Health Information Technology Advisory Committee

The Office of the National Coordinator for Health Information Technology

Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) INTEROPERABILITY STANDARDS PRIORITIES TASK FORCE 2021 MEETING

April 29, 2021, 2:00 p.m. – 3:30 p.m. ET

VIRTUAL

Speakers

Name	Organization	Role
Arien Malec	**Change Healthcare**	**Co-Chair**
David McCallie	**Individual**	**Co-Chair**
Ricky Bloomfield	Apple	Member
Cynthia Fisher	PatientRightsAdvocate.org	Member
Valerie Grey	New York eHealth Collaborative	Member
Jim Jirjis	HCA Healthcare	Member
Edward Juhn	Blue Shield of California	Member
Ken Kawamoto	University of Utah Health	Member
Victor Lee	Clinical Architecture	Member
Leslie Lenert	Medical University of South Carolina	Member
Clement McDonald	National Library of Medicine	Member
Ming Jack Po	Ansible Health	Member
Raj Ratwani	MedStar Health	Member
Ram Sriram	National Institute of Standards and Technology	Member
Sasha TerMaat	Epic	Member
Andrew Truscott	Accenture	Member
Seth Pazinski	Office of the National Coordinator for Health Information Technology	Acting Designated Federal Officer
Wanda Govan-Jenkins	Office of the National Coordinator for Health Information Technology	Staff Lead
Denise Joseph	Office of the National Coordinator for Health Information Technology	Staff Lead
Alix Goss	Imprado Consulting	Presenter

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

Operator
All lines are now bridged.

Seth Pazinski
All right, thank you. Welcome, everybody, to the Interoperability Standards Priorities Task Force. Thank you for joining the call today. My name is Seth Pazinski with the Office of the National Coordinator for Health IT. I will be serving as the designated federal officer for this call, and I will open things up and get started with the roll call, starting with our co-chairs. Arien Malec? David McCallie?

David McCallie
I am here, and I know Arien is on the way, but I do not think he is on the audio yet.

Seth Pazinski
Okay. Ricky Bloomfield?

Ricky Bloomfield
Hi, I am here.

Seth Pazinski
Cynthia Fisher? Valerie Grey? Jim Jirjis? Edward Juhn? Ken Kawamoto? Victor Lee? Les Lenert? Clem McDonald? Jack Po? Raj Ratwani? Ram Sriram?

Ram Sriram
Present.

Seth Pazinski
Sasha TerMaat?

Sasha TerMaat
Good afternoon.

Seth Pazinski
Hello. And, Andy Truscott? All right. Anyone I missed or who joined after I called their name?

Arien Malec
Just a note that I am on.

Seth Pazinski
Thank you, Arien. Okay, with that, I am going to turn it over to our co-chairs, Arien and David, to start us off on our agenda.

Introductions (00:02:14)

Arien Malec

Cool. Well, I think we have a pretty robust discussion this week, so first, we are going to hear from Alix Goss on the ICAD Task Force findings and recommendations. This is secondary to our standards priority discussion area of aligning administrative and clinical standards in order to review clinician and patient burden, and then, the rubber will start to hit the road. We have heard from a number of stakeholders, so we are going to talk about the disposition of public health, and then put together a framework and a timeline for recommendations and discussions relative to our commitments to get something to the HITAC by June, which, at one point, seemed very far away, and now seems alarmingly close, and then, as usual, we will go to public comment. So, we have a packed agenda, and we want to get to the meat as quickly as possible. So, let's go to the next slide, skip over the preamble, and go straight to Alix.

Alix Goss
Can you hear me okay?

Arien Malec
Perfect.

ICAD Task Force Findings & Recommendations (00:03:42)

Alix Goss
Thank you so very much. I believe I am going to be tag-teaming with folks advancing my slides today. It is a pleasure to be back and see some very familiar voices and faces. Today, it is my pleasure to present you with an overview of the HITAC Intersection of Clinical and Administrative Data Task Force report with a focus at the end of it around how we can take the recommendations in the report and advance them into the Interoperability Standards Priority Task Force consideration. So, without further ado, let's go ahead and get started. Go to the next slide.

I think as I take you on a relatively fast road trip through the hundred-page-plus report, it is important to give you a sense of how the process was undertaken and our ideal state and guiding principles, an overview of the recommendations, which I plan to do in about 30 minutes or so, and then really dive into a couple slides around alignment and advancement opportunities, as I have taken the 15 recommendations that came out of the report effort and categorize them so that we can have a framing about how they might fit into next steps of this task force's work, and we have provided for about 15 minutes of discussion time. So, without further ado, let's go ahead and go to the next slide, please.

So, some context is usually helpful because folks are often confused about who is on first with what obligations as it relates to federal advisory roles, and I would like to start out with some level-setting around the 21st Century CURES Act. The formation, as you probably all well know, created ONC's HITAC, and there are very specific obligations within 21st Century CURES for coordinating between ONC/HITAC and the National Committee on Vital and Health Statistics, which is a very longstanding federal advisory committee formed in 1949, and it advises the Secretary of HHS on health information, policy standards, and a variety of other aspects related to our nation's vital records, statistics, and overall standards adoption as it relates to the HIPAA frameworks.

We have known since 2003 that we have been on a journey to implement HIPAA transactions, but despite the mandates, we still have some low utilization rates, and it was a perfect opportunity to leverage the work of the standards subcommittee of NCVHS with the HITAC framework in coordination with ONC to figure

out how we could really bring together the clinical and administrative data standards and policy, as they were really starting to become a barrier in today's landscape as we pivot from fee-for-service to value-based-care, and that we were seeing the lack of harmonized standards leading to impacts in the ecosystem related to workflows and discovery of requirements, and these were ultimately all becoming barriers in process and technology platforms, but more especially in the quality and the safety of outcomes for patients. Next slide, please.

