Clinical Notes Data Elements
  - Consultation Note; Discharge Summary Note; History & Physical; Imaging Narrative; Laboratory Report Narrative; Pathology Report Narrative; Procedure Note; Progress Note
- Inclusion of Pediatric Vital Signs Data Elements
  - BMI percentile per age and sex for youth 2-20; Weight for age per length and sex; Occipitofrontal circumference for children <3 years old
- Missing Data Elements within Proposed Data Classes

Guiding Principles and Scope

The primary focus of the TF in Phase 1 was to make specific recommendations to include, revise, omit or add specific Data Elements to USCDI v1. The TF did not consider how the proposed Data Elements could be incorporated into current or future record systems. Nor did the TF make any recommendations regarding how that might occur.

Unless otherwise indicated, all of the recommendations apply to USCDI v1. Those recommendations that apply to subsequent versions of USCDI are labelled as such. The TF provided citations for the purpose of showing examples of applicable standards, however the recommendations are agnostic regarding transport. The TF assumed that all USCDI data elements will be tightly specified and semantically interoperable.

Recommendations

Inclusion of New Patient Demographics Data Elements

The TF identified (1) Patient matching, (2) Identity verification, and (3) Clinical care as the primary use cases supported by demographic Data Elements. The Patient Demographics Data Elements recommended by the HITAC support one or more of these use cases.

ONC proposed the following new Data Elements to include in USCDI v1:

- Address
- Phone number

Recommendation 1. **Accept Address for USCDI v1 Patient Demographics as proposed by ONC with the following additional recommendations:**

a. Include both current and previous addresses
b. Encourage the use of the USPS standardized addresses and recommend ONC request access for healthcare organizations to use the USPS standardized address for capture in clinical systems via APIs. The HITAC recognized that standardized address formats improve interoperability, improve patient matching and to reduce data entry errors.[7,8] The HITAC also recognized the need for address verification web services at a reasonable cost; and that ONC should encourage health systems to adopt them.
c. Explore the feasibility of using and/or supporting an international address standard. Potentially important given increased international exchange of health information.

Recommendation 2. **Accept Phone Number for USCDI v1 Patient Demographics as proposed by ONC with the following additional recommendations:**

a. Include designations for both mobile and landlines number(s). Software should support multiple phone numbers. Specifically identify mobile number.
b. Include a designation indicating whether each phone number is only associated with the patient or of another party. Software should support the designation of "Private" and "Shared" for phone numbers. This differentiation is important to support efforts to protect adolescent confidentiality, but applies as well for any patient who has a number used by a parent, spouse or guardian.
c. Designation for each number as to whether the patient has approved leaving a confidential message.

The HITAC recommends the addition of the following Data Elements to USCDI v1 Patient Demographics:

Recommendation 3. ONC include Destination(s) for electronic communications. Software should support the collection of email addresses; and ONC should consider requiring the collection of additional addresses (e.g. Direct address, PHR, provider gateway) in future versions of USCDI.

Recommendation 4. ONC include the individual(s) with authority to consent to treatment and data use. Software should support collection of the identity of the individual(s) with the authority to consent to treatment and data use, including name, contact information, and relationship. Software should also support collection of the identity of the individual(s) with the authority to make decisions outlined in the patient's advanced directive, including name, contact information, and relationship. This is required for

[7] https://academic.oup.com/jamia/article-abstract/26/5/447/5372371?redirectedFrom=fulltext
[8] http://perspectives.ahima.org/wp-content/uploads/2014/12/PatientMatchingAppendixA.pdf)

the care of minors and for individuals who cannot give consent and have guardians or activated health care proxies.

Recommendation 5. ONC include the last four digits of the Social Security Number. ONC should consider requiring systems to support the last four digits of the Social Security Number. The HITAC recognized the value of this data element for patient matching but also noted associated privacy concerns.

Recommendation 6. ONC include Optional identifiers including IDs issued by State or Federal governments. Systems should support state license/state identification numbers for the purposes of patient matching. ONC should consider supporting passport identification numbers for the purposes of patient matching.

Recommendation 7. ONC include Self-reported gender identity. There are robust recommendations for how to collect gender identity in an electronic health record in the ISA.[9] Self-reported gender identity is important for public health and for a health equity. Systems should continue to record sex assigned at birth.

Inclusion of Provenance Data Elements

The TF identified three use cases that are supported by the Provenance Data Class, which include: (1) establishing trust in a data source, (2) deduplication of Data Elements, and (3) Data Element versioning. The TF considered these use cases when discussing and determining recommendations for Data Elements in this Data Class. The Provenance Data Elements recommended by the HITAC support one or more of these use cases.

