



HTI-1 Proposed Rule Task Force 2023

Group 1: Information Blocking Meeting #4

Steven Lane, Co-Chair/Group 1 Lead

Steven Eichner, Co-Chair

May 2, 2023





Call to Order/Roll Call

Seth Pazinski, Acting Designated Federal Officer, ONC

HTI-1 Proposed Rule Task Force 2023 – Group 1 Roster



Name	Organization
Steven Lane*(Co-Chair/Group 1 Lead)	Health Gorilla
Steven Eichner* (Co-Chair)	Texas Department of State Health Services
Hans Buitendijk*	Oracle Health
Hannah Galvin*	Cambridge Health Alliance
Adi Gundlapalli**	CDC
Deven McGraw*	Invitae Corporation
Eliel Oliveira*	Dell Medical School, University of Texas at Austin
Fillipe Southerland*	Yardi Systems, Inc.
Sheryl Turney*	Elevance Health

* HITAC Member

** HITAC Federal Representative

Agenda

10:30 AM Call to Order/Roll Call

- Seth Pazinski, Acting Designated Federal Officer, ONC

10:35 AM HTI-1 Proposed Rule Task Force Charge and Topics Worksheet

- Steven Lane, Co-Chair/Group 1 Lead
- Steven Eichner, Co-Chair

10:40 AM IB Defined Terms – Proposals and IB RFI: Additional Exclusions for Offer Health IT & Discussion

- Rachel Nelson, ONC
- Cassie Weaver, ONC

11:55 AM Public Comment

- Seth Pazinski, Acting Designated Federal Officer, ONC

12:00 PM Adjourn



HTI-1 Proposed Rule Task Force Charge

Steven Lane, Co-Chair/Group 1 Lead

Steven Eichner, Co-Chair

HTI-1 Proposed Rule Task Force 2023

Overarching Charge:

The HTI-1 Proposed Rule Task Force 2023 will evaluate and provide draft recommendations to the HITAC on the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule.

Specific Charge: Provide recommendations on ONC's proposals that would:

- Rename all certification criteria within the ONC Health IT Certification Program (Program) as “ONC Certification Criteria for Health IT” and discontinue year themed “Editions”
- Establish a new baseline version of the United States Core Data for Interoperability (USCDI) from Version 1 to Version 3
- Implement the Electronic Health Record (EHR) Reporting Program as a new Insights Condition and Maintenance of Certification for health information technology (health IT) developers under the Program
- Enhance information sharing under the information blocking regulations



HTI-1 Proposed Rule Task Force 2023 (continued)

Specific Charge: Provide recommendations on ONC's proposals that would:

- Adopt new and revised standards and certification criteria, including:
 - Electronic case reporting certification criterion;
 - Clinical decision support (CDS) and decision support interventions (DSI) certification criteria;
 - Application programming interfaces (APIs) for patient and population services;
 - FHIR US Core Implementation Guide STU version 5.0.
 - HL7 CDA® R2 IG: C–CDA Templates for Clinical Notes STUR2.1 Companion Guide, Release 3 US Realm;
 - A new patient requested restrictions certification criterion; and
 - Requirements for health IT developers to update their previously certified health IT.
- Establish additional Assurances Condition and Maintenance of Certification requirements
- Solicit requests for information (RFIs) on Program standards, certification criteria, and information blocking to inform potential future rulemaking

Recommendations are due to the HITAC by the end of the 60 day public comment period.



HTI-1 Proposed Rule Task Force 2023 – Group 1 Topics

- Information Blocking Defined Terms – Proposals
- IB Request for Information (RFI): Additional Exclusions for Offer Health IT
- IB Manner Exception – TEFCA Manner Proposal
- IB RFI 2 – Possible Additional TEFCA Reasonable and Necessary Activities
- IB Infeasibility Exception Proposals
- Revise Existing Condition: Uncontrollable Events
- New Condition: Third Party Seeking Modification Use
- New Condition: Manner Exception Exhausted
- IB RFI 3 – Health IT Capabilities for Data Segmentation and User/Patient Access



Task Force Topics Worksheet

Steven Lane, Co-Chair/Group 1 Lead

Steven Eichner, Co-Chair



Information Blocking Defined Terms – Proposals and Information Blocking RFI: Additional Exclusions for Offer Health IT

