Transcript

HTI-1 PROPOSED RULE TASK FORCE 2023 MEETING

GROUP 1: INFORMATION BLOCKING (IB)

May 2, 2023 10:30 AM – 12 PM ET

VIRTUAL

Speakers

Name	Organization	Role
Steven Lane	**Health Gorilla**	**Co-Chair**
Steven Eichner	**Texas Department of State Health Services**	**Co-Chair**
Hans Buitendijk	Oracle Health	Member
Hannah Galvin	Cambridge Health Alliance	Member
Adi V. Gundlapalli	Centers for Disease Control and Prevention	Member
Deven McGraw	Invitae Corporation	Member
Eliel Oliveira	Dell Medical School, University of Texas at Austin	Member
Fillipe Southerland	Yardi Systems, Inc.	Member
Sheryl Turney	Elevance Health	Member
Seth Pazinski	Office of the National Coordinator for Health Information Technology	Acting Designated Federal Officer
Daniel Healy	Office of the National Coordinator for Health Information Technology	ONC Program Lead
Rachel Nelson	Office of the National Coordinator for Health Information Technology	Presenter
Cassie Weaver	Office of the National Coordinator for Health Information Technology	Presenter

Call to Order/Roll Call (00:00:00)

Seth Pazinski
All right. Hello and good morning, everybody. Welcome to the Health IT Advisory Committee HTI-1 Proposed Rule Task Force. I am Seth Pazinski with ONC, and I would like to thank you all for joining today. I will be serving as the designated federal official for today's call, filling in for Mike Berry. As a reminder, all Task Force meetings are open to the public, and your feedback is welcomed. You can do that by typing in the Zoom chat throughout the meeting, or you can verbally share your public comments towards the end of the meeting, during the public comment period this morning. I am going to begin with a rollcall of the Task Force members, so when I call your name, if you could please indicate that you are present, and I will start with our cochairs. Steven Lane?

Steven Lane
Good morning.

Seth Pazinski
Good morning. Steve Eichner?

Steven Eichner
Good morning.

Seth Pazinski
Good morning. Hans Buitendijk?

Hans Buitendijk
Good morning.

Seth Pazinski
Hannah Galvin?

Hannah Galvin
Good morning.

Seth Pazinski
Adi Gundlapalli? Deven McGraw?

Deven McGraw
Good morning.

Seth Pazinski
Good morning. Eliel Oliveira?

Eliel Oliveira
Good morning.

Seth Pazinski
Good morning. Fil Southerland? Sheryl Turney?

Sheryl Turney
Good morning.

Seth Pazinski
Good morning. All right, well, thank you, everyone, and now, please join me in welcoming Steven Lane and Steve Eichner for their opening remarks and getting us into the agenda today.

HTI-1 Proposed Rule Task Force Charge and Topics Worksheet (00:01:48)

Steven Lane
Thank you so much, Seth, and thank you, everyone, for your attention. I see we have quite a number of members of the public today, many of whom are old friends, so, welcome, everyone. We are here for the second meeting of the first workgroup of the HTI-1 Proposed Rule Task Force, and are really glad to have this level of engagement. We have a couple of topics to work through today related to information blocking, both defined terms as well as a request for information on exclusions, which we will be digging into. We have had a little bit of input from Hannah into our spreadsheet, but I think most of us are looking forward to hearing the discussion and offering any suggestions that come forward. So, this is what we are going to do. Go on to the next slide.

We will just review our charge briefly here. So, our charges are to really review the NPRM, which has been submitted. These bullets are the details of that, the renaming, the new baseline of V.3, the EHR reporting program, the changes to the information-blocking regulations, which we will be talking about today on the next slide, additionally, providing input on new standards, which, again, most of this is going to be handled in later meetings, the assurances, condition and maintenance requirements, which, again, we are discussing elsewhere, and as we said, there are some RFIs that we will be starting to dig into today. We only have the 60-day public comment period to put all this together, so we are on a bit of a fast track, so let's dive right in. Next slide.

So, these are the topics that this group, Group 1, is responsible for, so we are starting with Bullets No. 1 and 2 today, and we will go through the other ones at our subsequent meetings, so, again, we invite people to read ahead in the syllabus, as it were, and to add any comments or suggestions into the spreadsheet as we go along. Also, I will give a reminder that Group 1 participants are welcome to join any of the other two groups, No. 2 on Wednesday and No. 3 on Thursday, if there are topics that you are interested in. Next slide.

We mentioned the worksheet that is out there for which you are invited to provide comments and suggestions. I think we can display the worksheet briefly here, but what we are going to do in the meeting today is I will be holding the mic, and Ike will be watching for raised hands, and we will capture our discussion as we go along. So, you can see it is a pretty meaty spreadsheet with a lot of information. We will be focusing over in Column I in terms of capturing the recommendations of the Task Force. Let's go back to the slides here. There we go, good. So, now, I think Rachel and Cassie are going to walk us through the first topic, which is the additional exclusions and the defined terms first. Do you want to take it away, Rachel?

IB Defined Terms – Proposals and IB RFI: Additional Exclusions for Offer Health IT & Discussion (00:05:53)

Cassie Weaver

Actually, I am going to start. Thanks so much, Steven. It is great to be here. We have a lot to cover, for a change, so I am going to jump right in. Next slide, please. So, this is just our standard disclaimer slide. All the materials in this presentation are based on the proposed rule, Health Data, Technology, and Interoperability, Certification Program Updates, Algorithm Transparency, and Information Sharing, or HTI-1. We will do our best to be accurate, but this is just a summary and not a legal document, so, refer to the rule for the official proposals and note that other federal, state, and local laws may also apply. While we are happy to be here presenting this and discussing this, we do have to honor the rulemaking process and comply with the Administrative Procedure Act, which means we can only present information that is in the proposed rule as it is drafted there, and we cannot clarify, interpret, or provide further guidance. Finally, this communication is produced and disseminated at U.S. taxpayer expense. Next slide, please.