Rulemaking authorities are also separated in that for the HIPAA framework, the Secretary of HHS has delegated the rulemaking authorities to the national standards group within the Office of Burden Reduction and CMS. In contrast, for EHR standards and EHR certification, those authorities are under the Office of the National Coordinator. The nice thing about HITAC and the collaboration between NCVHS and ONC was that we were able to bring everyone together to really think about the opportunities with prior authorization at the center of some thinking, as we know that the landscape of technology standards is quickly advancing with Fast Healthcare Interoperability Resources. Oh, there was a typo in there. Next slide, please.

So, as part of the coordination between the two organizations, we also recognized that there was an opportunity to be efficient in how we garnered feedback from the industry related to the intersection of clinical and administrative data, which was already a topic within NCVHS as it related to predictability and efficiency of our healthcare standards under HIPAA and a part of the ONC framework for looking at burden reduction and trying to improve overall standards efficiency.

So, a charge was created and brought forward to produce information and considerations related to the merging of clinical and administrative data, its transport structures, rules, and protection, really using prior authorization as an exemplar so we can achieve the vision, which very much involves "record once and reuse." We had some very specific charges as a part of our conducting research to validate and extend the landscape analysis. We did stand on the shoulders of giants as a launch-off point in creating a compendium so that we would not necessarily circle the wagons unnecessarily, but we could then, rather, stand on those prior work efforts within the federal advisory committee spaces, as well as within the industry efforts that had been under way for a number of years, and that we were trying to really tackle that emerging end-to-end solution approach for medical and pharmacy prior authorizations, ultimately to lead us toward a report that I will showcase for you in the coming slides. Next slide, please.

The final report is available, if you have not already taken a look at it, and I have included the link here. From an overall process perspective, we launched in March of 2020, undertaking what turned out to be a 10-month process to really ground ourselves in an understanding of the current landscape, to solicit input from the industry, to help inform our considerations around prior authorizations, but also the larger conversation for what we needed to do to advance the industry's conversation around how to intersect the clinical frameworks, thinking about meaningful use, promoting operability, and hi-tech, really finding its marriage up to the HIPAA frameworks and really understanding that we are now living in a 21st Century CURES environment, what that means for us to describe an ideal state and our guiding principles, and to craft recommendations to tackle what needed to happen so that the hows could be addressed subsequently.

All of this was synthesized into our master report, along with research details and appendices. We brought it forward to HITAC for review and consideration several times, ultimately culminating to their approval vote November 10th, and I believe it was submitted about a week later, so it is available. Go to the next slide, please. A lot of our colleagues on this task force were also colleagues on the ICAD Task Force, but we are also grateful for the fact that we can include private-sector members to give some additional insights. Next slide, please.

As I noted, we really engaged with the industry. We had a number of presentations from April through July, listed on the left side of that screen, so these organizations came forward to give us their various thoughts and considerations as they related not only to prior authorization, but also to the larger intersection conversation. We also then had an opportunity for public review and comment on our draft report, and the list of folks who sent us written comments is included on the right-hand side, but we also took public comments along the way at each meeting, as you typically do here as well. Next slide, please.

The report took shape with some front matter providing some of the details I have just reviewed here related to vision, charge, and the members, and then got into a fairly lengthy executive summary. We understood that not everybody would read the entire report, so we did a very robust executive summary so that if somebody wanted to just pick up and get extensive cliff notes, they could do that with the executive summary. It had an introduction, analysis, a high-level view of the findings in the report, and the executive summary and conclusion was followed with very detailed write-ups of each of these four areas. We also included a variety of appendices so that we could tackle acronyms, glossaries, and a summary of each of the presentations that we received. Hats off to ONC staff, who prepared very robust couple-page summaries of each one of the key points of the presenters from April to July. I also noted early on that we stood on the shoulders of giants. The compendium of landscape artifacts is also provided as appendices, and it is a really great resource. Next slide.

Taking all the feedback that we heard from the members and the presenters and public comment, we created an ideal state of what it would look like to improve prior authorization and provide the opportunity for a broader intersection of clinical and administrative data frameworks, and this ideal state had a focus around an end-to-end, integrated, closed-loop process, reducing burden across all of the stakeholders, accounting for the vast majority of situations, leveraging existing investments and efforts where appropriate, acknowledging that there were existing gaps, but also to enable innovation and continuous improvement within the healthcare ecosystem. Next slide.

This ideal state provided us with an end goal in mind, but we also understood we needed to have guiding principles to really achieve that ideal state that I just described. At the core of it is a patient-centered design and focus, and these nine principles are discussed in depth within the report, but I wanted to give you a thumbnail sketch of what these guiding principles are really about. The patient-centered design and focus was really the one that grounded us in removing the roadblocks and supporting the care coordination of patients and their overall experience, ultimately improving their outcomes.

But, in order to do that patient-centered design, which really had to be factored in from the beginning, like privacy and security, we needed to ensure that we could promote more transparency in the process so that the patient did not necessarily have to be in the middle of what was going on in the administrative processes, but that they would have transparency and understanding of how their information was advancing through

the administrative processes as it related to their care, their coverage, and the price of the services, and how the prior authorizations were being handled so that we could minimize delays in processing overall.

We recognized that we were designing for the future, but we had to recognize that we needed to solve some problems in today's landscape, and that was a very interesting balancing act that needed to become a guiding principle because it is that constant give and take that we all experience. We also needed to ensure that we were creating a process that was measurable and meaningful because we needed to continue to be able to be a learning health system, and that reforms should have a significant impact, but we needed to be able to measure those to know whether we were hitting the mark. That would also help us with our next guiding principle of continuous improvement, of really embracing the concept of evidence-based, data-driven continuous improvement that is at the center of a learning health system.