HTI-1 Proposed Rule Subgroup 1

Presented by Rachel Nelson and Cassie Weaver

May 2, 2023





Disclaimer and Public Comment Guidance

- The materials contained in this document are based on the proposals in the "Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing" proposed rule. While every effort has been made to ensure the accuracy of this restatement of those proposals, this document is not a legal document. The official proposals are contained in the proposed rule. Please note that other Federal, state and local laws may also apply.
- ONC must protect the rulemaking process and comply with the Administrative Procedure Act. During the rulemaking process, ONC can only present the information that is in the proposed rule as it is contained in the proposed rule. ONC cannot interpret that information, nor clarify or provide any further guidance.
- This communication is produced and disseminated at U.S. taxpayer expense

Agenda

- Policy Overview
- Context and Background
- Proposals
 - IB Defined Terms – Proposals
 - Offer Health Information Technology or Offer Health IT
 - Health IT Developer of Certified Health IT: Self-Developer Health Care Providers
 - Information Blocking Definition
 - IB RFI: Additional Exclusions for Offer Health IT





Background & Context for Proposals

Information Blocking Defined Terms – Proposals

- ONC proposes to define what it means to “offer health information technology” or “offer health IT” for purposes of the information blocking regulations in 45 CFR Part 171. The definition would:
 - Carve out by explicit exclusion the provision of funding for obtaining or maintaining certified health IT.
 - Explicitly codify that we do not interpret health care providers or other health IT users to offer health IT when they engage in certain activities common amongst both health care providers that purchase certified health IT from a commercial developer or reseller and health care providers that self-develop certified health IT.
 - Propose to potentially exclude from what it means to offer health IT the inclusion of health IT in a package of items, supplies, facilities, and services that a management consultant handles for a clinician practice or other health care provider in a comprehensive (“turn key”) package of services for administrative or operational management of the clinician practice or other health care provider.
- ONC proposes to modify the health IT developer of certified health IT definition so that it is clear that health care providers who self-develop certified health IT would continue to be excluded from this definition if they supply their self-developed certified health IT to others under arrangements excluded from the definition of what it means to offer health IT.
- ONC proposes to revise the text of § 171.103, the information blocking definition, to remove paragraph (b) (see § 171.103(b)). Paragraph (b) established the period of time during which electronic health information (EHI) for purposes of the information blocking definition (§ 171.103) was limited to a subset of electronic health information (EHI) that was identified by the data elements represented in the USCDI standard adopted in 171.213. The end date of that period of time, October 5, 2022, has passed, and thus paragraph (b) of § 171.103 is no longer needed.

Background on “Offer Health Information Technology” or “Offer Health IT”

- *Health IT developer of certified health IT* is defined for purposes of the information blocking regulations as: “an individual or entity, other than a health care provider that self-develops health IT for its own use, that develops ***or offers*** health information technology (as that term is defined in [42 U.S.C. 300jj\(5\)](#)) and which has, at the time it engages in a practice that is the subject of an information blocking claim, one or more Health IT Modules certified under a program for the voluntary certification of health information technology that is kept or recognized by the National Coordinator pursuant to [42 U.S.C. 300jj-11\(c\)\(5\)](#) (ONC Health IT Certification Program)” (***emphasis added***, [45 CFR 171.102](#)).
- In the ONC Cures Act Final Rule ([85 FR 25642](#)), we noted that PHSA section 3022(b)(1)(A) expressly references both “a health information technology developer of certified health information technology” and “other entity offering certified health information technology” in the context of authority to investigate claims of information blocking ([85 FR 25798](#)). We further explained that including both developers and other offerors in the definition of “health IT developer of certified health IT” is consistent with the policy goal of holding all entities who could, as a developer or offeror, engage in information blocking accountable for their practices that are within the definition of information blocking in § 171.103 ([85 FR 25799](#)).
- The policy we finalized ([85 FR 25642](#)) makes no distinction between making certified health IT available for sale, resale, license, re-license, or sublicense under other types of arrangements and making certified health IT available under arrangements designed to benefit the recipient of free or below-cost certified health IT. We did not, in the ONC Cures Act Final Rule, specifically define what it means to *offer health information technology* or *offer health IT*.