So, here is a quick agenda for this portion of the presentation. First, I will discuss the policy, purposes, and overview of the proposals that we are discussing today and provide some context and background. These proposals cover some, but certainly not all, of the proposed information-blocking updates, so today, we are just going to talk about updating some of the definitions to what it means to offer health IT, update the definition of "health IT developer of certified health IT," and also discuss a small update to the definition of information blocking and discuss one of the requests for information for additional exclusions to offer health IT. Next slide, please.

All right, I will get us started with background and context for these proposals, and then Rachel will dig into the details for us. Next slide. So, currently, in the information-blocking regulations per the CURES Act final rule, a health IT developer of certified health IT is defined for the purposes of the information-blocking regulations as an individual or entity other than a healthcare provider that self-develops health IT for its own use, that develops or offers health information technology, 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 ONC's voluntary certification program. That is not a direct quote, just to be clear.

So, we propose to clarify what it means to offer health IT for purposes of the information-blocking regulations by carving out an explicit exclusion with a provision of funding for obtaining or maintaining certified health IT. We propose to explicitly codify that we do not interpret providers or other health IT users to offer health IT when they engage in certain activities that are common among both providers who purchase certified health IT as well as healthcare providers who self-develop health IT, and then, we also propose to potentially exclude from what it means to offer health IT the inclusion of health IT in certain packages or services that a management consultant handles for a clinician, practice, or provider and certain comprehensive turnkey-style packages of services.

We also propose to modify the definition of "health IT developer of certified health IT," the one I just semi-recited, to make clear that healthcare providers who self-develop health IT would continue to be excluded from the definition if they supply that self-developed certified health IT to others under arrangements that

are excluded from the definition of what it means to offer health IT. Finally, ONC proposes to revise the text of 171.103, which is the information blocking definition, to remove Paragraph B, which is the paragraph that set that time period that limited EHI covered by the information-blocking regulations to the elements represented by USCDI Version 1. Given that date, which was October 5th, 2022 has passed, and all EHI as defined in Section 171 is now covered by the regulations, we propose to just remove that paragraph. That is no longer needed. Next slide, please.

Steven Lane
Sorry, Cassie, can I just ask a question before you go on there?

Cassie Weaver
Sure.

Steven Lane
So, in that first bullet, if we can go back up a slide here, there is word "potentially." In the first bullet, we are carving out, we are codifying, but then we are potentially excluding. So, are you looking to us to provide some other flavor of input about whether we think that potential exclusion is a good idea?

Cassie Weaver
Yes. So, I will get into that as we go along, and Rachel will offer even more, but yes, good catch on that. It is a different sort of request for what types of exclusions we might need to be looking at.

Steven Lane
Great, thanks.

Steven Eichner
This is Steve Eichner. I am going to add on a question for clarification about "self-develop" in terms of looking at if we need to provide some clarification about what "self-develop" means, i.e., in-house staff or developed to be contracted as a custom developed tool. Where do those things split the difference?

Cassie Weaver
Sure. I do appreciate the question, and I believe Rachel will be covering that. If she does not, I will ask her to. When she starts her presentation, she will definitely be giving you the details on "self-developer."

Steven Eichner
Fantastic, thank you.

Cassie Weaver
Of course. Go on to the next slide, please. Here, again, is that current definition of health IT developer of health IT, with the emphasis added to show that it is intended to cover not just developers, but also those who offer health IT or health information technology. We explained in the CURES Act final rule that including both developers and other offerors in this definition is consistent with the CURES Act policy goal of holding all entities who could, as a developer or offeror, engage in information blocking, holding them all accountable for their practices that are within the definition of information blocking. The policy that we finalized in the ONC CURES Act final rule does not make any distinction between those who make certified

health IT available for sale, resale, license, relicense, or sublicense under certain types of arrangements and those who make certified health IT available under arrangements designed to benefit the recipient of free or below-cost certified health IT. So, we did not define specifically what it means to offer health IT, so that is sort of the lay of the land as it is currently. Next slide, please.

And so, in the context of that and the lack of the definition of "offer health IT," ONC understandably received questions and concerns from interested parties looking for more clarity. Specifically, some of the concerns were raised that healthcare providers and entities who are not otherwise actors under the information-blocking regulations might stop funding subsidies to providers who could not otherwise afford certified health IT, and so, more specifically, those concerns included whether subsidies themselves could be considered offering health IT, and therefore make the donors subject to the information-blocking regulations when they otherwise might not be considered actors, for example, philanthropic organizations or health plans. Another concern came from providers who might be in a position to offer cost subsidies to other providers, but then may be hesitant to do so because the penalties for information blocking obviously differ for health IT developers as compared to providers given that health IT developers face money penalties of up to $1 million per instance. Next slide, please.

Similarly, we received requests that we clarify that if a provider is implementing features and functionalities in their EHR systems such as APIs for patients or a hospital issuing login credentials that allows licensed healthcare professionals who are independent to use the hospital's EHR in order to furnish and document the regular care to patients in the hospital, is that hospital offering health IT when the hospital itself is using health IT purchased from a developer or a reseller? These are some of the questions we received in that context where these proposals came from. Next slide, please.

Now, here is some background on the self-developer healthcare providers and how that relates to the "health IT developer of certified health IT" definition. So, currently, for self-developers, healthcare 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 healthcare provider responsible for the certification status of any health IT modules were to offer or supply those health IT modules separately or integrated into a larger product or software suite to other entities for those entities' use in their own independent operation, that would be inconsistent with the concept of a healthcare provider self-developing health IT for its own use.