ONC proposed three new Data Elements for the new provenance Data Class:

- Author's Organization
- Author
- Author's Time Stamp

Recommendation 8. **Accept Author's Organization for USCDI v1 Provenance as proposed by ONC**

Recommendation 9. Accept Author for USCDI v1 Provenance as proposed by ONC with the following additional recommendations:

a. ONC should require the identity of the Author for certain data classes where the Author is straightforward and important. Examples include notes and medication prescriptions. These are situations in which the author is easily established as the creator of a progress note, the originator of a prescription, or the source of patient reported data. In such cases the identity of the author is clear, unambiguous, and valuable for establishing and communicating provenance. Given the difficulty of unambiguously identifying the author for most Data Element classes, the HITAC recommends that the use of Author should be limited to these very specific data types.
b. For data classes other than notes and medication prescriptions, use Author Organization. Future versions of USCDI should include more granular definitions of Author. The HITAC views the

[9] https://www.healthit.gov/isa/sex-birth-sexual-orientation-and-gender-identity

current recommendations as being the first step in building detail that enhances the documentation and communication of provenance data. As a consensus emerges around defining an "Author" with additional granularity for additional Data Classes, future USCDI versions should include standardized, role-based descriptions to identify authors with more specificity.

Recommendation 10. Amend Author's Time Stamp as written in the proposed rule to Time Stamp for USCDI v1 Provenance. Time stamp should be implemented locally. Each system can apply its own standards for Time Stamp in order to assert provenance.

The HITAC proposes the following additional data elements for consideration in USCDI v1 Provenance:

Recommendation 11. ONC should consider adding a unique organization identity and implement in USCDI version 1 if an adequate candidate is identified. The HITAC was unable to propose a taxonomy that covered all entities for this purpose. In situations where it is important to identify the organization it would be reasonable to start with a limited taxonomy.

Recommendation 12. ONC should require that software is capable of indicating when the patient is the author of the data.

Inclusion of Clinical Notes Data Elements

The TF identified two use cases that are supported by the Clinical Notes Data Class: (1) improving accessibility to information through more granular sorting of incoming notes based on content and (2) improving communication across the care continuum. The HITAC considered these use cases when discussing and determining recommendations for the Clinical Notes Data Elements in this Data Class. The Clinical Notes Data Elements recommended by the HITAC support one or more of these use cases.

ONC proposed eight new note types to include in the Clinical Notes Data Class:

- Consultation Note
- Discharge Summary Note
- History and Physical
- Imaging Narrative
- Laboratory Report Narrative
- Pathology Report Narrative
- Procedure Note
- Progress Note

Recommendation 13. **The HITAC recommends the inclusion of the following notes as proposed by ONC in USCDI v1:**

- Consultation Note
- Discharge Summary Note
- History and Physical
- Procedure Note
- Progress Note

Recommendation 14. The HITAC recommends that Imaging Narrative be amended to Diagnostic Imaging Report. The Diagnostic Imaging Report is now available for use and should be included in USCDI v1. Imaging Narrative is duplicative.

Recommendation 15. The HITAC recommends not to add the Laboratory Report Narrative in USCDI v1 Clinical Notes Data Elements as proposed by ONC. This note is duplicative of the Laboratory Results data class.

Recommendation 16. The HITAC recommends not to add the Pathology Report Narrative in USCDI v1 Clinical Notes Data Elements as proposed by ONC. This note is duplicative.

The HITAC request that the following note types be included in USCDI v1 Clinical Notes Data Elements:

Recommendation 17. Continuity of Care Document. Continuity of Care Document is commonly used and widely adopted.

Recommendation 18. Operative Note. Operative Note is commonly used and widely adopted.

Recommendation 19. Miscellaneous Note. Miscellaneous Note is a placeholder for new, as yet unspecified, document types (e.g. sharing pricing data with patients and providers). The definition of "miscellaneous" will change as more explicitly named notes are added. This note should only be used for content that is not adequately transmitted in other note types.

Recommendation 20. Include Transfer Summary Note as optional in USCDI v1. Transfer Summary Note has not been widely adopted but offers significant advantages compared to the Discharge Summary for specific clinical situations. The Transfer Summary provides specific information needed for the continued safe and effective immediate treatment of the individual. The Discharge Summary memorializes the hospitalization and includes information that is irrelevant to the next care team while often omitting information essential to ongoing patient care. A Transfer Summary note is best sent at the time of transfer. A Discharge Summary Note can be sent when finalized.

Recommendation 21. Include Advance Care Planning Note as optional in USCDI v1. Advance Care Planning Note has significant clinical importance especially in settings that perform emergent interventions. HL7 standards currently exist. The C-CDA version of this note is the first C-CDA to be constructed for patient use.[10]

Recommendation 22. Include Care Plan Note as optional in USCDI v1. Care Plan Note has not been widely adopted, but is increasingly used to coordinate care of clinically complex individuals.