Context for Proposals on “Offer Health Information Technology” or “Offer Health IT”

- Specific to the definition of *health IT developer of certified health IT*, interested parties posed questions and expressed concerns that health care providers and entities not otherwise information blocking actors might stop funding subsidies to providers who cannot otherwise afford certified health IT. Concerns included:
 - A lack of certainty as to whether such subsidies could be considered to be offering health IT, resulting in the donor/benefactor entities becoming subject to the definition of *health IT developer of certified health IT* across all of their technology, business lines, and activities.
 - For (potential) donors who are not otherwise information blocking actors, such as philanthropic organizations or health plans, a key concern reportedly affecting their willingness to subsidize certified health IT to providers in need under current policy is presumably that their choice to *offer* certified health IT is also a choice to subject all of their technology and business practices potentially affecting access, exchange, or use of EHI across their entire business to the information blocking regulations in [45 CFR part 171](#) as well as up to \$1 million per violation civil monetary penalties authorized in the Cures Act's information blocking provision ([42 U.S.C. 300jj–52\(b\)\(2\)\(A\)](#)).
 - For health care providers, those who might be in a position to offer cost subsidies to other providers may be hesitant to do so because of the differences in the information blocking definition and consequences for a health IT developer of certified health IT compared with those for a health care provider.

Context for Proposals on “Offer Health Information Technology” or “Offer Health IT”

- We have also received several requests that we clarify, in a manner providing certainty, that a provider using certified health IT acquired from a developer or other offeror will not come to be considered a *health IT developer of certified health IT* if the provider implements features and functionalities in their EHR systems, such as:
 - APIs for patients and clinicians to use third-party apps of their choosing.
 - a hospital issuing login credentials allowing licensed healthcare professionals who are in independent practice to use the hospital's EHR to furnish and document care to patients in the hospital to be “offering” certified health IT to other entities when the hospital in question uses health IT they obtained from a developer or offeror (such as a reseller).



Background on Self-Developer Health Care Providers and the Health IT Developer of Certified Health IT Definition

- Currently, for reasons discussed in the ONC Cures Act Proposed ([84 FR 7511](#) to 7512) and Final ([85 FR 25799](#) to 25800) Rules, health care providers who self-develop certified health IT *for their own use* are excluded from the “health IT developer of certified health IT” definition. However, if a health care provider responsible for the certification status of any Health IT Module(s) were to offer or supply those Health IT Module(s), separately or integrated into a larger product or software suite, to other entities for those entities' use in their own independent operations, that would be inconsistent with the concept of the health care provider self-developing health IT for its own use.
- In our experience, self-developers continue to comprise a very tiny segment of the health IT developer of certified health IT population. However, we do not have optimal visibility of the extent to which self-developer health care providers may be providing their self-developed certified health IT to other health care providers—particularly those who, like skilled nursing facilities and other long term/post-acute care (LTPAC) providers, are not eligible to participate in any CMS programs that specifically track use of Certified EHR Technology (CEHRT)—on any terms.

Context for Proposals on Self-Developer Health Care Providers and the Health IT Developer of Certified Health IT Definition

- To date, we have received no questions, concerns, or other feedback specific to treating, for purposes of information blocking, self-developer health care providers who offer or supply to others their self-developed certified health IT the same as we would any developer of certified health IT.
- However, we believe it is appropriate to revisit the *health IT developer of certified health IT* definition in § 171.102 in light of the proposed new definition of what it means to *offer* certified health IT, to ensure it remains clear on the face of the definition when health care providers who self-develop certified health IT remain outside the definition of *health IT developer of certified health IT* and when they would fall within that definition. certified health IT the same as we would any developer of certified health IT.



Background and Context on Revising the Text of the Information Blocking Definition