In our experience, self-developers are a very tiny segment of the health IT developer of certified health IT population, but we also do not have visibility of the extent to which these self-developer healthcare providers may be providing their self-developed certified health IT to other healthcare providers, particularly those, like skilled nursing facilities and other LTPAC providers, who are not eligible to participate in any CMS programs that specifically track use of certified EHR technology on any terms. So, again, that is the lay of the land now. Next slide, please.

While, to date, we do not have any questions or concerns necessarily specific to treating self-developer healthcare providers who offer or supply to others their self-developer certified health IT the same as we would any developer of certified health IT, we do think it is appropriate to revisit this definition in light of the proposed new definition of what it means to offer certified health IT to ensure that it remains clear, just on the face of the definition, that when healthcare 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. That is a little clearer there, sorry. Next slide, please.

I am going to go through this one fairly quickly because it is kind of a simple proposal, but as many of you recall, in the CURES Act final rule, the definition of information blocking and the content and manner exception were limited to a subset of EHI that was narrower than the EHI definition that ONC finalized in 171.102, and this narrower subset included only the EHI identified by data elements represented in the USCDI for the first 18 months in order to provide that sort of glide path for actors to get used to the information-blocking regulations with a smaller subset of data. That glide path ended on October 26, 2022, which was actually the date from the interim final rule that ONC passed in light of the COVID-19 public health emergency, so, because that October 26, 2022 date has passed, we proposed to revise 171.103 and remove Paragraph B, which is the paragraph that designates that period of time for which that definition is limited, and we also included that date in two paragraphs of the content and manner exception.

We propose to also revise those two paragraphs to remove 171 through 1A1 and 2 as no longer necessary, and then, we would also renumber several of those existing provisions and rename the exception the manner exception, since the content part of that name had referred to the limited subset of data, and given that that has expired, we propose that it makes sense to rename it to just the manner exception. Please note that we do not propose to change the scope of EHI for purposes of information blocking definition, just to update the CFR text. Next slide, please. With that, I will hand it over to Rachel, who will get into more specifics about these proposed revisions. Rachel, if you are speaking, you are double muted, I think.

Rachel Nelson
No, I am attempting to update my technology, and as we know, I am not the best at operating simple office technology. So, I am taking over here at the proposed revisions. Next slide, please. There is not a lot more to say here that was not covered in the background. Just to go very quickly, this is exactly how the new revised proposed definition would look. We are just taking out the reference to that initial period of time that was the glide path, where the information blocking definition was only focused on information described in USCDI Version 1. Next slide, please.

And now, there is a lot here. The offer health IT… So, to give clarity around the definitional occasion, funding subsidies and certain features are used as a certified health IT. We propose to codify this definition of what it means to offer certified health IT, and also, when we get a little further, you will also see to codify that certain things are not considered offering health IT, so those explicit exclusions are for one of two purposes: To encourage beneficial arrangements under which providers in need can receive subsidies for the cost of obtaining, maintaining, or upgrading certified health IT without prospective donors worrying that they will change how they fit under the information-blocking regulations, or, the other purpose, to give healthcare providers and others who use certified health IT concrete certainty that implementing certain features and functionalities, as well as engaging in certain practices that are common and beneficial in a CHR-enabled healthcare environment will not be considered offering a certified health IT regardless of who develops it.

We had talked about some of these excluded activities in the preamble of the 2020 final rule, but this would… We talked about it in context specifically of the exclusion of self-developer healthcare providers from the developer definition. This proposal would not only codify that some of these activities are never considered to be an offering of health IT, it would also be very clear that we do not care who developed it,

these particular activities just do not kick you into the offer definition. We did also propose potential exclusions that we are considering that would provide that an individual entity would not be considered to be offering health IT when furnishing certain legal health IT expert consulting or management consulting services to healthcare providers or others who obtain and use certified health IT. Next slide, please. I will try to pick up the pace a little bit.

So, this is basically a lot of the proposal on a slide, and I am not going to try to read it allowed to everyone unless somebody asks me to, in which case I will sit here and dutifully read it word for word. Exclusion No. 1 would remove from the definition the provision of subsidies, and this would be "I know you need something, I will kick in some of the cost, here is the discount code that I have already paid for, use that when you go get it, and it will be cheaper for you than it would otherwise be to go get the certified health IT from whichever vendor or offeror you want to get it from."

The exclusion does depend on the subsidy being made without conditions that would limit the interoperability or the use of the technology to access, exchange, or use electronic health information for any lawful purpose that the recipient of the subsidy would want to use that technology for, and we note here we would interpret conditions broadly so that in terms of where the strings could be attached, it would not only be the explicit terms of any written agreement, but also oral statements and patterns of conduct on the part of the subsidy's source toward the subsidy's recipient or that the subsidy recipient would know about. We give an illustrative example that the health system offers to give any independent safety net provider in its multistate service area a code that enables the safety net provider to contract with a developer for a developer-hosted, fully supported EHR product suite that includes all certified functionality needed to successfully participate in Medicare's Quality Payment Program and to 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 cost of what is minimally necessary for QPP in 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 or 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 cost on the safety net provider limiting its use of the health IT or its access, use, or exchange of EHI in ways specified or signaled by the health system, the health system's cost covered subsidy of the safety net provider's EHR suite subscription would not be considered an offer of certified health IT under the proposed definition. One warning on the back of the box which you will find if you go into the preamble of the proposed rule is that this proposal is all about information blocking definitions and implications, and it would remain separately the owner or the source of the subsidy's responsibility to make sure that whatever this arrangement is that they are entering into is not violating some other law that could be implicated, such as the anti-kickback statute. So, having given the obligatory warning on the back of the box for Exclusion 1, next slide, please.