The HITAC recommends that the following note types be considered for a future version of the USCDI:

Recommendation 23. Referral Note. Referral Note currently is less commonly used. The Interoperability Standards Priorities Task Force is investigating tighter specification of content in collaboration with the AMA and 360X. These additional specifications would be appropriate for future consideration by USCDI.

[10] http://wiki.hl7.org/index.php?title=Revisions_for_C-DA_R2.1_Advance_Directives_Templates

Recommendation 24. Long Term Services and Supports Care Plan Note. Long Term Services and Supports Care Plan Note is a bridge between providers of clinical services and providers of supportive services. It is currently in ballot at HL7 and should be added to a future USCDI version when standards are established.[11]

Inclusion of Pediatric Vital Signs Data Elements

The TF identified two use cases that are supported by the inclusion of Pediatric Vital Signs: (1) exchange of vital sign measurements and (2) exchange of calculated values derived from vital sign measurements. The HITAC considered these use cases when discussing and determining recommendations for Data Elements in this Data Class.

ONC proposed three new Data Elements to support pediatric vital signs:

- BMI percentile per age and sex for youth 2-20
- Weight for age per length and sex
- Occipitofrontal circumference under 3 years old

Recommendation 25. The HITAC recommends that BMI percentile per age and sex for youth 2-20 be adopted as part of USCDI v1 with the following additional considerations.

a. The requirement to store and exchange this calculated value presents a significant burden for systems that do not already store these values, but rather dynamically calculate and display them to users, based on a specific nomogram, without storing the values generated. A reasonable alternative for systems that do not store these calculations is to send the underlying measurements (weight, age, sex) for the receiving site to be able to perform the calculations based on their usual processes.
b. ONC should consider requiring the storage of this data element whenever the system provides it to the patient/guardian, acknowledging that such storage may be in the form of a copy of a patient handout or growth chart as opposed to a discrete data item.

Recommendation 26. The HITAC recommends that Weight for age per length and sex be adopted as part of USCDI v1 with the following additional considerations.

a. Amend data element to “Weight for length percentile by age and sex for youth 2-20”.
b. The requirement to store and exchange his calculated value presents a significant burden for systems that do not already store these values, but rather dynamically calculate and display them to users, based on a specific nomogram, without storing the values generated. A reasonable alternative for systems that do not store these calculations is to send the underlying measurements (weight, age, length, sex) for the receiving site to be able to perform the calculations based on their usual processes.
c. ONC should consider requiring the storage of this data element whenever the system provides it to the patient/guardian, acknowledging that such storage may be in the form of a copy of a patient handout or growth chart as opposed to a discrete data item.

[11] http://wiki.hl7.org/index.php?title=ELTSS:FHIR_IG_Proposal

Recommendation 27. The HITAC recommends that Occipitofrontal circumference for children under 3 years old be adopted as proposed by ONC in USCDI v1.

Inclusion of Missing Data Elements within Proposed Data Classes

The HITAC recommends the following Data Elements for inclusion in USCDI v1 as part of currently proposed Data Classes.

Recommendation 28. Add provider demographic data elements to the Care Team Members Data Class in USCDI v1:

a. Name
b. Contact information
c. Identifier (e.g., NPI, certification, state license). The use of an identifier is mandatory if the identifier is defined/provided/managed by a national or regional professional body. If there is no identifier provided by a national or regional professional body then the user shall indicate that no such identifier exists.

Recommendation 29. Add Indication and/or associated diagnosis for each medication in USCDI v1 Medications Data Class. The absence of this medication information presents serious risks to patient safety.

Recommendation 30. Include a designation and address entry standards for individuals without a current fixed address (e.g., those experiencing homelessness, displaced persons and refugees). This designation identifies a population at high risk for adverse health outcomes and addresses persons displaced by natural and other disasters who pose data matching challenges. Additionally, include null address separately.

Inclusion of Missing Data Class for a Subsequent USCDI Version

Recommendation 31. The HITAC recommends beginning the process to develop a Quality Measures Data Class in a subsequent version of USCDI. There is an important use case for the generation, documentation, and exchange of data used in standardized quality measures. There are Data Elements used in quality reporting that are scattered throughout the USCDI and across many Data Classes. By creating a Data Class for the specific elements used for quality measurement and reporting, the HITAC believes it will be possible to identify gaps in Data Elements and enhance the quality reporting process. The HITAC also recognizes the difficulty of implementing this recommendation but believes it is important to start. This is important to support deduplication and versioning.

Other Recommendation

Recommendation 32. The HITAC recommends beginning the process to assign a unique and persistent identity for each Data Element with a governance structure to oversee its use. The HITAC had no specific recommendations regarding the implementation of this recommendation.

On behalf of the HITAC, we are supportive of the proposed rule and hope these recommendations will improve and inform the final rule. Please let us know if additional information is needed.

Respectfully submitted,

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/s/
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