Real-time data capture and workflow automation really embodies this idea of "record once and reuse," and also reduces burden overall. If you are going to bring the clinical and administrative data standards and policies together, it really had to take hold within the workflows so that you could automate as much as you could in real time in the background, but also had to improve usability and efficiency for all the stakeholders. The processes would focus on information that could be exchanged to make shared care decisions better, faster, and more transparent.

In doing so, we needed to make sure that we were aligned to national standards. National standards help us reduce burden, help elevate the floor, and help provide a solid foundation on which to innovate, and also takes the technical debt and proprietary frameworks out of the mix, which ties back to a lot of the other principles.

I briefly mentioned information security and privacy. Knowing that this is as centered a design issue as the patient focus, we wanted to really make sure that the minimum necessary aspects of our HIPAA frameworks and thinking about security and privacy at the core of our work was not lost. Ultimately, all of this is about reducing burden for all the stakeholders. We were very focused initially around the provider reducing the burden from prior authorizations as our exemplar, but we also recognize the burdens for patients and their caregivers, for the payers, as well for as the vendors that support all three of those prior stakeholders. Next slide, please.

This is just a little bit of an eye chart. These 15 recommendations fit very snugly on the slide. They are listed in no particular order. They focus on what needs to change, not how it will happen. We did not have enough time to take that on, and hopefully, ICAD Part 2 will help us with tackling the how. I suspect some of the ISP Task Force work can also help move us into the how, and I think that it is important to call out that most of our recommendations are standards-related and have implications for your body of work, so I am very appreciative that Arien, as a very active contributing member of the ICAD Task Force, thought to bring this back into the fold.

What I would like to do in the next handful of slides is to give you a snapshot of what each of these recommendations are about so that you have an effective setup for discussing where they might fit into your current charge. So, let's go to the next slide, please. So, Recommendation 1, "Prioritizing administrative efficiencies in relevant federal programs," is really about ensuring that we have not only federal programs advancing administrative efficiency objectives, but that we would also be looking at

establishing joint relevant certification criteria and considering the targeted incentives that maybe needed to bring along the smaller practices that typically have challenges with adopting new standards.

Recommendation 2, "Establish a government-wide common standards advancement process": As we look to converge our frameworks, such as HIPAA and the HITAC coming together under 21st Century CURES, we really need to think about the overall governance approaches to establish a single, consistent process for standards advancement for relevant standards and to make sure that we are continuing to apply our lessons learned by incorporating multiple rounds of development testing and production pilots prior to adopting national standards. Recommendation3 is on the next slide, please.

"Converging the healthcare standards" was Recommendation 3, and this is a fairly lengthy recommendation. This is trying to garner not only a recognition of maintaining the principle of minimum necessary, which may be up for a little bit of consideration under today's NPRM framework from OCR, but it also is about harmonizing standards to create a consistent set of code sets, content, and standards that were really tied to an underlying data model, and that is the key piece I want to call out here: The data model aspect. We have to think about that data model and how it translates into our clinical workflows and administrative processes and how we can really underscore that "record once and reuse" by creating that converged framework.

Recommendation 3 works with Recommendation 4. Can we go to the next one, please? We need to provide the industry with a clear roadmap and timeline for harmonized standards, so if we are going to be thinking about a data model that links all of this together that can enable us to have governance frameworks and version control frameworks all working together, that kind of a roadmap, along with the convergence specifics, needs to be socialized to bring everybody along to understand how this process is going to work and the timeline for making this all converge. We need to think about some of the pivots that we have been discussing. Today, we have a ceiling in HIPAA. We want to make that a floor, more like we are doing within the current standards versions advancement process that ONC has adopted as a part of their CURES Act rules.

Recommendation 5 is about harmonizing the code and value sets. This recommendation really makes a nod to the National Committee on Vital and Health Statistics' February 2019 report that talks about terminologies and vocabularies adoption and implementation processes, and really extending some opportunities for improved guidelines for curation and dissemination. There are also some value set authorities and supports that the National Library Medicine is a really critical component of, and they were a big part of producing that February 2019 report. Next slide.

Recommendation 6 is to make the standards open to implement without licensing costs. We see a very mixed model in the landscape today, and we recognize very clearly that there is a need for financial support for the development and curation of standards. A lot of the work that is done today is driven by membership within standards development organizations, with volunteers rolling up their sleeves and doing a lot of work as a part of their jobs or off the side of their desks, but we recognize that if we are going to continue to advance standards and want to address burden and converge them more effectively, we could look at figuring out a way for those that are named in certification programs to be available to implementers without licensing costs. Next slide, please.

Recommendation 7 is for developing patient-centered workflows and standards. I think it is very important to understand that patient-centered workflows do not necessarily mean that the patient has to be in the middle of the workflows, they just have to be in the middle of the thought about how we design our workflows and our standards, and there was some concern early on in our feedback that folks interpreted this as wanting to actually put the patients into the workflows, and that was never our intention, but it is often important to have their visibility into the workflows, as they can help resolve some challenges.

But, there is also an aspect related to the designated records set and some considerations there that may be addressed under the current NPRM from privacy, but really, what we are trying to do is create more visibility into those bidirectional workflows and exchanges of data so that patients are not disconnected and can contribute as appropriate. Next slide, please.

Recommendation 8 was adopting a member ID card standard. There has been a lot of work done in this space. The Workgroup for Electronic Data Interchange did a very large report on this topic a number of years ago, and some of that work influenced the recommendation here for adopting a standard for member ID cards, and so, we will talk a little bit more about that when we get into the discussion area because there is further work happening today for digital ID cards.