So, Exclusion 2. I might actually read this one, but in short form. We propose to explicitly exclude a variety of activities that we have gotten questions about, and we wanted to make it very explicitly clear that we do

not care who develops the certified health IT that you are implementing to do this with. We just do not think these particular activities are offering health IT. As we said in the preamble of the prior rule, this would codify and maybe build out specificity, as one does when one is codifying things, so any or all of the following under this proposed Exclusion 2 from the offer definition would not be considered an offer of health IT.

Issuing login credentials to employees, whether they are W-2 employees, 1099 contracted, or gig employed, whatever you want to call them, however they came to be, however you got that travel nurse present in your facility, whatever your other implications under accounting or what have you for how that ER doc came to be staffing your ER, issuing login credentials to these folks for purposes of accessing, exchanging, or using EHI within the scope of their duties or their employment contract is just not an offer. This would also include, though it is not limited to, if your in-house counsel, while acting within the scope of their employment as in-house counsel, needs to have some form of access, have a login, and work with or within the EHR, so it is not just your clinical staff, it is pretty much any employee records, what have you.

Production instances of API technology, supporting patient access, or other legally permissible access, exchange, or use of EHI that you have or can get would not be offering health IT, just standing up the portal, switching it on, and letting patients use it to get at stuff you have. Production instances of online portals for patients, clinicians, other healthcare providers… In other words, we do have sort of a list there, so we can be clear it is not just patient portals, and it is also portals that might be used by a variety of providers, including outside independent providers. You just want them to have an option to get information about patients of theirs that you have given care to. Issuing login credentials or user accounts to production or development testing environments to public health authorities and their employees as a means of accomplishing or facilitating public health exchange purposes.

We also propose to explicitly exclude from the offer health IT definition the issuance of login credentials by the operator of a healthcare facility for non-employed independent 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 part of the proposed Exclusion 2, but we do not propose to establish a formal definition of "production instance" specific to this purpose. It does not mean that simply having any preproduction instances of health IT would, of itself, constitute offering health IT. It also explicitly does not mean, as we explain in the rule, that using nonemployee volunteers or independent clinician volunteers in user experience testing and improvement activity for preproduction instances would, of itself, be considered offering health IT under the proposal. Next slide, please. Exclusion 3 is a bundle of exclusions.

Steven Eichner
Rachel, this is Steve Eichner. Before you go on, I am going to ask two questions on the preceding slide.

Rachel Nelson
Sure.

Steven Eichner
I do not want it to get lost down the line. No. 1, looking at user credentials, you have discussed that several times here. Do you also mean machine credentials, looking at facilitating machine-machine exchange?

Rachel Nelson
I am trying to be careful because of respecting the process. We did not necessarily dig into that type of user. You can see what is there. You can see what we were covering and bringing to the surface.

Steven Eichner
Right, and I appreciate the point. I was just looking for clarification on what the base intention was and making comments appropriately. That is what the process is about. Secondly, looking at where you discuss public health entities, authorities, or activities like syndromic surveillance, for clarification, is the scope public health authorities, or other clinical registries as well, or is that something we should provide down the line?

Rachel Nelson
Offering a comment or requesting clarification on which nuances or facets of how the technology actually works or some of the use cases where you are not sure it is clear from what is in the rule right now and how they would play out could be useful.

Steven Eichner
Right. As an example, there are some registries that are operated directly by public health agencies, there are a bunch of rare disease organizations that operate patient registries that are similar in function with perhaps a different scope, so that would be an example of similar function through different implementers where a comment might differentiate between the two. Thanks. I think Deven has a question as well.

Deven McGraw
Yes, thanks, Ike. It seems to me that even though this is part of defining who is covered under the rule, like who is offering health IT, it seems to me that much of these exclusions are about trying to draw a line that is kind of a functional line versus who you are, public health authority or registry, and more about what you are doing to facilitate the use of certified health IT, and does that equivocate to offering health IT? So, these seem to me to be more about types of functionalities that you all are looking to say, "That is not really offering health IT," potentially regardless of who is necessarily doing that activity.

And so, I am just wondering if I am off base in thinking about it through that lens, first of all, from a question standpoint, and then, the other question I have is what if you have somebody who is doing one of these activities that is excluded, but is also offering health IT, for example, a certified electronic medical record vendor who offers a discount or helps someone to pay for their health IT? You have this exclusion category for providing financial assistance, but they are also doing the thing that frankly would have triggered coverage, and arguably still oud, even under the proposed rule.

Rachel Nelson
I am trying to take your comment and then question. I believe we do say in the preamble for this proposal that what we were attempting to do here is codify this. There are just certain things that people who use certified health IT tend to do that, now that we are codifying a definition of "offer," even though without the login credential, the nurse on the floor cannot use that health IT, without a token, something cannot connect, in certain circumstances, to the API, we are saying just doing what is necessary to let people use the health IT that you have implemented is not about who you are and does not change your category and just doing that thing does not change your category, regardless of who develops the health IT that you are letting people interact with in order to do your main line of business facilitated by health IT.

When it comes to the question, I am free to say that, as we do explain in the preamble, if you are both, so if the developer definition is in for a penny, in for a pound, if, yesterday and today, I am selling health IT, and tomorrow, I give a subsidy, I do a discount, or whatever, that does not make me magically no longer in for a penny, in for a pound. They cannot kick themselves out of the developer definition by doing something that would, of itself, remove them from the developer definition. So, the example we gave was a healthcare provider that offers to cover some costs for another healthcare provider, no inappropriate strings attached, and just offering that funding support, as it would not be considered an offer of the health IT itself, would not cause that funds-providing healthcare provider to then fall into the developer definition under the proposal.