- As finalized in the ONC Cures Act Final Rule ([85 FR 25642](#)) and the Cures Act Interim Final Rule ([85 FR 70085](#)), the definition of information blocking (§ 171.103) and the Content and Manner Exception (§ 171.301(a)) were limited to a subset of EHI that was narrower than the EHI definition ONC finalized in the ONC Cures Act Final Rule in § 171.102. The narrower subset included only the EHI identified by the data elements represented in the United States Core Data for Interoperability (USCDI) for the first 18 months after the applicability date for [45 CFR part 171](#) ([85 FR 25792](#)). The interim final rule extended the date to October 6, 2022 ([85 FR 70069](#)).
- Because October 6, 2022, has passed, we propose to revise § 171.103 (information blocking definition) to remove § 171.103(b), which designates the period of time for which the information blocking definition is limited to EHI that consists of the data elements represented in the USCDI. Similarly, because we included the same date in two paragraphs of the Content and Manner exception (§ 171.301(a)(1) and (2)), we propose to revise § 171.301 to remove the existing § 171.301(a)(1) and (2) as no longer necessary. The proposed revised version of § 171.301 refers simply to EHI as defined in § 171.102. We further propose to renumber several of the existing provisions in § 171.301 accordingly; and rename the exception as the “Manner” exception.
- We note that we do not propose to change the scope of EHI for purposes of the information blocking definition, only to update the CFR text to remove the paragraph specific to the period of time now passed.





Proposed Revisions

Update Definition of Information Blocking – Proposal

§ 171.103

Information blocking.

(a) Information blocking means a practice that except as required by law or covered by an exception set forth in subpart B or subpart C of this part, is likely to interfere with access, exchange, or use of electronic health information; and

(b) If conducted by:

- (1) A health IT developer of certified health IT, health information network or health information exchange, such developer, network or exchange knows, or should know, that such practice is likely to interfere with access, exchange, or use of electronic health information; or
- (2) A health care provider, such provider knows that such practice is unreasonable and is likely to interfere with access, exchange, or use of electronic health information.

Proposals on Defining “Offer Health Information Technology” or “Offer Health IT” – Summary

- To give clarity about the definitional implications under information blocking regulations of making available funding subsidies and certain features or uses of certified health IT, we now propose to codify a definition of what it means to *offer* certified health IT. The definition we propose generally includes providing, supplying, or otherwise making available certified health IT under any arrangement or terms, but explicitly excludes certain activities for one of two purposes:
 - (1) to encourage beneficial arrangements under which providers in need can receive subsidies for the cost of obtaining, maintaining, or upgrading certified health IT; or
 - (2) to give health care providers (and others) who use certified health IT concrete certainty that implementing certain health IT features and functionalities, as well as engaging in certain practices that are common and beneficial in an EHR-enabled healthcare environment, will *not* be considered an offering of certified health IT (regardless of who developed that health IT).
- We further propose potential exclusions we are considering that would provide that an individual or entity is not considered to be *offering health IT* under the proposed definition while furnishing certain legal, health IT expert consulting, or management consulting services to health care providers or others who obtain and use health IT.



Proposals on Defining “Offer Health Information Technology” or “Offer Health IT” – Exclusion 1

- Exclusion (1) would remove from the definition of *offer health information technology* or *offer health IT* the provision of subsidies, in the form of funding or cost coverage subsidy arrangements for certified health IT. The exclusion depends, however, on the subsidy being made without any conditions limiting the interoperability or use of the technology to access, exchange, or use electronic health information for any lawful purpose.
 - We would interpret conditions broadly, to include not only the explicit terms of any written agreement but also oral statements and patterns of conduct on the part of the subsidy's source(s) toward, in the presence of, or made known by the source(s) to the subsidy's recipient.
 - For an illustrative example, a health system offers to give any independent safety net provider in its multi-state service area a code that enables the safety net provider to contract with a developer for a (developer hosted and fully supported) EHR product suite that includes all certified functionality needed to participate successfully in Medicare's Quality Payment Program (QPP) and have the cost of that EHR subscription charged to and paid by the health system. In this illustrative example, the health system clarifies that it is willing to cover the costs of what is minimally necessary for QPP, and a particular level of service from the EHR developer. The safety net provider in this example may, without discouragement, interference, or inducement on the part of the health system choose at its own expense to contract with the developer for additional functionalities or levels of service, or contract with other developers for other applications to interface with and use in complement to the EHR suite supported by the health system. So long as the health system does not, in writing or through oral statements or courses of conduct, condition any initial or continued payment of the safety net provider's subscription costs on the safety net provider limiting its use of health IT or its access, use, or exchange of EHI in ways specified or signaled by the health system, the health system's cost coverage subsidy of the safety net provider's EHR suite subscription would not be considered an *offer* of certified health IT under the proposed definition.