So, I am going to skip on to Recommendation 9, which is one of my favorites, naming an attachment standard. I suspect this may happen in my lifetime. It has been something I have been working on since the early 2000s and is a part of our HIPAA obligations and statue, as well as of the Affordable Care Act, that we will figure out how to effectively exchange clinical data to support clinical information for administrative processes, and how we do that in a standardized format will take some federal rulemaking, proposed rulemaking with industry comments, and finalization, so we would like to get that ball rolling. Next slide, please.

Recommendation 10 is to establish a regular review of the prior authorization rules. So, considering that our exemplar was prior auth, we really wanted to ensure that the industry was taking a look at their own rules for when they apply prior authorization requirements, and that sometimes, they are sunsetting those rules and adding new ones, and that for all of us to keep pace more effectively, we thought it would be good to have a recommendation that they should be reviewing those no less frequently than annually and that it may be helpful to provide some visibility into that process by having metrics on the authorization and denial rates, rates of appeals, and metrics on appeals. Next slide.

Recommendation 11 is about establishing standards for prior authorization workflows. There was a lot of discussion about automating the processes. We did receive a number of demonstrations related to pharmacy electronic prior authorization, as well as the emerging Fast Healthcare Interoperability Resource Standards, FHIR, in the Da Vinci project, having a clinical three-part conversation and a set of implementation guides that were demonstrated and shown to us as to bring some overall efficiencies into the ecosystem so that it could be automated between an electronic health record and a payer system so that it could effectively do that clinical conversation and minimize the current manual workload within the provider organizations dedicated to just handling prior authorizations every week. This also would include sufficient guidance on operating rules, service level requirements, and… Let's go to the next slide, please.

Recommendation 12 was about creating extensions and renewal mechanisms for authorizations. This is a part of the standards process that we need to think about. How can we create a mechanism to more effectively renew and extend an existing prior authorization? Sometimes, services have long durations, and it is clear to us that there are negative consequences in this situation to patient care delivery and outcomes because there would be gaps and delays in services because prior authorizations were expired and had to be renewed, and we need to find a way to do that in a very automated fashion.

Recommendation 13 is about including the patient in prior authorizations, and that we wanted to ensure that was a part of the design goal that I mentioned earlier, and that they could receive notifications and status of key activities just so they had a sense of how it was moving through the process and whether or not they needed to get involved. Next slide, please.

Recommendation 14 was about establishing patient authentication authorization to support consent. This was about enabling patients and caregivers to more easily authorize the sharing of their data with the tool of their choice by having efficient third-party authentication methods. I would imagine that we are making some progress towards this, but probably have not solved it completely. A number of these activities are getting easier or tackled more effectively because of our API implementations that are going on, but this was identified as an inefficient area that we needed to further investigate. Next slide, please.

The final recommendation was to establish a test data capability to support interoperability. Earlier, I mentioned the data model concept and also our need to learn from our past lessons about testing and pilot production proof of concepts so that part of that vision is also that we need to be able to have a really good set of test data. We do not want to be testing with real production data, which goes against privacy and security concepts, but what we need is to have a really good, robust set of test scripts and test data that we can use to run the rigor against our information models, our transaction standards, our implementation guidelines, and guidance that people use for implementing standards into their workflows. We have not been able to tackle this under HIPAA or on HITAC, and it is time to take a look at how we can have a really good, robust test bed. Next slide, please.

So, in summary, these recommendations are about creating patient-centered design approaches to benefit the experiences, the safety, and the outcomes while protecting patient preferences and their consents, the privacy and security of their data throughout the process, that we can use digital capabilities to automate manual time-consuming activities, we can truly achieve the “record once and reuse” vision, and we can address key barriers to effective information exchange while improving transparency and timeliness of prior authorizations and decision-making processes for all stakeholders, that we build and extend our current standards, recognizing that we have some haves and have-nots in our world, that we all want to advance to a level of enabling automation and having a solid foundation on which we can innovate that would also a give us a path forward for harmonizing today’s policies, vocabularies, and transport standards that create an ecosystem that really lets the patients and their caregivers focus on their wellbeing rather than problem-solving administrative process complexities. Okay, let’s take a breath on that fast road tour and go to the next slide.

This is just Alix’s work. I have not vetted this with anybody else. This is my attempt to group all those 15 recommendations into a couple of slides for us to think about and to prompt some robust discussion. So,

Arien, I am not sure if you want me to just go over these couple slides and then back up and let you run the discussion. It might be a good way to approach it. Does that sound okay?

Arien Malec
Yeah, just go over the slides, and then we will tee up discussion. Thanks.

Alix Goss
You are welcome. All right. So, as we think about SVAP, the standards version advancement process, convergence and a roadmap and access to harmonized standards, we can really encompass Recommendations 1-7 and 15. This is about iterating HIPAA and 21st Century CURES governance exception processes. When we think about the HIPAA exception world, there is process you have to go through, which is rigorous and a little bit nebulous, under 162.940 regulations for how you can get an exception from one of the current HIPAA transactions to try something different, and so, I think we need to think about that as a part of our ongoing governance process. But, we also need to be thinking about our certification criteria, testings, and pilots as a part of how to iterate HIPAA, meaning HITECH and 21st Century CURES. I think we also need to take a look at advancing the USCDI data model to promote efficiencies and reusability of bidirectional exchanges for the data model content mapping.

The second category is around member ID cards. This is Recommendation 8. In the report, we did cite a very specific standard that came out of the work from that WEDI report I briefly mentioned, but I think it is important to also note that there is current work going on within the HL7 community related to the CARIN Alliance, and they have brought forward the idea for a project that would take shape in the form of an implementation guide for a digital insurance card using FHIR, and that this implementation guide has been sponsored by the Payer/Provider Information Exchange, or PIE, work group, with Financial Management being a cosponsor, and I think it is important to put context around the PIE work group. This is also the same work group that owns the attachment standard within HL7. Next slide, please.