Deven McGraw
Okay. In other words, merely doing one or more of these types of functionalities that arguably operationalize health IT does not make you an offeror of health IT, but if you are an offeror of health IT, the fact that you may be doing some of these functional things does not mean that you are not… It does not negate the core business.

Rachel Nelson
Yes.

Deven McGraw
Okay, thank you.

Steven Eichner
Hans?

Hans Buitendijk
Thank you, Ike. On that note, I am not sure where exactly this fits, but it does fit in the part of functionally what one does and what, therefore, the role is. Where you have HIT suppliers who offer and are used by the users…I will just use "provider" as the general term…to use the systems through outsourcing their IT staff who are otherwise part of it, that then falls under the same logic on how this is being assigned or considered, or, in their role, as they are now functioning in a role of the provider, they are considered in the context of that provider. Does that play in anywhere into the definition as you intend it to be as part of "offeror," the way that shifts roles? Because now we have people on behalf of the provider doing their work, but they happen to be outsourced or sourced by an external party that is actually also providing some or all of the software. Where does that fit in this discussion? Because this is a fluid back-and-forth, where does that fit?

Rachel Nelson
As I listened to that fact pattern play out, it sounded to me like it was hopping back and forth between Exclusion 2 and another exclusion, perhaps Exclusion 3, so I think there may be situations where a healthcare provider licenses software from three, four, or five different developers, and they contract with a firm to do the work that their in-house health IT shop might do, and I think what is going on there is just going to be case by case. I think it might be helpful to look at Exclusion 3 at this point, so, next slide, please. So, there is this bundle of exclusions in Paragraph 3. Some services might need only one of them when we

look at them a little more closely. So, there is consulting and legal services, and one of this bundle of exclusions would be legal services furnished by attorneys that are not in-house counsel. We talked earlier about how giving in-house counsel access that they need to use your health IT is not offering health IT to your in-house attorneys.

Legal services furnished by attorneys that are not in-house counsel as a provider are commonly referred to as outside counsel, and there is more detail in the rule itself, but even if those legal services require them to interact with your health IT in some way or they are representing you in legal actions related to getting, using, etc. that health IT, they are furnishing legal services. That does not make them an offeror of health IT. The health IT expert consultant services engage to help a provider, say, define their business needs, evaluate, select, negotiate, or oversee the configuration, implementation, or operation of a health IT product that the consultant themself does not sell, resell, license, relicense, or otherwise supply to the customer, so I think it would be case by case whether… You would need to look at the specific facts and circumstances to see whether either of these exclusions apply to certain arrangements that we have seen or heard of out there in the world, or which of them applied, and to which extent, for example, to potentially render viewing what the consultant did as not considered to be an offer of health IT.

And then, the third of the bundle proposed exclusions from the offer health IT definition would be a clinician, practice, or other healthcare provider, administrative, or operational management consultant services arrangement where the practice or the provider, administrative, or operational management consulting firm effectively stands in the shoes of the provider in dealings with 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, and other healthcare provider, partners, owners, or staff. In the interests of time, to really dig into that one, I would highly recommend you do a word search or whatever you have to do, skim down, and look at that directly in the preamble. We did include preamble discussions knowing that that one… We provided some discussion there that I think would be helpful in the context of the questions that have come up here. Next slide, please. Someone who is watching for hands and not looking at slides, please call for the pause.

Steven Eichner
We have you covered. There are no hands up.

Steven Lane
Go right ahead, Rachel.

Rachel Nelson
Okay. So, to wrap up, “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 the ONC statutes definition section that includes one or more health IT modules certified under the ONC health IT certification program for use by other individuals or entities under any arrangement other than one of the exceptions. So, “provide or supply health information” is intentionally broad, as you can tell, and then we have the carveouts proposed. The rest of these slides, if I remember correctly, is the entire proposed reg text on slides.

Here is No. 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 cost of a healthcare provider's acquisition, augmentation, or upkeep of health IT, provided such individual or entity offers and makes such subsidy without conditions limiting the interoperability or use of the technology to access, exchange, or use electronic information for any lawful purpose. Next slide. Here is the list. I think we have seen them before, but this is actually pasted out of the reg text, if I recall. Implementation and use activities conducted by an individual or entity as follows: Issuing user accounts and/or login credentials for employees, use… Okay, is it just my computer that decided that it saw stripes?

Steven Lane
Yes, we are still seeing the slide just fine. As you say, it is presenting information that you have just talked us through, so I am not sure we have to talk it through a second time.

Rachel Nelson
Thank you, that is helpful. I do have a second copy secretly stashed on my other monitor over here. Next slide. This digs a little bit deeper into what we just talked about with consulting and legal services arrangements. Outside counsel does not offer health IT when they are helping the client pick, negotiate for, or resolve disputes over contracts or arrangements by which the client obtains certified health IT. Outside counsel would also not be considered offering health IT if or when facilitating limited access or use of a client's health IT or the EHI within it by independent expert witnesses that are engaged by counsel to opposing party's counsel and experts or special masters or court personnel as necessary or appropriate to legal discovery.

There is the second of the bundle, health IT consultant assistants, so, selection, implementation, use provided by an individual or firm. It breaks out what we already talked about when we were looking at stuff drawn more from the preamble. And then, the third one is comprehensive and predominantly non-health IT clinician, practice, or other healthcare provider administrative or operations management services. There is actually a lot more about the comprehensive and predominantly non-health IT clinician, practice, or other provider administrative ops and management services exception. There is discussion of terms within there in the preamble, so I would highly recommend reviewing to inform any comments folks might be interested in making on that particular aspect of the proposed definition. That is all of our slides on the proposed offer definition.

Steven Eichner
We have a couple questions. Steven?