Proposals on Defining “Offer Health Information Technology” or “Offer Health IT” – Exclusion 2

- We therefore propose to explicitly exclude from the *offer health information technology* or *offer health IT* definition in paragraph (2) of the definition the implementation, operation, or maintenance, by any health care provider or other entity (such as a HIN/HIE or public health authority) of any and all of the following:
 - Issuing login credentials to employees (whether “W2”/traditional or “1099”/contracted or “gig” employee) of the individual or organization for purposes of accessing, using, or exchanging EHI within the scope/duties of their employment or contract. This would include, though it is not limited to, in-house counsel while acting within scope of their engagement as in-house counsel.
 - Production instances of API technology supporting patient (also known as “individual”) access or other legally permissible access, exchange, or use of EHI that the individual or entity has in its possession, custody, control, or ability to query from/across a HIN/HIE.
 - Production instances of online portals for patients, clinicians, or other health care providers (including employed, affiliated, non-affiliated, or independent providers), or public health entities to access, exchange, or use EHI that the that the individual or entity has in its possession, custody, control, or ability to query from/across a HIN/HIE.
 - Issuing login credentials or user accounts to production or development/testing environments to public health authorities or such authorities' employees as a means of accomplishing or facilitating access, exchange, and use of EHI for public health purposes including but not limited to syndromic surveillance.
 - We also propose to explicitly exclude from the *offer health information technology* or *offer health IT* definition the issuance of login credentials such as EHR login credentials, by the operator of a healthcare facility—such as a hospital, nursing facility, clinic, or dialysis center—for non-employed/independent healthcare professionals who furnish care in the facility to use the facility's EHR in connection to furnishing and documenting that care.
 - We reference production instances in proposed paragraph (2) but do not propose to establish a formal definition of “production instance” specific to this purpose. The reference to production instances in the proposed paragraph (2) explicitly does *not* mean that simply having any pre-production instance(s) of health IT would, of itself, constitute offering health IT. It also explicitly does *not* mean that using non-employee volunteers, such as patient volunteers or independent clinician volunteers, in user experience testing and improvement activities with pre-production instances of any health IT would, of itself, constitute offering health IT.



Proposals on Defining “Offer Health Information Technology” or “Offer Health IT” – Exclusion 3

- The bundled exclusions we propose in paragraph (3) of the definition would address specific legal and consulting services related to obtaining and maintaining health IT or involving health IT in certain ways. The services addressed by the subparagraphs of the paragraph (3) “consulting and legal services” exclusion would include:
 - legal services furnished by attorneys that are not in-house counsel ^[407] of the provider (commonly referred to as “outside counsel”);
 - health IT expert consultants' services engaged to help a health IT customer/user (such as a health care provider) define their business needs and/or evaluate, select, negotiate for or oversee configuration, implementation, and/or operation of a health IT product that the consultant does not sell/resell, license/relicense, or otherwise supply to the customer; and
 - clinician practice or other health care provider administrative or operational management consultant services where the clinician practice or other health care provider administrative or operational management consulting firm effectively stands in the shoes of the provider in dealings with the health IT developer or commercial vendor and manages the day-to-day operations and administrative duties for health IT and its use alongside other administrative and operational functions that would otherwise fall on the clinician practice or other health care provider's partners, owner(s), or staff.

Defining “Offer Health Information Technology” or “Offer Health IT” – Proposal (Slide 1 of 3)

- Offer health information technology or offer health IT means to hold out for sale, resale, license, or relicense; or to sell, resell, license, relicense, or otherwise provide or supply health information technology (as that term is defined in 42 U.S.C. 300jj(5)) that includes one or more Health IT Modules certified under the ONC Health IT Certification Program, for use by other individual(s) or entity(ies) under any arrangement other than the following:
 - (1) Donation and subsidized supply arrangements are not considered offerings when an individual or entity donates, gives, or otherwise makes available funding to subsidize or fully cover the costs of a health care provider's acquisition, augmentation, or upkeep of health IT, provided such individual or entity offers and makes such subsidy without condition(s) limiting the interoperability or use of the technology to access, exchange or use electronic health information for any lawful purpose.

Note: for readability, this slide shows sub-bullet 1 of 3. For bullets 2 and 3, please see the following slides.