Speaking of attachments and prior authorization workflows, if we look at Recommendations 9, 11, 13, and 14, we can consider revisiting the standards that are needed to really underscore the attachments recommendations letter. So, as a former member of NCVHS, I have been involved in several iterations of recommendations to HHS on what we should adopt as a nation for solving the attachments exchange. I have been working on attachments since at least 2003 in my role before as a representative of X12 and coordinating with HL7. It has always been envisioned in the world of EDI that there would be an exchange capability of the 275 and the 277 transactions to augment the claims or prior authorization transactions, and as a part of that structure, we always envisioned that the clinical payload would be of an HL7 ilk, either as a V.2 message or, more currently, as the CCDA framework.

When we wrote our last recommendation to HHS, which was dated July 5th, 2016, with a link to the letter included there, we did not really have the current FHIR capabilities getting as much traction, so I think there is an opportunity to revisit what we really need moving forward to harness the current landscape under 21st Century CURES, and I will leave it at that.

I also think that the proposed API rule promoting the reduction of burden, which was CMS 9123, is currently in a hold status until the administration can get a chance to look at that rule and figure out how they want to advance it either as another NPRM, et cetera. The reducing-burden APIs really take into account the

capacity to leverage the Da Vinci implementation guides for coverage requirements discovery, document template rules, and prior authorization support, being able to do that EHR-to-payer-system, under-the-covers automated exchange.

As I just noted, the CRD, DTR, and PAS implementation guides are definitely something to consider, as well as the Da Vinci member attribution and payer data exchange implementation guides, which we affectionately refer to as PDEX, and can take shape as provider directories and formulary exchanges, so some of those have been adopted under existing final rules. Additionally, I think we need to be thinking about the HL7 CARIN Blue Button implementation guide, as that is another guide that I think would need to be brought into the fold of consideration for bulk data. Let's go to the next slide.

So far, I have tackled the recommendations that have concrete standards or pathways tied to those recommendations for standards adoption and your priority focus, but there are a handful of recommendations that need to be further explored or more specially developed into actual technical specifications that could be cited under a certification program or promulgated rules. The first one is Recommendation 10, about enabling transparency and prior authorization processes. How do we report metrics? How do we know what is really happening with denial rates, appeal rates, et cetera? It would be great to have an implementation guide that would help us do that reporting.

The idea of creating an extension and renewal mechanism for authorizations would also need to be tackled. That was Recommendation 12. Ensuring the appropriate visibility for patients of the status of authorizations with their ability to contribute data points is something that we would need to take into consideration if we wanted to bring Recommendation 13 to life. The final area to explore implementation guide opportunity development is supporting efficient authentication authorization processes. There is probably a fair good amount of work done out there, but I do not know if it is quite where we would need it to be today. I think that is my last slide.

Arien Malec
Thank you. That is obviously a lot for this task force to wrap their heads around, and just as a framing approach for this, if you believe, as I do, that administrative burden in this country is high, then standards advancement and standards prioritization for reducing administrative burden should be a national priority and a focus of this task force and the HIT Advisory Committee. That is No. 1.

No. 2 is if you believe that the end-stage vision for administrative workflows, which is everything associated with healthcare getting paid for as opposed to healthcare getting delivered, should ultimately get done as far upstream in the process as possible, then you should seek to align clinical and administrative transactions, and in particular, if you believe, as I do, that the common source of truth for both administrative and clinical workflows are the facts on the ground for the patient-reported problems, the diagnosis and treatment plan, and the clinically appropriate care that is delivered to the patient, then you want a workflow where much of the administrative process is sourced from the same source of truth as is documented in the EHR to provide care. So, we should be seeking to line up the common standards advancement and common data model that serves both the needs of clinical care and administrative processes.

Also, just as a gloss for people who are confused, as I was momentarily, as this task force normally thinks about it, HIPAA is about security and privacy. In this case, we are talking about HIPAA relating to

administrative transactions and HIPAA-authorized transactions, such as the actual current EDI transactions that are associated with administrative workflows, which are the first information exchanges in this country. So, that is just a gloss for people who see the word "HIPAA" and are confused. That is what that means. So, maybe we should just go on. David, do you have any comments before we go on for questions?

David McCallie
I just have one question going all the way back to the very beginning, Alix. First off, thanks for an incredibly dense and efficiently presented summary. That was awesome. But, from the very beginning, you tied this task force's work back to CURES legislation, and my question is what lever arms exist to address the recommendations that you guys made? Is there a mandatory follow-up that will happen? Are agencies on the hook to respond to them, or was this more of an information-gathering exercise?

Alix Goss
That is a great question. So, part of the genesis of all this ICAD work was not only the fact that the 21st Century CURES Act said that the national coordinator shall ensure that the relevant available recommendations and comments from NCVHS are considered in the development of policies, it was also the fact that because of the 21st Century CURES language, increase dialogue was happening between ONC and NCVHS. NCVHS was already on the path of addressing a number of these issues as a part of our review committee responsibilities that were given to us under the Affordable Care Act, as well as the ongoing conversation around upgrades to the existing HIPAA transactions.

So, when Arien mentioned that when I was talking about HIPAA here, I was talking about how transactions, code sets, identifiers, and privacy are all within the realm of NCVHS's gating responsibilities that anything that advances into HHS for consideration for a foundational HIPAA transaction code set privacy framework comes through us, but also, all the upgrades come through us. So, one of the things that we know from years of testimony and a little bit of performance art from the industry about their frustrations is that there is no predictability.