Steven Lane
I will just say thank you, Cassie and Rachel, for the detailed presentation. I am impressed that ONC took so seriously the questions that obviously came in from members of the community wanting to be sure that their activities did not constitute offering health IT. With the level of detail that went into these, I can just imagine the sigh of relief on the part of all sorts of attorneys and compliance folks in seeing these clarifications. I do not personally find any of them very controversial. They certainly do take a little while to digest, but once you do, they seem to make perfect sense, so I will just say for my part that I can support all of this. I also want to just point out that I think the specific exclusions related to APIs that support individual access services, portals supporting various users, and other public health access are all

consistent with the direction that the ONC and the community is going, really supporting those particular use cases of individual access and public health access, and the general sense of lowering barriers to interoperability, so, again, you guys packed a lot in here, and I, for one, am supportive.

Steven Eichner
I would like to second that. I recognize a lot of hard work and thoughtful consideration of some of the definitional changes that really help clarify some of the concerns that I think a number of entities had with the initial set, so I am really happy to see some of these updates.

Steven Lane
Hannah, I see your hand is up.

Hannah Galvin
Thanks, Steven. So, I agree with your point that this is very comprehensive in terms of addressing some of these comments that have come in, and I agree with everything that has been put forward. I did have a question about the self-developed certified EHR technology. Coming from a region where there is at least one major medical center that is still, though not for very long, using its own proprietary electronic health record that is certified EHR technology that has not, as far as I know, sold or distributed this proprietary system, I wanted to better understand how that would fall within the self-developed certified EHR technology exception. So, if I am a health system, I have developed my own proprietary EHR, and I am only using that within my health system, would that potentially fall under the exception as it is written currently? Because I would expect that we would want that type of health system and that type of technology to abide by information blocking standards.

Rachel Nelson
So, the distinction here is a very important thing. Right now, today, under the existing regulations, which the proposal does not change and we have an aspect where we propose to update the definition to maintain the same standard, a healthcare provider that chooses to self-develop some health IT, chooses to get some piece of that health IT certified under the ONC certification program, is still a healthcare provider. They are still subject to the information-blocking regulation. As long as they do not offer their health IT to someone else and they are only doing it for their own use, though I would have to actually pull up the reg text to recall the exact current wording, but right now, let's assume they have not made it available under any terms to anybody else. Within their system, they are using their self-developed certified health IT. Right now, today, hypothetically, such a healthcare provider would fall under the exclusion from the developer definition, but they would not excuse the result from the entirety of information blocking.

Hannah Galvin
Understood, okay, got it. It is the level of penalties. Thank you.

Rachel Nelson
There are also two different knowledge standards. I just want to encourage everyone here to remember that there are two different knowledge standards. We have had a lot of providers who were hearing their developers talking about the developer knowledge standard and becoming extremely concerned in the early days about potentially being held accountable for doing things that they should have known were likely to interfere, whereas the actual statutory knowledge standard for healthcare providers, as I am sure

this whole group knows, is things that the healthcare provider knew were likely to interfere and knew were unreasonable. Next slide, while we are also seeing if there are more questions.

Hannah Galvin
Thank you.

Steven Lane
There is another question. We are also a little concerned about time, so, Deven, is your question quick?

Deven McGraw
It is actually not a question. I thought we were in the comment phase, and I was going to agree that I thought these were a reasonable set of clarifications. I think the only downside to doing this is that you set yourself up for whack-a-mole. You have defined some circumstances that people have written in about, and ultimately, there will be innumerable fact patterns that people will not necessarily see in the regulation and will want to see in there, so that is always the downside of, rather than creating some more specificity around the definition, "You are excluded if you do this and you are excluded if you do that," then, inevitably, there will be another situation that people will not see, and you will be constantly messing with it.

The other thing I would say, which we may want to make a comment on, is that I do think it is worth not just putting the preamble, but making clearer in the regulatory text itself that these are triggers for coverage. It is the question I raised before. You do not end up excluding yourself as a developer because you also engage in one of these excluded types of activities because your preamble is only guidance and does not have the force of regulation, and you definitely do not want to have somebody wiggling out of info blocking coverage when they should be covered because they get to point to one of these exclusions and say that they are out.

Steven Lane
Good point, Deven. Let's let Rachel get through the last few slides because I think these actually do ask us to provide more input.

Rachel Nelson
There is an RFI that talks about potential additional exclusions, so we are actually soliciting activities or arrangements that you all believe are beneficial to patients or healthcare providers that you can demonstrate maybe occurring less often and specifically due to the concerns of prospective participants in these arrangements about potential information-blocking liability, for example, kicking themselves from the provider category to the developer category or an outside foundation that would not otherwise be an actor kicking itself in to become a developer.

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, including potentially insulating individuals or entities with shoddy practices or nefarious intent from accountability, subjecting their customers, clients, patients, or exchange partners to information-blocking conduct. We also welcome comments on other steps that the public will recommend ONC consider taking to further encourage lawful donation or other subsidized provision of certified health IT to healthcare providers who may otherwise struggle to afford it. Next slide, please. In the interests of time, I am trying to move on faster.

So, there is a summary here of the proposal, and we note the proposal of updating the "developer of certified health IT" definition. I think I previewed this earlier, so, in the interests of time, I am not going to read it, but we proposed to adjust the wording of the "health IT developer of certified health IT" definition so that it would continue to operate with a codified definition of what it means to offer certified health IT in the same way that it currently functions to allow healthcare providers that self-develop health IT to get certified and only use it for themselves to just remain a provider and not come to also be considered a developer. Next slide, please. That is what it would look like. It is not a big change. I will let you all read that for your own purposes, unless anyone really wants to hear me read it today. And then, I think next up is discussion led by Drs. Lane and Eichner.