Defining “Offer Health Information Technology” or “Offer Health IT” – Proposal (Cont. – Slide 2 of 3)

- (2) Implementation and use activities conducted by an individual or entity as follows:
 - (i) Issuing user accounts and/or login credentials for the individual's or organization's employees to use the individual's or organization's health IT to access, exchange, or use *electronic health information* (as defined in this section) in the course of their employment.
 - (ii) Implementing, operating, or otherwise making available production instances of application programming interface (API) technology (whether certified or not) that supports access, exchange, and use of *electronic health information* (as defined in this section) that the individual or entity has in its possession, custody, control, or ability to query or transmit from or across a *health information network* or *health information exchange* (as defined in this section).
 - (iii) Implementing, operating, and making available production instances of online portals for patients, clinicians, or other health care providers, or public health entities to access, exchange, and use *electronic health information* (as defined in this section) that the individual or entity has in its possession, custody, control, or ability to query or transmit from or across a *health information network* or *health information exchange* (as defined in this section).
 - (iv) Issuing login credentials or user accounts for the individual's or entity's production, development, or testing environments to public health authorities or such authorities' employees as a means of accomplishing or facilitating access, exchange, and use of *electronic health information* (as defined in this section) for public health purposes including but not limited to syndromic surveillance.
 - (v) Issuing login credentials or user accounts for independent healthcare professionals who furnish services in a healthcare facility to use the facility's electronic health record or other health IT system(s) in furnishing, documenting, and accurately billing for that care.



Defining “Offer Health Information Technology” or “Offer Health IT” – Proposal (Cont. – Slide 3 of 3)

- (3) Consulting and legal services arrangements as follows:
 - (i) Legal services furnished by outside counsel—when furnishing legal services to a client in any matter or matters pertaining to the client's seeking, assessing, selecting, or resolving disputes over contracts or other arrangements by which the client obtains use of certified health IT. Outside counsel also does not offer health IT if or when facilitating limited access or use of the client's health IT or EHI within it to independent expert witnesses engaged by counsel, opposing parties' counsel and experts, and special masters and court personnel, as necessary or appropriate to legal discovery.
 - (ii) Health IT consultant assistance selection, implementation and use consultant—provided by an individual or firm when furnishing expert advice and consulting services to a health IT customer or user that help the customer or user, or on the customer's behalf, do any or all of the following with respect to any health IT product that the consultant does not sell or resell, license or relicense, or otherwise supply to the customer under any arrangement on a commercial basis or otherwise:
 - (A) define the customer or user business needs; evaluate or select health IT product(s);
 - (B) negotiate for the purchase, lease, license, or other arrangement under which the health IT product(s) will be used; or
 - (C) oversee configuration, implementation, or operation of health IT product(s).
 - (iii) Comprehensive and predominantly non-health IT clinician practice or other health care provider administrative or operations management services—provided by an individual or entity when furnishing a clinician practice or other health care provider administrative or operational management consultant services where the management consultant acts as the agent of the provider or otherwise stands in the shoes of the provider in dealings with the health IT developer or commercial vendor, and/or in managing the day-to-day operations and administrative duties for the health IT, as part of a comprehensive array of predominantly non-health IT administrative and operational functions that would otherwise fall on the clinician practice or other health care provider's partners, owner(s), or staff.

Information Blocking RFI: Additional Exclusions from Offer Health IT

We seek comment on whether we should consider proposing in future rulemaking any additional exclusions from the *offer health information technology* or *offer health IT* definition proposed in § 171.102 of this proposal. We seek comment in particular on health IT developers and users' experience with activities or arrangements that they believe are beneficial to patients and/or health care providers and that they can demonstrate may be occurring less often specifically due to prospective participants' concerns about potential information blocking liability.

We further welcome observations, evidence, or feedback specific to how potential additional exclusions could be structured or balanced by other measures to mitigate risks of unintended consequences of such exclusions—not limited to, but specifically including potentially insulating individuals or entities with shoddy practices or nefarious intent from accountability for subjecting their customers, clients, patients, or exchange partners to information blocking conduct.

We also welcome comments on other steps that the public would recommend ONC consider taking to further encourage lawful donation or other subsidized provision of certified health IT to health care providers who may otherwise struggle to afford modern, interoperable health IT without reducing the assurances and other benefits ONC's information blocking and Health IT Certification Program regulations provide to these recipient health care providers in comparison to providers who obtain certified health IT directly from its developer or under other non-subsidized arrangements.