So, we had undertaken a process to ask how we were going to create more predictability in advancing our standards to meet the pace of industry, and not be barriers to innovation, and apply our lessons learned so we can pivot from a ceiling approach to a floor approach in HIPAA. We were well on the way to addressing that when 21st Century CURES came about, so we started these conversations, and we paused some of the NCVHS project work because ICAD kicked off, and as the co-chair for the standards subcommittee, I was extended the opportunity to be the co-chair of the ICAD Task Force, the goal being that we were efficiently bringing together industry to talk about this golden nugget all in one place so that the ICAD report could infuse next steps for ONC and HITAC, as well as the NCVHS subsequent project that we wanted to engage on. It was called the Convergence Project, and I believe that they retitled that at the end of March to 21st-century Standards Landscape in Post-Pandemic America. I totally mangled that, and I apologize to Denise and Rich, the current co-chairs of that subcommittee.

The point, David, is that I believe that there is an ICAD Part 2 Task Force slated for HITAC to advance the body of work from ICAD report as well as NCVHS taking on the report to inform their next work because if you want to change any of the HIPAA regulations for transactions, code sets, et cetera, it needs to go through NCVHS, and if you want to tackle the EHR certification platform and the ISA, it needs to go through ONC because the laws gave authorities to different bodies, although HHS could elect to bring them all

together under one house if they wanted to, since the Secretary of HHS delegates the HIPAA regulations advancement as informed by NCVHS to CMS.

Arien Malec
If I had my druthers, I would interleave NCVHS and HITAC, and clearly, there are different bodies of work for advancing clinical care and administrative transactions, but as I said in my preamble, I do believe that we are going to move administrative transactions upstream in the process in order to drive better administrative efficiency. That is going to put more dollars in the pockets of all Americans, both in the form of decreased premium dollars and out-of-pocket dollars as well as decreased tax dollars, and to do that, we have to consider these things not as separate worlds, but as two different work streams that are associated with common rules. I see that Clem has his hand up.

Clement McDonald
I have a comment and a question. Personally, I have had the same experience with attachments. I think it is like 10 elephant's gestational ages that we have gotten to now, and maybe it will still be born, but leaving that aside, I understood that in terms of trying to simply and unify administrative and clinical content, I heard a lot of enthusiasm about ICD-11 from NCVHS. Can you comment on that?

Alix Goss
I can. "A lot of enthusiasm" is an interesting way to put it, Clem. There was some very extensive work done to understand the change from ICD-10 to ICD-11 and what we need to do as a nation to move towards ICD-11 now that the World Health Organization has officially blessed and rolled out ICD-11 so that it can start the implementation efforts across the world, and that there are some very thoughtful, well-documented opportunities on the NCVHS website related to what we need to do to do some research and analysis and get ourselves ready to effectively migrate from ICD-10 to ICD-11.

Clement McDonald
Thank you.

Alix Goss
You are welcome.

Arien Malec
Any other questions from the task force?

David McCallie
Arien, I have a question while people are thinking and working on raising their hands, and it is a really broad, zoomed-out question about claims attachment. I understand how long and fraught the history is of trying to design a claims attachment standard, and I wonder if we should be thinking less about claims attachment and more about just attaching access to the record itself so that the payer could get what the payer needs without putting the burden on the provider to bundle up something that they think is what the payer needs. Is there a way that we could just skip claims attachment entirely and have record attachment?

Alix Goss

We have definitely advanced. We no longer say "claims attachments," we just say "attachments," which was one progress we made. The second piece of this is that you are right, we need to harness the capabilities of that new electronic health record capability with payer exchanges under the covers so that we can extend the automation, and one of the reasons I brought up that 2016 letter from NCVHS to HHS was that it was the best and brightest thinking at that time to really use a continuity-of-care document as the payload inside those EDI transactions, and it is outdated.

We really need to get at what you just said, David, which is enabling the clinical data exchange to happen in an automated, effective way, using those capabilities that the API frameworks can enable. We have been waiting to see some kind of a proposed rule come out so that the industry could weigh in on that, and I think we need to elevate the industry's readiness so that they can weigh in because I do not know that CMS will be able to propose anything beyond what was put in that NCVHS letter, and we need industry to give the feedback so that the regulators understand that in my view, the time delays to act on those recommendation letters made null and void what we said in 2016. We need a refreshed look, and if we do not think about FHIR as part of a critical ecosystem solution, we are missing the boat. We are never going to reach Arien's vision.

Arien Malec
It is weird that we got to this sort of radical view on the ICAD Task Force that we should harmonize the standards, and what we really meant by that was the same standards, understanding that there is difference in usage and difference in workflows, and you need slightly different data for an administrative workflow than a clinical workflow, you need a member ID to do an eligibility check but not to provide clinical care, but as we get to FHIR-based standards for clinical interoperability, we probably should have FHIR-based standards for administrative operability as well and harmonize to an API ecosystem as opposed to an EDI ecosystem.

Alix Goss
It is going to be really hard to create that reduced efficiency if we do not go there, Arien, and we need to provide a way to crack open that nut and have that conversation, so if this task force can help elevate that… And, I know there is expanded thinking in NCVHS about where we need to go next, especially when you think about all the downstream efforts such as all-payer claims databases and research, there are a lot of other implications that need to be considered in this more modern view.

Arien Malec
Yup. Clem, I see your hand is up. Is it still up from the last time, or is it back up?

Clement McDonald
It is back up. So, from what you have all just talked about from the last round of HITAC and USCDI, I understand you are going to get that in the clinical messages. It was brought up about getting the member ID put as part of the standard part of the package we send for whatever purpose, so that is one step. The other one is most of the kinds of reports you need for adjudication are expert reports, this report, and that report, and most of those are also going to be required to be part of routine message passing, so this stuff might be **[inaudible] [00:57:52]** there. We still have not got final approval of all that stuff, but it looks like there is a lot of support for it.