Steven Lane
Do we have any more hands up? I do not see them. I will freely admit, this is meaty stuff. There is a lot of detail that you guys put into this. So, part of this was asking for potential additional exclusions, these arrangements that are beneficial to providers, and how to mitigate risks of unintended consequences. Does anybody have any thoughts in those areas in particular? Okay, that is reassuring. I certainly did not. When I read through this, I wracked my brain trying to think of other things. It seems like you guys have thought about so many. I am sure, with broad public comment, you will get something back in these areas.

Hans Buitendijk
Steven, this is Hans. Maybe one comment. It is not as much of a question, so I think there is a lot of clarity that has been provided with these updates where there has been concern, confusion, or otherwise, so I think it is very helpful in that sense. I think we are into a couple areas for additional clarification that are honing in on very particular aspects, like the question that we were asked earlier on self-developed versus custom code and outsourced staff. I think Rachel helped point in a couple of good directions to make sure that might still lead to some comments, and around infeasibility, at least from our general perspective, there are some questions that I do not think need a clarification, but it is more a discussion on potential suggestion to consider for inclusion. So, depending on when you want to jump to thoughts about potential suggestions that have started to be marked up in the spreadsheet, I think they are going to be fairly light, overall tremendously helpful couple of areas for further clarification or adjustment.

Steven Lane
Thank you, Hans, and maybe we can go back to the spreadsheet. We can touch on Hannah's points, and Deven, thank you for clarifying this in the webinar chat. Deven, would you mind entering that as a suggestion in the spreadsheet itself?

Deven McGraw
Sure.

Steven Lane
That would be great.

Steven Eichner
While we were busy talking, I was entering a couple of options for some additional text in the spreadsheet, so, Deven, you may want to take a look and modify some of the entries I had started.

Steven Lane
Let's start with Hannah, since your hand is up and you have the top suggestions here.

Hannah Galvin
I actually did modify my top suggestion because it was clarified during the call, so that was very helpful, thanks. My only remaining thought was related to the definition of information blocking, which we did not touch on at length, but I definitely support us modifying and removing the October 6th, 2022 date. I will just say that, again, as someone responsible for that auditing and awaiting OCR giving further definitions around how that is going to be done and penalties that might be incurred, for my organization, I would certainly want to make sure that there was some definition somewhere ensuring that if an audit was done, that it was clear that USCDI V.1 was all that was required prior to 10/6/22, so I am sure that is captured somewhere historically, and I do not think it needs to be in the definition going forward, but I think that audits are still high in people's minds, and I would want to make sure that they know where to look to know that that is captured historically in the event of an audit. That is my only comment there.

Steven Lane
To that point, Hannah, I think that we have received reassurances, though I am not sure where exactly it is written down, that the OCR will not be looking back in time and trying to prosecute or otherwise identify information-blocking activities that occurred prior to the finalization of the rule, so I think that… You are right, it will be important to remember what happened on October 6th, but I do not think it is going to be super applicable once we get into this.

Hannah Galvin
Yes, that is helpful as well. So, that was my only comment there.

Steven Lane
Hans and Ike, you guys both made this point about clarifying the line between self-development and the implementation of custom code provided by an external supplier. Could one or both of you work to turn that into language for a recommendation so that we have that piece of the work done?

Hans Buitendijk
Generally, sure. We will figure out who takes No. 1, and then we will go back and forth.

Steven Lane
Yes. It sounds like it will be a relatively short sentence, but it still needs to be framed as "recommend to ONC."

Steven Eichner
Right. It is just clarification because, as an example, a state health department contracts out for a bunch of work, both in terms of shrink-wrapped deliverables, but also looking at contracted staff as well as staff that are directly employed by the state.

Steven Lane

Hannah, similarly, if you could take your recommendation and reword it as "recommend ONC" and provide clarification related to the applicability date of the new scope of information, that will make our life easier when we get into drafting the recommendations.

Hannah Galvin
Sure.

Steven Lane
Ike, did you want to provide more color on the recommendations that you entered after Hans?

Steven Eichner
Absolutely. Looking at the bottom, looking at providing additional information or clarification for data registries operated by entities other than public health, such as how a bunch of rare disease organizations operate registries that are very similar to those operated directly by public health authorities, in many ways for similar purposes, so whether they are in scope as offering health IT or not is something that probably should be considered. The other one is looking at providing clarification, as Deven mentioned, in the preamble about scoping out or clarification that you may not be a health information technology provider for one thing, but you may indeed be doing it for something else, and just because you may not be an HIT vendor in the one space does not get you out of being a health IT vendor in those other spaces.

Steven Lane
For the benefit of all, I sent Deven a private message of the needed link.

Steven Eichner
Deven, I can work with you to help take that phraseology and build it out into a better-phrased recommendation.

Deven McGraw
I am not actually suggesting that it be added to the preamble. It is in the preamble. I am suggesting it be in the reg because there could be a downstream… There sometimes are issues with agencies enforcing preambles because it is just guidance. It does not have the force of law. It is interpretive.

Steven Lane
Okay. Anything else on this first item, the defined terms? If not, shall we go on? Hans, do you want to speak to your recommendation for the RFI?

Hans Buitendijk
Yes. I think they are in the next row on the outsourced staff, which I think you are looking at. That one is to dive a little bit deeper into clarification, and I will provide some more specific language based on Rachel's feedback on the question, but that notion of outsourced staff that works for a provider, where exactly that fits, and how it needs to be determined… I understand the considerations about fact-based, and that is where I need to flesh it out a little bit more. I will fix the typo.

Steven Lane
Great, okay. Any other comments? I am looking for hands.