Proposal on Revising the Health IT Developer of Certified Health IT Definition – Summary

- To ensure it is immediately clear from the face of the regulations' text that we had put all health care providers that engage in other activities consistent with exclusions (1) through (3) from the *offer health information technology* or *offer health IT* definition on the same footing regardless of who develops the health IT involved in these activities, we would revise the *health IT developer of certified health IT* definition in § 171.102. Specifically, we propose to replace “other than a health care provider that self-develops health IT for its own use” with “other than a health care provider that self-develops health IT not offered to others.”
- We note that regardless of whether we finalize this proposed change to the *health IT developer of certified health IT* definition, a health care provider that self-develops certified health IT and that *offers health IT* to others under any arrangements would continue to be considered a health IT developer of certified health IT (as such developers have been since the ONC Cures Act Final Rule became effective in 2020).
- Should we finalize the *offer health information technology* or *offer health IT* definition to include the exclusion in (1) of certain donation and subsidized supply arrangements, a self-developer health care provider that makes funding or cost coverage subsidies available to others consistent with the finalized (1) exclusion would stand on the same footing as any other health care providers who supply funding or cost coverage subsidies for certified health IT. We have not proposed to except self-developer health care providers from this exclusion.
 - The provision of funding or cost coverage subsidies consistent with the (1) exclusion from the *offer health information technology* or *offer health IT* definition would *not* cause the self-developer health care provider to be considered a *health IT developer of certified health IT* under our proposed revision to the definition in § 171.102.

Health IT Developer of Certified Health IT – Proposed Revised Definition

- *Health IT developer of certified health IT* means an individual or entity, other than a health care provider that self-develops health IT not offered to others, that develops or offers health information technology (as that term is defined in [42 U.S.C. 300jj\(5\)](#)) and which has, at the time it engages in a practice that is the subject of an information blocking claim, one or more Health IT Modules certified under a program for the voluntary certification of health information technology that is kept or recognized by the National Coordinator pursuant to [42 U.S.C. 300jj–11\(c\)\(5\)](#) (ONC Health IT Certification Program).





Discussion

Steven Lane, Co-Chair/Group 1 Lead

Steven Eichner, Co-Chair

Public Comment

To make a comment please
Use the Hand Raise Function

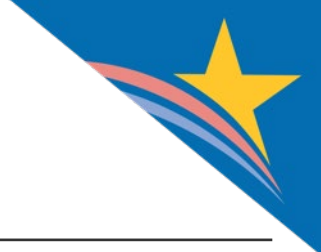
If you are on the phone only, press “*9” to raise your hand

*(Once called upon, press “*6” to mute/unmute your line)*

All public comments will be limited to three minutes

You may also email your public comment to onc-hitac@accelsolutionsllc.com

*Written comments will not be read at this time,
but they will be delivered to members of the task force and made part of the public record*



Upcoming Meetings – Group 1

Month	Task Force/HITAC Meeting Dates	Task Force Topics
May	5/9	<ul style="list-style-type: none"> • IB Manner Exception - TEFCFA Manner Proposal • IB RFI 2 – Possible Additional TEFCFA Reasonable and Necessary Activities
	5/16	<ul style="list-style-type: none"> • IB Infeasibility Exception Proposals <ul style="list-style-type: none"> ○ Revise Existing Condition: Uncontrollable Events ○ New Condition: Third Party Seeking Modification Use
	5/17 (HITAC)	<ul style="list-style-type: none"> • TF Update
	5/23	<ul style="list-style-type: none"> • IB Infeasibility Exception Proposals • New Condition: Manner Exception Exhausted
	5/30	<ul style="list-style-type: none"> • IB RFI 3 – Health IT Capabilities for Data Segmentation and User/Patient Access
June	6/6 (Full TF)	<ul style="list-style-type: none"> • Develop transmittal report/slides
	6/7 (Full TF)	<ul style="list-style-type: none"> • Develop transmittal report/slides
	6/8 (Full TF)	<ul style="list-style-type: none"> • Develop transmittal report/slides
	6/13 (Full TF)	<ul style="list-style-type: none"> • Develop transmittal report/slides
	6/15 (HITAC)	<ul style="list-style-type: none"> • Final Recommendation and Vote



Adjourn