Arien Malec
Yeah, and if the team can go up two slides, I just wanted to call out the simple matter of mapping USCDI and FHIR to the X12 standards. So, just in "Convergence roadmap and access to harmonized standards," just the exercise of mapping the USCDI data model and mapping HL7 FHIR to the implied HIPAA transaction data models and EDI standards and then mapping value sets would be tremendous progress toward this idea of convergence.

Alix Goss
Do not forget NCPDP. We have the pharmacy in there.

Arien Malec
Oh yeah, definitely NCPDP as well. It actually overlaps with the OMOP guidance that we heard when we thought about use of data for broader purposes, such as research, that getting to a common upstream model helps us use the data that is surfaced off of clinical care, both for providing clinical care driving administrative workflows and driving research, and in fact, as you mentioned in terms of all-payer claims databases, many of the research needs that we have are fed through a mixture of administrative data transactions and clinical transactions, and then, many of the clinical quality measures are fed off of administrative transactions as well. So, it occurs to me that just this simple matter of getting to a harmonized USCDI, OMOP, and HIPAA transaction view and mapping both OMOP and the implied HIPAA data model to FHIR would be a really foundational piece of work that ONC could help fund and advance that would put us all in an improved position for harmonization.

Alix Goss
Well said. I agree.

David McCallie
And, do not forget the licensing cost point, which I think came up in several other of our presentations, and in particular, the OMOP…

Arien Malec
There were licensing costs for some other proprietary terminology sets that I think were also part of the findings that we got from OMOP, and actually, some of the ICAD Task Force recommendations as well were that we probably should not be using proprietary code sets that do not have standard licensing terms as functionally required code sets for doing business in healthcare in the U.S. Do we have any other comments from the task force?

David McCallie
One more question from me. Alix, you mentioned Da Vinci a couple of times. Was there any other particular activity of the Da Vinci work that caught your group's attention as something that maybe you did not call out as a recommendation, but is worthy of either support or resistance?

Alix Goss
In all fairness, I am a consultant to the Da Vinci Project, so I just want to be transparent with my potential conflict there. The Da Vinci Project has really provided a framework for value-based care, and that is one of the things that I did not really call out yet, which is as we are going from fee-for-service to value-based

care methodologies as the prevailing way we reimburse for healthcare, and also the coordination between payers and providers, I think we really need to be thinking that there is a lot within the Da Vinci Project that can help with automation efficiency, and so, the Clinical Document Exchange, the CDex, knowing who your member attributions or cohorts are, and your reporting efficiencies, there are a number of implementation guides that we could be thinking about, and if you go to the next slide, I think I tried to call out those specifically on Slide 30.

And, I may not have clearly called out or enumerated what the PCDE acronym was. It is the Payer Coverage Decision Exchange, which would be really important when you think about the burden reduction CMS 9123 rule. Let's say I am going to change health plans from Acme Health Plan to Tomorrow's Health Plan, the policy concept would be that I could instruct that my information for the past five years could go from Acme to the Tomorrow Health Plan and I could opt in for that data-sharing at the beginning to ensure the continuity as well as, say, not the model where I am changing, but I have concurrent plans, such as Acme and Tomorrow as two health plans that cover me, I might want to have concurrent data sharing happening, and so, getting a standard around payer-to-payer coverage decision exchange would be great to get that PCDE IG recognized formally in rules.

David McCallie
Arien, it occurs to me that one of the things we could do is to go through this and come up with a list of areas for standards enumeration and focus for the ISA, even if we do not go deep on recommendations. So, we are saying this is an area of activity.

Arien Malec
I think that makes sense, and again, I just go back to my thoughts on foundational versus particular activities that doing the data model mapping, as we think about with OMOP and this work, that doing the basic data model mapping may really be an area of foundational importance, and there is a whole set of workstreams that come off of that that relate to the variety of workflows that you drive through that level of harmonization. Is there anybody on the phone who is not able to raise their hand who wants to get a question or a comment in? Okay, having waited the requisite number of beats, Alix, I think we want to free you up and move on with our agenda, but we really appreciate the work, which, as David said, is an incredibly dense set of output that was masterfully summarized and made comprehensible through a really nice presentation, and then, I really appreciate your thoughts in bringing it home in terms of how we could take this work and turn it into ISP Task Force recommendations.

Alix Goss
You are welcome. Thanks for inviting me, and I look forward to seeing what comes out next out of all this because it is really critical work that you guys are all doing, and I would love to see how we can truly take ICAD to the future. Take care, everybody.

Considerations Public Health Standards (01:06:05)

Arien Malec
Absolutely, thank you. Okeydokey. Public health work plan and prioritization: So, as people know, ONC stood up a Public Health Data System, or PHDS, Task Force. As an ISP Task Force, we attempted briefly and with great perseverance to find and schedule the appropriate public health folks for testimony to this task force, and the stars did not align, and so, we met yesterday with the respective task force chairs for

the PHDS Task Force and formally recommended that we pass on the work associated with the priority areas for public health that we assessed on to that task force, and in turn, they noted that because the intent of the ISP Task Force is to take on work iteratively, they can pass work back on to us.

So, I just want to pause there and see if there are any concerns with that approach. I think given the timeframe that we have for making recommendations, given the fact that we have not been able to line up testimony, it is just not feasible for us to do anything more than just gaze at our own belly buttons and come back with a set of public health findings. I think they are going to be better situated to do that, but I wanted to pause to see if anybody had any significant concerns about that approach.