Hans Buitendijk
Yes. Actually, a little bit lower down, Row 6, No. 5, I added an additional comment. We did not specifically talk about it because it did not come up in the slides, and that is okay, but there is a topic **[inaudible] [01:16:39]** currently as infeasibility is addressed. There is currently a 10-day infeasibility response timeline from the moment that you receive the request, and generally, there are concerns in that space because certainly, as you get into more complex requests requiring alternatives to be considered, you run into a very short time window that is not attainable as you get into that, yet everybody is working in good faith to sort it out, see what the best approach is, and then work through that, so there is a bit of a challenge with that, that we need to find a more practical time window/timeline progression to help manage that productively, so that is what this is about, to identify an opportunity to consider that once the evaluation is done by the respective parties, that is more of a drive to say that you can now full respond and provide alternatives or not, or the original form or not.

Steven Lane
Thank you, Hans. We will take that up at our meeting in two weeks on 5/16 when we get to that row, but that is good to have that in there as a heads up.

Hans Buitendijk
Sorry, my window was a little bit further to the right. I missed Column B there.

Steven Lane
No, it is all good, and we encourage people to be reading ahead. Again, getting your ideas down and giving us a chance to come back to them is perfectly fine.

Steven Eichner
Hans, this is Steve. I would suggest in that space addressing as part of the recommendation what the impact on usage of that data may be because for some things, 10 days makes the data still perfectly useful, but 20 days later, the data may not have as much utility.

Hans Buitendijk
I completely agree. It depends on the complexity and the topics at hand.

Steven Eichner
Right, absolutely, but I think that is something that, if we are looking at modifying it, we need to make sure we address.

Hans Buitendijk
Fair point.

Steven Lane
So, we are scheduled for public comment here in a couple more minutes. If there are no other hands or comments that we need to address within the Task Force, I think we can go to public comment a little early. I must say, ONC and Excel teams, putting public comment five minutes before the end… I know that we rarely have public comment, but it seems like we do not leave a lot of time. Since public comments are

supposed to be three minutes each, we do not even have time for two public comments. I would suggest that we at least consider moving public comment up to 10 minutes before the end just in case we have a day where we have more than one public comment.

Seth Pazinski
We can take that and make the shift for the upcoming workgroup meetings. If there is no public comment, we can always then return to any discussion in question.

Steven Lane
Yes, we can always get back to work. I seem to recall that 10 minutes before is our routine at HITAC, though I might be wrong.

Seth Pazinski
Yes, I am happy to make that adjustment. I appreciate the suggestion there.

Steven Eichner
I wholeheartedly agree because if there is a public comment, we want to make sure there is sufficient time for the individual or individuals to make their comment, and then enough time to provide an appropriate response in scope and not be overly rushed.

Steven Lane
Right. Also, before you read the slide, Seth, I want to encourage our friends who are attending from the public to feel free to jump in. We are very interested in your observations. Again, I know many of you, and I know how thoughtful you are, so please contribute if you have something to share. Go ahead, Seth.

Public Comment (01:21:06)

Seth Pazinski
All right, thank you. I echo those comments. Also, feel free to share in the chat, too, as things come up as folks are presenting or as the Task Force is deliberating. So, this is our time for public comment. If you are on the Zoom and would like to make a comment, just use the raise hand feature, which is located on the Zoom toolbar at the bottom of your screen. If you are just participating by phone only, you can press *9 to raise your and, and then, once called upon, just hit on *6 to mute and unmute your line. We will pause here and give folks a few seconds to raise their hands.

Steven Lane
While we are waiting, I will just point out that we have specific representation from CDC, which is clearly helpful here given the specific exclusions that we were discussing related to public health access and use of health IT. We do not see any hands raised, so, again, if some of you decide you want to jump in, feel free. We will keep an eye out for the hands. With five minutes remaining, again, I want to praise Rachel and our other presenters here. Cassie and Rachel did a great job with a lot of complex material that I think you clarified nicely, but we do not need to fill the airtime of the last few minutes if people feel like they have had a chance.

Again, we really invite people to go back to the spreadsheet and reword your recommendations into recommendations themselves that we can then use to transition over to our other document once the time

for that comes, and then, perhaps, ONC team, what we can do is come back and just take a moment to revisit those at our next meeting, or if we feel we would rather wait until the end of the crafting, that would be fine, too, but we want to make sure that we come back to those. The other thing I would remind people of is looking ahead at future topics, again, for this group, we are going to be meeting on the 9th of May, which is actually the seventh meeting for the entire Task Force, but just the third for this workgroup. It says here that we are going to be looking at information-blocking manner exception, which I guess we did not fully… Did we cover that one? Wasn't that here?

Cassie Weaver
Partially. We talked about the date change.

Steven Lane
Right. Was there anything else in manner that you were going to present to us next time?

Cassie Weaver
This is what I get for speaking up on the spot, especially since I am the one who drafted it. Look at that. I do not know that there will be anything else to cover there, but there are plenty of other topics on the agenda that day to take up the time we have.

Steven Lane
Yes. The other big one that I am seeing in the spreadsheet is RFI No.2, possible additional TEFCA reasonable necessary activities, so…

Cassie Weaver
Oh yeah, sorry, the TEFCA proposal is the proposed new condition for manner.

Steven Lane
Oh, that is right.

Cassie Weaver
Sorry, now that I am looking at it, there it is, right there in my face, so that will be that as well.

Steven Lane
Hopefully, Zoe will come back again and join us for that. Okay, good. Well, having said that, Ike, any parting remarks?

Steven Eichner
Nothing to add. Thank you, everybody, for your participation, and continue to make comments on the worksheet. We will see some of you tomorrow, some of you Thursday, and some of you next week.

Steven Lane
Thank you so much. Have a great day.

Hans Buitendijk
Thank you. Take care.

Adjourn (01:25:44)