Okey dokey. Hearing no major concerns, let's go on to the next segment, which is framework for recommendations. So, just as a reminder, if we go on to the next slide, we have 10-15 minutes more here, and we are tasked with submitting final recommendations for the June HITAC meeting. We are sitting in late April, and so, there is a fair amount of synthesis work that we need to get to from the input that we have gotten to a set of final recommendations, and if we go on to the next slide, I think we have heard from good sets of input for our top two priorities, which are health equity standards, real-world comparative effectiveness and recovery-style EHR data use, and public health situational awareness.

I think if you look at the things that are in italics relating to public health, I think we have made recommendations that we passed on to the PHDS Task Force, and so, the ones that are starred here are the ones that we are proposing focusing our efforts in, and in particular, really doing that on priority order, health equity standards, real-world evidence, and then, the clinical administrative and standards burden reduction items. We may make appropriate comments on public health situational awareness relating to the input that we got there.

If we go on to the next slide, it summarizes what I just said. We will make recommendations on these three bullet items, consider recommendations on public health situational awareness, care plans, chronic disease management, pending task force discussion, and data-sharing federal and commercial entities where we have the experts, just not the timeframe to get through it, so this would be basically best effort and time willing if we are able to get to it, but we will really focus on the top three bullets.

If we can go on to the next slide, our timeframe is this meeting and for homework. We would like to discuss the testimony that we have received and come up with a set of high-level, bullet-level recommendations. So, an example of this would be we recommend that ONC map OMOP HIPAA administrative standards and USCDI together, come up with a set of gaps, and then, subsequently map that common data model to HL7 FHIR. That might be an example of a high-level recommendation as opposed to a very detailed recommendation on terminology set X and the need to advance yada, yada, yada, which we would turn into detailed recommendations relating to the June meeting.

There is a HITAC meeting on the 13th, and so, by next week, we would like to come up with a draft list of high-level recommendations from task force members, consolidate those, and discuss by next week a proposed set of high-level recommendations, get to a consensus next week, and then draft those for presentation to the HITAC for the 13th meeting. And so, our homework to you all, which we will memorialize and summarize with an email out to the task force, is considering the three priority areas and considering

the feedback that we have heard to date, what high-level recommendations would you like to recommend that we consider?

And, you are free to give as many recommendations as you want, but it might be helpful to come up with three to five high-level recommendations in bullet form that we can then take, consolidate, and consider for the meeting on the 6th, and just in order to give us all enough time to get decks out, we would like all of the input to come in by about 12:00 p.m. Eastern Time or 9:00 a.m. Pacific Time on the 4th so that we can consolidate and summarize on Tuesday for draft presentations to go out to the task force for discussion on the 6th. So, I am going to pause there in that short-term work plan so that we can summarize some of the learnings into very high-level recommendations for consideration by the full HITAC that will then inform the next month's work plan as we get through final recommendations in June. So, I will pause there and look for hands to be raised or other comments or considerations. And, if you are on audio only, feel free to raise your voice, and we will try to get you into the queue, but let me just pause two or three beats.

Okay. Let me take the silence as consent that we all agree this is an appropriate work plan, and also take this as agreement to go through the homework. I think we tried to balance getting good input with the timeframe. Maybe if we had to do this over again, we would have focused all our efforts on the top two and given ourselves more time to get to actual recommendations, but I do think we have enough time, basically a month and a half, to summarize all of our input and get to recommendations, but this is crunch time with respect to providing actionable feedback for ONC, so I just would appreciate the task force members' diligence in putting together the title of a recommendation and working with us. We will assign you more homework as we get to the high-level recommendations to break the high-level recommendations down to detailed recommendations for ONC consideration. David, anything more from your side? Or, again, if you have additional comments or considerations as task force members, feel free to raise your hand or speak up.

David McCallie
We will send an email redefining exactly the three areas that we want to focus on, Arien.

Arien Malec
Perfect. Yes, absolutely.

David McCallie
We will send out a homework assignment email later today, hopefully, which just gives you exactly the topic areas. I think once we get your submissions and have started to consolidate them, we will put them online in a Google Doc or something so that we can jointly edit them after that, but for the first turn of the crank, you are on your own to go back and look at your notes and the slides and come back with what strikes you as the most important recommendations that we could draw from what we heard and what you know about those three areas. It obviously does not have to be limited to what we heard. It could be things that you are concerned about in the general topic.

Arien Malec
Okeydokey. Well, with that, I do not know if there is any objection for us going to public comment early or if we want to wait around for four minutes and fill the time before 12:25 to go to official public comment. Is there any objection for us to go to public comment early? Seth, I think that would be to you.

Public Comment (01:17:11)

Seth Pazinski
Okay. No, I think we should proceed to public comment. Operator, if we could open up the public comment line, please.

Operator
Yes. If you would like to make a public comment, please press *1 on your telephone keypad. A confirmation tone will indicate your line is in the queue. You may press *2 if you would like to remove your line from the queue, and for participants using speaker equipment, it may be necessary to pick up the handset before pressing *. One moment while we poll for comment.

Arien Malec
Okeydokey. So, as we look for public comment to come in, as we noted, we are going to draft an email to go out to the whole task force this evening or afternoon, depending on what time zone you are in, and again, we will make this all clear in the email, but we ask for you to think about this on Friday, draft an email over the weekend, and send it in no later than 12:00 p.m. Eastern or 9:00 a.m. Pacific, or modulate for whatever time zone you are in, get that information back to us, and then, we will consolidate that and put that into a deck for consideration for our next meeting. It does not sound as if we have any public comment.

Operator
No comments.

Seth Pazinski
I do not see anything else in the chat, so, Arien or David, anything else before we adjourn the meeting?

Arien Malec
No. I think we would like to give everybody a few minutes of their time back.

Seth Pazinski
All right. Thanks, everyone, for participating today, and we will officially adjourn the meeting.

Arien Malec
Thanks so much.